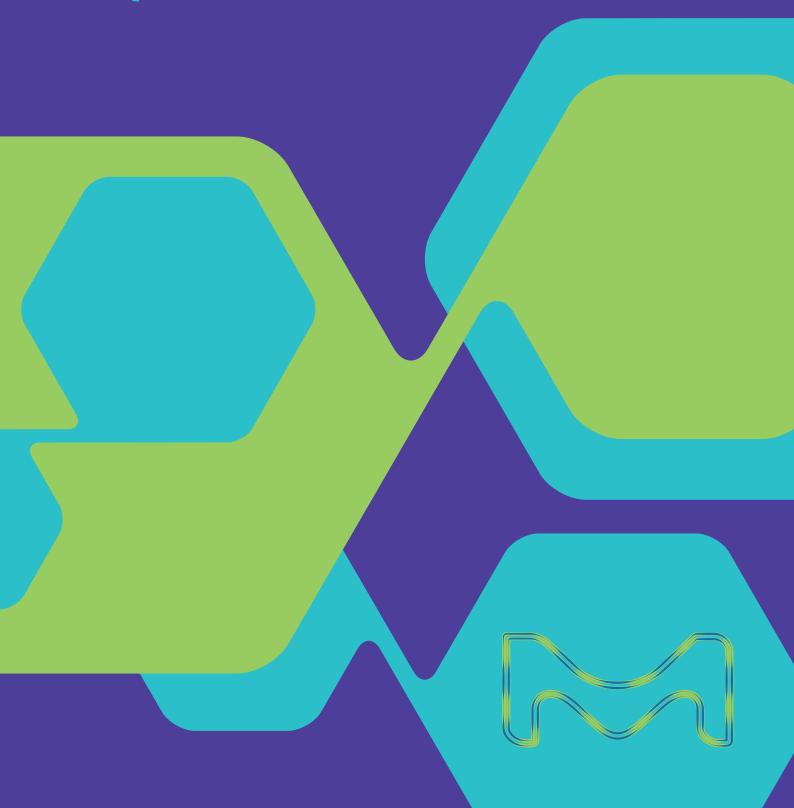
# CORPORATE RESPONSIBILITY Report 2017



# contents

3		
		THE CED

# 5 STRATEGY & MANAGEMENT

- **6** Company profile
- **8** Governance
- **9** CR strategy
- 11 Compliance
- 17 Human rights
- 19 Stakeholder dialogue
- 22 Materiality analysis

# 28 PRODUCTS

- 29 Innovation and digitalization
- **32** Sustainable products
- 38 Access to health
- 46 Prices of medicines
- 47 Health awareness
- **50** Chemical product safety
- **53** Patient safety
- **55** Counterfeit products
- **57** Transport and warehouse safety
- **59** Responsible marketing
- **61** Bioethics
- **63** Clinical studies
- 67 Animal welfare
- 70 Interactions with health systems

# 72 EMPLOYEES

- **73** Attractive employer
- **77** Diversity
- **80** Health and safety
- **82** Employee engagement
- 84 Good leadership

# 86 ENVIRONMENT

- **87** Environmental stewardship
- 90 Climate protection
- **94** Resource management
- 100 Plant and process safety
- **102** Biodiversity

# 103 SUPPLIERS

- **104** Supply chain standards
- **106** Mica supply chain

# 109 COMMUNITY

- 110 Community Involvement
- **111** Health
- 114 Education and culture

# 117 FACTS & FIGURES

- **118** Report profile
- **120** Indicators
- **148** Goals
- **159** Recognition and rankings
- 161 Sustainable Development Goals
- **164** Non-financial report
- 173 GRI Content Index
- 190 Global Compact CoP



# Letter from the ceo

# Ladies and gentlemen, Dear friends of our company,

This year we are celebrating a very special anniversary: 350 years of our company. Our history has taught us that remaining successful in the market depends not only on what a company does, but how it does it. At Merck KGaA, Darmstadt, Germany, we recognize the great importance of this "how" and have therefore created a binding code of values that we use to measure our actions. One of our key Values is responsibility. Responsible conduct means safeguarding the interests of our employees, customers, shareholders, and the community. In reflection of this ethos, we support the United Nations Global Compact and the principles it espouses.

In our efforts, we particularly pursue three strategic spheres of activity, specifically health, environment, and culture & education. We made great strides in these areas in 2017.

In April 2017, for instance, we laid a health milestone by founding our Global Health Institute. This organization is mandated to develop innovative, integrated solutions to improve the health of underserved populations in the developing world. Its efforts to address key unmet medical needs focus particularly on women and children, as well as antimicrobial resistance and infectious diseases. A good example is schistosomiasis, an insidious parasitic infection that afflicts approximately 220 million people worldwide. Roughly 10% of those impacted are children younger than six, an age group that cannot currently be treated using praziquantel, the standard therapy. But we intend to change this. The Global Health Institute is thus partnering within the Pediatric

Praziquantel Consortium to develop a pediatric formulation of this active pharmaceutical ingredient.

Good healthcare is not possible without effective, safe medicines. Counterfeit drugs are extremely dangerous for patients and pose a global threat. The World Health Organization estimates that more than 10% of all medicines in developing countries are fake. As a provider of high-caliber products, we intend to lead the vanguard in the fight against counterfeits. We are therefore not only working with agencies across the world, but are also actively battling the spread of counterfeit medicines. Flagship efforts here include the Minilab from the Global Pharma Health Fund (GHPF), a philanthropic organization sponsored by our company. This portable, compact kit fits in a suitcase and can now test for 90 different active pharmaceutical ingredients. The Minilab enables people to identify counterfeit drugs quickly, which is especially useful in remote areas with inadequate infrastructure

For us, taking on responsibility also means minimizing our products' environmental impacts, as exemplified by our "green" solvent Cyrene™. Products such as Cyrene™ are bioderived from natural resources, making them more environmentally compatible, more biodegradable and easier to recycle. Through these sorts of green solvents, our customers in the pharmaceutical and agrochemical industries can make their own production processes safer and more ecofriendly.



As a science and technology company, we seek to make students passionate about science. We are therefore dedicated to improving biology and chemistry education and have been supporting the "Jugend forscht" young scientist competition in Germany for over 30 years. In 2018, we'll be marking our big jubilee by hosting the "Jugend forscht" nationals in Darmstadt for the third time and welcoming Germany's top young scientists to our site.

As you can see, social responsibility plays a key role at our company. To efficiently oversee our efforts across all businesses and countries, in 2017 we created a new Group function called Corporate Affairs. We also founded a philanthropic foundation dedicated to improving access to innovative healthcare solutions among underserved communities in developing nations. These endeavors illustrate how we make responsible governance an integral part of our operations.

Rather than hindering sustainable success, this approach represents the foundation on which our success is built. It has been our creed for 350 years – and will continue to be so far into the future.

Yours,

Stefan Oschmann

Stefan Oschmann, Chairman of the Executive Board and CEO

# strategy & management



- **6** Company profile
- **3** Letter from the CEO
- **8** Governance
- **9** CR strategy

- 11 Compliance
- **17** Human rights
- 19 Stakeholder dialogue
- 22 Materiality analysis

# company profile



### Part of the non-financial report

We are a global science and technology company headquartered in Darmstadt, Germany. With a history of nearly 350 years, we are the oldest chemical and pharmaceutical company in the world. In line with our strategic direction, Merck KGaA, Darmstadt, Germany comprises three business sectors: Healthcare, Life Science, and Performance Materials.

In Healthcare, we discover, develop and manufacture prescription medicines used to treat cancer, multiple sclerosis, and infertility. Our products help millions of people around the world. In Life Science, we conduct research for researchers, providing scientists with laboratory materials, technologies and services. Our aim is to make research and biomanufacturing easier, faster and more successful. Performance Materials develops specialty chemicals and materials for demanding applications – from liquid crystals and OLED materials for displays to effect pigments for coatings and cosmetics up to high-tech materials for the manufacture of integrated circuits.

### Who we are

We hold the global rights to the "Merck" name and brand. The only exceptions are Canada and the United States. In these countries, we operate as EMD Serono in the biopharmaceutical business, as MilliporeSigma in the life science business and as EMD Performance Materials in the high-tech materials business.

Apart from our three business sectors, our financial reporting presents the five regions Europe, North America, Asia-Pacific (APAC), Latin America as well as Middle East and Africa (MEA). As of December 31, 2017, we had 52,941 employees worldwide, which compares with 50,414 on December 31, 2016.

In 2017, our 217 subsidiaries with employees in 66 countries generated sales of  $\in$  15.3 billion. Our 98 production sites are located across 24 countries.

### Employees and sales by region - 2017



# **Group structure**

Merck KGaA, Darmstadt, Germany is a vibrant science and technology company.

Our **Healthcare** business sector comprises the three businesses Biopharma, Consumer Health, and Allergopharma. Our

Biopharma business discovers, develops, manufactures and markets innovative pharmaceutical and biological prescription drugs in four franchises: Oncology, Neurology & Immunology, Fertility, and General Medicine & Endocrinology. Biopharma is the largest of our Healthcare businesses. Our streamlined R&D pipeline positions us with a clear focus on becoming a leading specialty innovator in oncology, immuno-oncology and immunology, including multiple sclerosis. Our Consumer Health

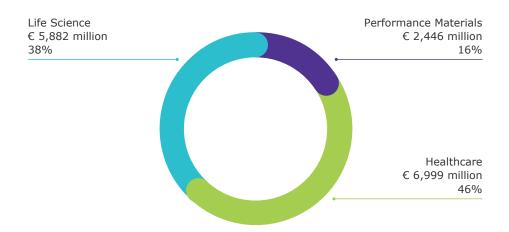
business focuses on consumer-centric innovation under the umbrellas of several strategic brands such as Neurobion®, Bion3®, Nasivin®, Femibion®, Sangobion®, Vigantoletten® and Kytta®.

In the **Life Science** business sector, our purpose is to solve the toughest problems in life science by collaborating with the global scientific community – and through that, we aim to accelerate access to health for people everywhere. We serve customers in academia, biotech and pharma – helping them to deliver the promise of their work better, faster and safer. As a leading player in the life science industry, we offer innovative solutions for scientists and engineers at every stage. Our 300,000 products range from lab water systems to genome-editing tools, antibodies and cell lines, as well as end-to-end bioprocessing systems to support the manufacturing needs of both emerging biotech and large pharma companies. After successfully orchestrating the largest integration in the

history of Merck KGaA, Darmstadt, Germany, the Life Science business sector redesigned its organizational structure in the second quarter of 2017. Strategic Marketing & Innovation units and commercial teams have been streamlined into three distinct business units – Research Solutions, Process Solutions and Applied Solutions.

Our specialty chemicals business is combined in our **Performance Materials** business sector. The portfolio includes high-tech chemicals for applications in fields such as consumer electronics, lighting, coatings, printing technology, paints, plastics, and cosmetics. Performance Materials comprises four business units: Display Materials, Integrated Circuit Materials, Pigments & Functional Materials, and Advanced Technologies.

### Net sales by business sector - 2017



# Governance

Based in Darmstadt, Germany, our company operates in the legal form of a corporation with general partners (Kommanditge-sellschaft auf Aktien – KGaA). The general partner E. Merck KG., Darmstadt, Germany holds around 70% of the total capital of Merck KGaA, Darmstadt, Germany (equity interest); the share-holders hold the remainder, which is divided into shares (share capital). Our shares have been included in the DAX<sup>®</sup> 30, the blue chip index of the Deutsche Börse, since 2007. In September 2008, our company was added to the FTSE4Good Index, a sustainability index that assesses the social, ecological and ethical conduct of companies.

# **Group strategy**

Over the past decade, Merck KGaA, Darmstadt, Germany has transformed itself from a classic supplier of chemicals and pharmaceuticals into a global science and technology company. The main driver was the transformation of our business portfolio, particularly through the divestment of our Generics business (2007) and the acquisitions of Serono (2007), Millipore (2010), AZ Electronic Materials (2014), and Sigma-Aldrich (2015). In addition, we focused our businesses on innovation-driven and highly specialized products, extensively revamped our internal structures and processes, and expanded our presence in global growth markets. In line with this strategy, we completed the divestment of our Biosimilars business in 2017. In addition, we are preparing strategic options for our Consumer Health business, including a potential full or partial sale of the business as well as strategic partnerships.

Read more on our Group strategy in our Annual Report 2017.

# **GOVERNANCE**



# Part of the non-financial report

Responsibility has been an integral part of our corporate identity for 350 years. It is therefore one of our six Values, together with Courage, Achievement, Respect, Integrity, and Transparency. These core values guide us in our daily work, defining how we interact with our customers and business partners. We research and develop products to enhance life in all its diversity, from the great questions facing humanity to the little everyday pleasures. We endeavor to give patients and customers the best – and find solutions for the world of tomorrow.

# Our approach to responsible governance

Our Mission Statement and Values, along with the external regulations and initiatives to which we are committed, give rise to requirements for responsible governance that are integrated in both our Corporate Responsibility strategy (p. 9) and our Group-wide guidelines.

Our Group-wide guidelines comprise charters and principles valid for the entire company, as well as specific standards and procedures for individual business sectors and sites.

Take for example our Corporate Environment, Health and Safety (EHS) Policy, which forms the basis for implementing the chemical industry's Responsible Care<sup>®</sup> Global Charter. Or our Safety Policy for chemical products, which defines product safety processes and the corresponding management structures.

# How we live responsible governance

Derived from the provisions contained in charters, principles and policies, our internal standards give specific guidance to those responsible for operational processes. They are constantly updated by the relevant departments and are available on our Intranet. Our managers implement these standards in their respective areas of responsibility and ensure that they are adhered to. We moreover educate and train our employees on all guidelines that apply to them.

We employ management systems to steer processes as well as define goals, actions and responsibilities. These systems are based on standards such as the internationally recognized quality management standard ISO 9001, good working practices (GxP) in the pharmaceutical industry, and ISO 14001 for environmental management. We regularly undergo ISO 14001 and ISO 9001 certification, which is conducted by an independent auditing firm, and hold Group certificates for both.

We support the following responsible governance initiatives:

- **The United Nations Global Compact:** Since 2005, we've been a member of the United Nations Global Compact and are committed to complying with its principles. Our annual progress report illustrates how we live our responsibility in our day-to-day actions.
- Responsible Care<sup>®</sup>: As a signatory to the chemical industry's Responsible Care<sup>®</sup> Global Charter, we voluntarily go above and beyond what is required by law and have adopted mandatory standards for product responsibility, environmental impact mitigation, health, and safety.
- **Together for Sustainability:** As a member of the Together for Sustainability (TfS) network, we are dedicated to improving the supply chain with respect to environmental, compliance and social standards.
- Chemie<sup>3</sup>: We are a member of Chemie<sup>3</sup>, a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE). Through this globally unique alliance, the partners aim to make sustainability a core part of the chemical industry's guiding principles and to jointly drive the sector's position within the German economy as a key contributor to sustainable development. This initiative has developed a system of 40 indicators to measure the progress of sustainable development within the chemical industry.

# cr strategy



Part of the non-financial report

Mankind is facing major global challenges such as climate change, growing resource scarcity, aging populations, threats to human rights, and barriers to health – the latter particularly in low- and middle-income countries. To overcome these issues, not only policy makers and civil society but also the private sector must join forces to find solutions.

sible conduct a pillar of our corporate culture. This approach is also the foundation of our sustained success. Through our innovative top-quality products for the healthcare, life science and performance materials sectors, we seek to help resolve global challenges.

and the people around us, which is why we've made respon-

# Our approach: Looking, listening and doing better

We are aware that as a leading science and technology company our business operations impact our environment

Our Group strategy aims to maximize our success, which goes hand in hand with respecting the interests of our employees, customers and shareholders, as well as those of the community. Our Group strategy underpins our corporate responsibility (CR) strategy. All our CR activities fall under the heading of "responsible governance", which for us most importantly means looking, listening and doing better.

### **Our CR strategy**



We take responsibility for our products, the environment and the people around us – especially for our employees and the communities in which we operate. Through our products, we endeavor to meet people's current and future needs. In doing so, safety and ethical aspects matter just as much to us as business success. In our production activities, we seek to impact the environment as little as possible, which requires safe manufacturing techniques, high environmental standards and strict quality management. Furthermore, we strengthen our company by recruiting, developing and moti-

vating talented employees. We strive to set an example for ethical conduct and actively contribute to the communities we live in.

We aim to quickly identify new global trends and challenges, for instance by fostering dialogue with stakeholders (p. 19), participating in initiatives and engaging other companies, as well as by evaluating media coverage. This allows us to minimize risks while also leveraging business opportunities that arise. In our efforts, we have chosen to pursue three

strategic spheres of activity, namely health, the environment, and culture  $\&\,$  education.

### Health

An estimated 400 million people lack access to adequate, affordable health care. Through our Group-wide Access to Health strategy, we seek to eliminate barriers in low- and middle-income countries in an effort to provide underserved populations and communities in these countries with better, sustainable access to high-quality health solutions. Developments such as rising life expectancy and simultaneously declining birth rates are also reflected in our health solutions, including our cancer research, for instance, or our fertility treatments. You can find more information under Access to health (p. 38).

### Environment

Many of our innovative products from our Performance Materials and Life Science business sectors help mitigate environmental impacts. Moreover, we strive to continuously enhance the sustainability footprint of our products while also helping our customers achieve their own sustainability goals.

As the global market and technology leader in liquid crystals, we are driving the creation of state-of-the-art, energy-efficient displays. Furthermore, we are developing materials for energy-saving lighting and photovoltaics, one of the ways we're tackling the issue of climate change and energy scarcity. You can find more information under Sustainable product design (p. 32).

# Education & culture

Culture inspires people and opens their minds to new possibilities, which is why we promote cultural initiatives worldwide and support education projects. After all, education is key to making culture accessible. Cultural inspiration in turn nurtures characteristics that are essential to our business activities as a high-tech company, such as creativity, enthusiasm for new discoveries and the courage to transcend boundaries. You can find more information under Community (p. 110).

# Corporate responsibility entwined with governance

Our CR strategy is approved by our Executive Board, which meets regularly to make decisions regarding our CR goals and reporting. Also charged with overseeing corporate responsibility, our Group function Corporate Affairs was created in September 2017 and reports to Stefan Oschmann, Executive Board Chairman and CEO. Oschmann bears overall responsibility for the committee, which is chaired by the head of Corporate Affairs.

Our CR Committee steers the implementation of our CR strategy and submits recommendations regarding CR goals to the Executive Board. This council consists of representatives from our business sectors as well as from relevant Group functions such as EQ, HR, Compliance, and Procurement.

Our CR Committee also reviews our CR strategy to ensure that it covers the issues relevant to our company. In doing so, we draw on regular input from our stakeholders (p. 19) as well as the results of a materiality assessment (p. 22). This council also defines measures to put our CR strategy into practice and reviews the success of these efforts. In addition, it ensures that the initiatives of our business sectors, Group functions and subsidiaries align with our Group-wide CR strategy. The measures adopted by the CR Committee are implemented by our line managers as well as by interdisciplinary project teams.

The CR Committee meets three times a year. In 2017, its meetings primarily focused on human rights, environmental and social standards along the supply chain, environmental targets, animal welfare, bioethical principles, and community involvement.

# Taking on responsibility worldwide

Our corporate responsibility activities align with the United Nations Sustainable Development Goals (SDGs). Here, we focus particularly on those SDGs that best reflect our business ethos. You can find more information on our efforts to support these goals under Sustainable Development Goals (p. 161).

# Understanding and minimizing the impacts of our operations

We work to mitigate the ethical, financial and legal risks of our business activities, thereby ensuring our social license to operate. To this end, we have put comprehensive structures and systems in place to ensure compliance with legal requirements, along with ethical, social and ecological standards, which are explained in detail in the individual sections of this report. Our environmental management activities, for instance, aim to minimize environmental impacts at our production sites.

# compliance



# Part of the non-financial report

First and foremost, responsible entrepreneurship means acting in accordance with the law, a practice also known as compliance. All our activities must adhere to laws and regulations worldwide because compliance violations might not only involve legal prosecution but could also seriously compromise our reputation as an employer and business partner.

# Our approach to compliance

Compliance is one of our primary considerations worldwide. Particularly as an international company with operations in developing and emerging countries, we have extremely stringent requirements for effective compliance management. Yet for us, there is more to compliance than adhering to regulatory provisions. We consistently aspire to act in accordance with the principles defined in our Values and believe that profitability should go hand in hand with the very highest ethical standards.

### How we ensure compliance

Our Group Compliance organization manages the core topics of anti-corruption, antitrust, data privacy, dawn raid preparedness, healthcare compliance, and transparency reporting. Other compliance related issues are managed by the responsible functions (such as Quality, Pharmacovigilance, and Environment, Health, and Safety (EHS)). To cover the core compliance topics, we have Group-wide compliance policies, procedures and processes in place to ensure that our business activities align with the relevant laws and regulations.

Supported by our Group Compliance organization, our Group Compliance Officer is responsible for our compliance program, which consists of the following elements:

- Efficient solution oriented systems and processes
- Enabling policies
- Monitoring and controls
- Case management
- Anonymous reporting
- Continuous improvement tailored to business risks
- Target-group focused training

Our compliance program is regularly updated to reflect new requirements such as those resulting from amendments to legislation, relevant industry codices or changes within our company.

The Group Compliance Officer reports to the Executive Board every six months on the status of our compliance activities, possible risks and serious compliance violations. In turn, the Executive Board updates our supervisory bodies at least twice a year on key compliance issues. As part of regular reporting processes, we annually compile a comprehensive compliance and data privacy report detailing the status of our compliance program, updates that have been made, compliance and data privacy cases, and training figures. Additionally, an update is prepared at the mid-year mark highlighting current developments and the status of relevant projects and initiatives.

Worldwide, our Group Compliance Officer oversees 79 Compliance Officers who are assigned to business sector teams and implement the measures of our compliance program within their respective areas of responsibility. In executing their tasks, these Compliance Officers receive guidance from our Group Compliance Programs & Support team, a centralized body that drives the design and update of our compliance program across all business sectors and Group functions and is responsible for initiating necessary measures.

### **Compliance organization**



In addition to these efforts we have created a global Transparency Operations team to incorporate current and upcoming **transparency reporting requirements in the health sector** – such as those of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the U.S. Physician Payments Sunshine Act.

Since 2017, our compliance framework has been integrated more closely within the business sectors. For example, we are developing a new holistic concept that combines the existing monitoring controls into a single system, providing a dashboard view of potential compliance risks across the organization.

In updating guidelines and training curricula, we also link compliance requirements specific to each business sector by integrating them into employee training material.

To support local Compliance implementation, we introduced designated Compliance Ambassadors who operate independently of our Compliance Organization. We appointed ambassadors in the following regions:

- Africa: Algeria, Angola, Botswana, Egypt, Ghana, Kenya, Mauritius, Morocco, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Tunisia, Uganda
- Middle East: Bahrain, Iran, Iraq, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen
- South America: Argentina, Chile
- China
- Germany

### Clear chain of command for reporting violations

Reports of potential compliance violations received via our SpeakUp Line are reviewed by Group Compliance before being submitted to the Group Compliance Case Committee, which consists of senior representatives from Internal Auditing, Group Compliance, Corporate Security, Data Privacy, and Human Resources. Stefan Oschmann, Executive Board Chairman and CEO, heads the committee. An associated sub-committee advises on disciplinary action if necessary.

# Conflicts of Interest

We take all potential conflicts of interest seriously. Every conflict is disclosed to the employee's supervisor and the disclosure is documented. Such issues are mainly managed in a direct relationship between employee and supervisor, but can also be routed to superior HR or employment law functions. To involve the Executive Board, we have implemented a specific governance process, including a periodical request for information on potential conflicts to be provided to shareholders and related parties.

Furthermore, we document our commitment to an appropriate conflict of interest process in our Annual Report.

# Data Privacy integrated into Compliance

Our Data Privacy unit has been organizationally integrated into Group Compliance. As required by law, this unit acts independently and compiles a comprehensive data privacy report as a part of the compliance report. Furthermore, the Data Privacy team submits regular data privacy updates as part of our overall Compliance reporting. Since 2017, the team has comprised four employees in Darmstadt. We have Data Safety Officers in place at numerous sites.

### **Our commitment: Guidelines and standards**

Our compliance program builds on our Values and integrates these into our compliance framework, which contains guidelines for entrepreneurial conduct that are mandatory for all our employees Group-wide:

- Our Code of Conduct provides our people with a tool that promotes ethical business practices. At the end of 2017, we started the roll-out of an updated version of our Code of Conduct called "What guides us". Approved by the Executive Board, this version has a strong relation to our Values along with newer topics such as data protection, supplier due diligence and bioethics. The updated code is available to employees both digitally and as a print brochure. Available in 22 languages, it explains the principles for interacting with business partners, employees, and the communities in which we operate.
- Our Human Rights Charter supplements our Code of Conduct with globally valid principles regarding human rights as well as the core labor standards of the International Labour Organization (ILO).
- Our Anti-Corruption Policy stipulates that all business activities must be conducted in accordance with legally applicable anti-corruption standards. All forms of bribery whether giving or receiving are strictly prohibited. We have reinforced our policy by adding and updating relevant corruption prevention sections. One example is the changes made to the gifts and hospitality section. Additionally, we have created guidelines on local limits and thresholds in giving or receiving gifts and hospitality to or from third parties (including public officials and external business partners). Moreover, in 2017 we also incorporated our Global Business Partner Risk Management principles into our Anti-Corruption Policy.
- Our Pharma Code (for prescription medicines) and our Consumer Health Code (for over-the-counter medicines) set out key principles for interactions with our partners in the health industry.
- Our Group-wide Antitrust and Competition Law guideline stipulates that all business activities across the Group are to be carried out in compliance with applicable competition regulations at all times. We acknowledge the importance of fair competition and expect the same of contract organizations acting on our behalf.

Since 2016 we have been using an online confirmation process to send Group-wide policies to relevant managers, Group Compliance and Legal. Recipients then confirm not only receipt of the policies, but also that they are being adhered to and implemented appropriately at the relevant sites.

# Guidelines for new business units

Where necessary, we update our policies according to external requirements. In 2017, we integrated the Medical

Devices and Services unit into the scope of existing Biopharma Compliance policies and created separate legal and compliance guidance for business interactions with our key stakeholders.

We recognize the fact that we are increasingly **interacting** with patients and patient organizations and therefore revised our corresponding compliance policy.

### Requirements for our business partners

To be effective, compliance management needs to go beyond the boundaries of our own company, which is why we expect all our business partners worldwide to comply with our compliance principles. We only collaborate with partners who pledge to comply with all applicable laws, reject all forms of bribery, adhere to environmental, health and safety guidelines, and refuse to tolerate discrimination. Furthermore, we contractually require our business partners to demonstrate a commitment to internationally recognized human rights and labor standards, as well as to our own compliance requirements. We also monitor adherence to these standards for existing business relationships – usually when a contract is being considered for renewal, or alternatively at least every four years.

While our supplier management processes (p. 104) focus on vendor compliance with our standards, our Global Business Partner Risk Management Process governs interactions with sales partners such as distributors and wholesalers. Our Business Partner Risk Management approach was updated in 2017 and integrated into our Anti-Corruption Policy.

In general, we are not able to negotiate social and environmental responsibility, compliance or integrity issues with each of our customers individually. Therefore in 2017, our Performance Materials business sector compliance team developed a global approach for responding to external Code of Conduct acknowledgment requests. To implement this framework, our Performance Materials Compliance team introduced the Corporate Responsibility Letter of Merck KGaA, Darmstadt, Germany and a correlation clause, starting with the Performance Materials business sector.

# Harmonizing data privacy Group-wide

Our "Policy for Data Protection and Personal Data Privacy" defines the standards according to which we process, save, use, and transmit data. This approach allows us to achieve a high level of protection for the data belonging to our employees, contract partners, customers, and suppliers, as well as patients and participants in clinical studies. Our **Group-wide understanding of data privacy** is based on European and German legislation. However, we also take into account local data privacy requirements, as not all requirements at all sites are covered by EU standards. In case of doubt, the respective national legal obligations take precedence. Whatever the situation, we fundamentally respect the rights of those affected.

We are already applying the new requirements of the European General Data Protection Regulation. In line with this regulation, we have established working groups to review the compliance of our various business units and improve existing measures where necessary.

# **Compliance audits**

As part of operational audits, our Group function Internal Auditing regularly reviews matters relating to compliance at our sites to determine which compliance guidelines, processes and structures are in place and how effective they are. In addition, Internal Auditing also checks for violations of our Code of Conduct and our Anti-Corruption Policy, and reviews the workplace requirements set out in our Human Rights Charter.

Our audit planning aims to provide comprehensive risk assurance through the best possible audit coverage. Our annual audit planning process is risk-based and includes factors such as sales, employee headcount, systematic stakeholder feedback, and the Corruption Perceptions Index (CPI) published by the non-governmental organization Transparency International. If an internal audit results in recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the prescribed corrective actions.

# **Compliance training**

We regularly provide compliance training in the form of classroom and online courses that cover our Code of Conduct, anti-corruption, antitrust awareness, data privacy, and healthcare compliance standards. These courses are attended by employees at all levels as well as independent contractors and supervised workers (such as temporary staff). We regularly update our training plan and adapt it to new developments.

11,521

people were trained on our Code of Conduct and sensitized to the consequences of compliance violations through our elearning system in 2017. A further component of this training focuses on preventing compliance violations.

We are currently working on a **business sector-specific e-learning program** centered on our new Code of Conduct. We plan to roll this program out in 2018.

We continually educate our employees on new compliance requirements, guidelines and projects, and also offer an online course on our Anti-Corruption Policy **in 15 languages**. In 2017, a total of 7,315 employees and contractors took part in anti-corruption training.

Some seminars on special topics are specifically developed for professionals in certain roles. When participating in pharma-specific training, for example, employees in our Healthcare business sector also receive training on relevant compliance issues.

To complement the online courses we offer, numerous classroom courses are also held for employees Group-wide with a particular focus on local issues. In 2017, we furthermore developed a game for our sales representatives that **simulates typified behaviors** tailored to a multitude of compliance scenarios that our sales heads experience on a regular basis.

In addition to these training offerings, Group Compliance has partnered with our Chief Medical Office team to develop a training course for our Medical employees. Accessible via our education portal, this course comprises important modules containing compliance-related topics such as Medical Education Funding (p. 71), Medical and Commercial Interactions (p. 70) and Patient Support Programs (p. 46). The course is also open to all interested employees, including those from other units.

We also regularly provide data privacy training courses that new employees must complete, focusing especially on data privacy rules and the **new European General Data Protection Regulation**. Furthermore, we keep all employees up to date through regular refresher training.

## "Compliance. Because we care"

Our internal "Compliance. Because we care" initiative aims to increase awareness of compliance throughout our Group. Harnessing the power of emotion, we have incorporated evocative visuals to bring key compliance aspects closer to our employees, thus heightening their sensitivity to these issues. Launched in 2017, the initiative is being implemented gradually Group-wide.

In addition to providing training in the form of webinars, Skype meetings and on-site events, we inform our staff about compliance issues through a variety of media, including our Intranet, newsletters, our employee magazine "pro (p. 83)", and posters.

# SpeakUp Line for potential compliance violations

All Group employees are encouraged to report potential compliance violations to their superiors, Legal, HR, or other relevant departments. Worldwide, they can also use our central SpeakUp hotline to report violations by telephone or via a web-based application in their respective national

language, free of charge – and, if desired, anonymously. Based on recommendations from the Group Compliance Case Committee, where necessary disciplinary actions may also be taken by the responsible superiors against employees who have committed a compliance violation. These actions may range from a simple warning to dismissal of the employee, depending on the severity of the violation. Our Business Partners who have undergone the Business Partner Risk Management Process can also use the SpeakUp Line to report violations of internal or external rules.

Both the number of reports of suspected compliance violations and the number of actual compliance cases has remained largely stable in recent years. In 2017, 39 compliance-related reports leading to investigations were received via the SpeakUp Line and other channels. In 2017, there were 14 confirmed cases of violations of the Code of Conduct. The majority of these constituted minor, isolated incidents resulting from the misconduct of individual persons, and appropriate disciplinary action was taken. One case concerned a testing facility and comprised issues relating to site management as well as control deficiencies in certain areas. Another case related to interactions with healthcare professionals and organizations where local practices did not meet the requirements of our Group policy.

# Risk analysis and management of business partners

We apply a risk-based approach to selecting sales-related business partners. The greater we estimate the risk to be regarding a certain country, region or type of service, the closer and more carefully we examine the company before entering into a business relationship with them. For these risk assessments, we use the Corruption Perceptions Index (CPI) maintained by Transparency International and assess potential partners against other parameters such as the nature of the intended service. We also tap into background information from various databases and information reported by the business partners themselves, for instance on their own compliance programs.

In 2017, we re-designed our Business Partner Risk Management Process and automated certain processes. This change allows us better scrutiny of our business partners in highrisk environments such as countries with a CPI rating below  $50 \ (0 = \text{highly corrupt/100} = \text{very clean})$ . This enables us to further reduce legal and reputational risks that may arise from bribery committed by third parties.

If we encounter compliance violations, we decide whether to reject the potential business partner or terminate the existing relationship. However, our partners are generally willing to adapt their structures and processes in line with our strict compliance requirements. Since launching this process in 2013, we have assessed more than 2,800 business partners, and in 2017 we used this process to assess 690 new business partners.

In 2017, we continued our compliance training for the employees of our business partners as part of our Business Partner Risk Management Process. This training is mandatory for all personnel who come into contact with our company or products. It is available in eight languages and focuses on general compliance, corruption prevention and competition law. In 2017, 3,699 employees from our partner companies completed this training.

# **Ensuring data privacy and information security**

We operate a data privacy management system as part of our Group Compliance organization. This system has been harmonized across the Group. Moreover, we also protect our information systems, their contents and our communication channels against criminal activities (eCrime, cyber attacks) of any kind, including unauthorized access, information leaks and misuse. To do so, we work with our Group Security unit to undertake a variety of technical, organizational and process-based measures based on recognized international standards. We have harmonized electronic and physical security measures (such as access control) to bolster our ability to handle sensitive data such as trade secrets. Group Internal Auditing verifies that we are implementing and complying with our data privacy policy and data security programs.

Our data privacy management system aligns with the PDCA principle (plan, do, check, act), which is intended to ensure that data privacy policies and tools (plan), data privacy training (do), inspections and assessments (check), and an incident and issue management process (act) are all in place.

To support local Data Privacy Officers at our sites, we have introduced **standardized data privacy consulting services** that can be requested by data controllers and processors as needed. We have also implemented a central IT tool to provide a single source for data privacy processes, e.g. answering data privacy questions and reporting potential data privacy incidents.

# **EFPIA Transparency Initiative**

Since 2016, members of the Transparency Initiative of the European Federation of Pharmaceutical Industries and Associations (EFPIA) have been required to publish all contributions to medical professionals and organizations in the health sector, along with the names and addresses of individual recipients. Beyond this initiative, several countries have introduced legislation to further increase transparency in the pharmaceutical industry. We comply with these requirements and additional standards governing interactions in the healthcare industry (p. 70) and have been including them in our EFPIA reporting since 2016.

# **Alliance for Integrity**

We are a member of the Alliance for Integrity Steering Committee. Established by the German Society for International Cooperation (GIZ), the German Global Compact Network (DGCN) and the Federation of German Industries (BDI), this initiative aims to achieve a corruption-free business world in developing and emerging countries. Its activities are concentrated in Argentina, Brazil, Ghana, India, and Indonesia. The Steering Committee leads the decision-making process for developing measures in these countries, while local advisory groups oversee implementation at the country level. Our local Compliance organizations also collaborate with these groups and provide training that is offered to small and medium-sized companies. We furthermore support anti-corruption conferences such as the World Conference hosted by the German Chamber of Commerce, which will be held in February 2018 in Frankfurt. Beyond these efforts, we continuously assist the Alliance for Integrity through business-to-business workshops and training

courses, and by sharing best practices on how to develop and implement effective corruption prevention systems.

# **Engaging stakeholders**

In 2017 as well, we engaged stakeholders in a dialogue primarily through our memberships in various associations. Amongst other organizations, we are members of the German Chemical Industry Association e.V. (VCI), the German Institute for Compliance (DICO), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Alliance for Integrity, and the German Association for Supply Chain Management, Procurement and Logistics e.V. (BME).

# Human rights

First and foremost, all nations have a duty to establish a regulatory framework to protect human rights. Particularly for international enterprises, it is important for this framework to be implemented across all countries to level the playing field for competition. As a company, we in turn also have a duty to uphold human rights, taking steps to ensure that they are not compromised by our business activities. We are constantly working to integrate human rights due diligence into our processes in an effort to minimize the risk of human rights violations and to protect these rights within our sphere of influence.

# Our approach to human rights due diligence

We are committed to upholding and protecting human rights. To this end, we seek to better understand the potential impact of our business activities and relationships on human rights. Moreover, we examine our processes to identify the practices already in place at our sites that fulfill the function of human rights due diligence. This knowledge helps us adapt our Group-wide human rights due diligence efforts to better meet local needs and adapt our processes in response to the respective risk profiles. In doing so, we can develop approaches to overcome particular challenges. At the same time, we are working to identify the opportunities presented by the positive impacts of our operations.

Within the German Global Compact Network (DGCN), we are a member of the Business & Human Rights Peer Learning Group, a working group in which we engage with other companies to share lessons learned as well as successes in implementing human rights due diligence.

# How we promote respect for human rights

Our Executive Board bears ultimate responsibility for upholding human rights within our organization. Our Group function Corporate Affairs handles the coordination of activities and processes relating to human rights due diligence. Progress and measures are regularly discussed at CR Committee meetings, while subject matter experts within our Group functions, business sectors and local units are in charge of implementing measures.

# Our commitment: Guidelines, charters and laws

Our Human Rights Charter affirms our commitment to respecting human rights while also defining the relevant requirements for our company. This charter furthermore unites and complements existing policies and guidelines on

human rights such as our Code of Conduct, our Corporate Environment, Health and Safety Policy, our Responsible Sourcing Principles, and our Charter on Access to Health in Developing Countries. Our Human Rights Charter was developed in collaboration with human rights experts from various countries, including representatives from trade unions and business federations.

At the end of 2016, the German federal government adopted a **National Action Plan for implementing the UN Guiding Principles for Business and Human Rights** (NAP). We are committed to these principles, which codify the duty of states to protect human rights as well as the responsibility of companies to uphold them, providing a framework for how nations and businesses should do so. Through our current efforts and initiatives, we are on the right track to fulfilling the requirements stipulated in the National Action Plan.

In the United Kingdom, the **UK Modern Slavery Act** requires us to report on the steps we are taking to counter forced labor and human trafficking. Our company issued its first UK Modern Slavery Statement in 2017. This statement has been endorsed by our Executive Board and is available on our website.

# Constantly improving our risk management

Based on the findings from our 2012 Group-wide human rights risk assessment and our 2014 human rights impact assessment pilot in India, all our subsidiary heads conducted a human rights self-assessment at the end of 2016. Using an electronic survey we created, they provided detailed information on the main subject areas covered by our Human Rights Charter. This survey will help us better understand how our subsidiaries perceive human rights risks and manage them locally, while also raising human rights awareness and creating a foundation for systematic support.

In 2017, we evaluated the results of the survey and held discussions with subject matter experts in Group functions such as Procurement, Human Resources and Compliance. The conclusion was that our subsidiaries are thoroughly aware of human rights risks, guidelines and processes. This includes their employees' work conditions, potential product impacts, data protection, privacy protection, and access to health. Many of our subsidiaries also displayed sound knowledge of and great interest in human rights. At the same time, we identified some areas where we can improve. Regarding several issues, we need to increase risk awareness within our subsidiaries and must work to implement due diligence more stringently, embedding this approach more deeply at the operational level. We intend to use these findings to make our Group-wide approach to risk management more

effective. In the course of enhancing our processes, we will implement risk-based measures to increase awareness of slavery (such as forced labor and human trafficking) within the Group. Furthermore, in an effort to constantly improve ourselves, we will be reviewing our mitigation actions with respect to external staff, product and service sourcing, and collaboration with local contract partners.

In September 2017, we launched an electronic confirmation course for our Human Rights Charter as one of the first follow-up actions from our human rights self-assessment. This course is mandatory Group-wide for all site directors as well as all managers directly below Executive Board level. Procurement executives from the second and third managerial tiers below the Executive Board are also required to take the course, which focuses on modern slavery and the increasing regulatory requirements for companies such as those set out in the National Action Plan and the UK Modern Slavery Act. By taking the course, participants confirm that they have read and understood our Human Rights Charter, and are implementing it within their area of responsibility.

In early December 2017, we informed all self-assessment participants of the aggregated results and called on them to take steps within their sphere of responsibility to implement the corrective actions identified. Furthermore, we've used the results to formulate numerous measures aimed at reinforcing human rights due diligence within our company. In 2018, for instance, we plan to review our company's existing grievance mechanisms, focusing particularly on their scope and effectiveness.

# **Human rights and investment decisions**

When projects exceed a certain cost threshold, our Investment Committee must approve the expenditure. The committee's decision takes into account factors such as environment, safety and health. When it comes to investment projects, we are also bound by our Code of Conduct, which stipulates compliance with the principles of the UN Global Compact and therefore also with the core labor standards of the International Labour Organization (ILO), such as the prohibition of child and forced labor.

# **Keeping employees informed**

We use a variety of channels to educate our employees on human rights, including specific Intranet sites along with videos and other articles featuring employees explaining how their work intersects with human rights.

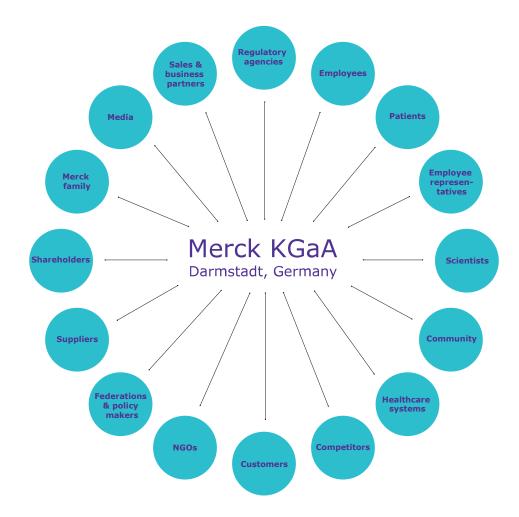
# stakeholder dialogue

Our business activities converge with the interests of many people, which is why engaging with our stakeholders is particularly important to us. We aim to unite divergent interests as far as possible, as well as build and sustain trust. Through this dialogue, we communicate our decisions and actions transparently in an effort to ensure social license to operate.

# **Dialogue at various levels**

Our key stakeholders include our employees, customers and business partners, patients, the Merck family, and our suppliers. We maintain continuous contact with them through a variety of channels, including stakeholder surveys, issue-specific dialogues, roundtable discussions, and information forums. We also engage stakeholders through our advocacy work and industry coalitions.

### **Our stakeholders**



# Regular stakeholder surveys

We regularly conduct surveys among our employees, customers and business partners, as well as other relevant stakeholder groups. We want to know which issues they consider to be of importance to our company now and in the future, along with how they rate our performance in addressing the individual issues. We also seek to understand their expectations of us as a responsible company. Our CR Report reflects the results of these surveys and presents the actions we've taken in response.

In November 2017, we conducted a Group-wide employee survey in 22 languages. Around 42,100 employees took part, representing an 84% response rate.

# Issue-specific dialogue

Our business operations in the areas of healthcare, life science and performance materials intersect the interests of various social groups, whom we engage via questionnaires, workshops and seminars, or even at major conferences. Our departments organize such forms of exchange at the local, national and international level, depending on the topic and degree of importance. Beyond this, we are also involved in industry networks and participate in symposia. In 2017, we intensified our efforts in the following areas:

Improving access to health: As part of our aim to improve access to health in low- and middle-income countries, we continuously engage various stakeholders through channels such as our Access Dialogues, which in 2017 focused on open innovation, intellectual property, and local supply chain challenges. Launched in 2013, this event series provides a platform for public and private sector stakeholders to exchange important information and share best practices pertaining to access to health. You can find more information under Access to health (p. 38).

**Sourcing mica responsibly:** In November 2017, we attended the Delhi kick-off of the Responsible Mica program, which was launched in response to the 2016 Mica Summit. As founding members, we are committed to increasing the traceability of mica all along the supply chain and to improving the living conditions of the communities in the mining regions. At the event, members endorsed a five-year action plan that defines steps for establishing a responsible and completely traceable mica supply chain. Further information can be found under Mica supply chain (p. 106).

**Partnering with pioneers:** We seek to engage with pioneers who look far into the future and develop cutting-edge technologies. To this end, we established the annual Displaying Futures symposium, which was held for the eighth time in 2017. Under the banner of "Digital Transformations", we convened in Tokyo (Japan) to examine digital transformation from different angles and explore new societal trends. At this conference we asked ourselves how we could use our

Performance Materials products to advance various ideas and serve as a source of inspiration. We also discussed how to guide research and development efforts onto the right track from the very beginning. Further information can be found under Sustainable product design (p. 32).

### Roundtables and informational forums

We have set up roundtable discussions and informational forums for local residents at our major sites. Since 1994, we have been holding an annual public planning forum in Darmstadt to discuss the development of our site with members of the city council, local authorities and the community. In 2017, this forum mainly focused on the changes resulting from our ONE Global Headquarters initiative (p. 82), particularly the new sewer system being laid by the City of Darmstadt and the future design of Frankfurter Strasse.

# Advocacy groups and industry coalitions

We actively participate in the political process and advocate our views by engaging policy makers in a direct dialogue as well as through our work with industry coalitions. Below are several examples of major national and international industry associations in which we are members and hold positions:

- German Chemical Industry Association e.V. (VCI)
- European Chemical Industry Council (Cefic)
- German Association of Research-based Pharmaceutical Manufacturers e.V. (vfa)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Examples of positions held by members of our Executive Board include:

# Stefan Oschmann, Chairman of the Executive Board and CEO:

- European Federation of Pharmaceutical Industries and Associations (EFPIA), President
- German Chemical Industry Association e.V. (VCI), Board of Directors
- Deutsche Welle, Business Advisory Board

# Udit Batra, Executive Board member and CEO Life Science:

- Greater Boston Chamber of Commerce, Board member
- Massachusetts High Technology Council (MHTC), Vice Chair

 University of Delaware College of Engineering, member of the Advisory Council

# Kai Beckmann, Executive Board member and CEO Performance Materials:

- Federal Employers' Association for the German Chemical Industry e.V. (BAVC), President
- Darmstadt Rhein Main Neckar Chamber of Industry and Commerce (IHK), Vice President
- Fraunhofer Institute for Computer Graphics Research (IGD), Chairman of the Advisory Board
- Confederation of German Employers' Associations (BDA),
   Vice President

### Walter Galinat, Executive Board member:

- German Chemical Industry Association e.V./Hesse
   Chapter (VCI Hessen), Chairman of the Hesse Chapter
- Trade Policy Committee of the German Chemical Industry Association e.V. (VCI), member
- Board of Trustees of the Chemical Industry Fund (FCI) within the German Chemical Industry Association e.V. (VCI), member

# Belén Garijo, Executive Board member and CEO Healthcare:

 Pharmaceutical Research and Manufacturers of America (PhRMA), Board member

# Marcus Kuhnert, Executive Board member and Chief Financial Officer:

- German Committee on Eastern European Economic Relations, member
- Deutsches Aktieninstitut e. V. (DAI), Board member

### Involvement in initiatives

We collaborate with numerous civically engaged organizations such as the Goethe-Institute, the Joint Conference Church and Development (pharma dialogue) and the World Environment Center (WEC). Furthermore, we are also involved in initiatives and projects (p. 8) that share our interpretation of responsible entrepreneurial conduct. That is why we support, for instance, the Code of Responsible Conduct for Business and are members of the Chemie<sup>3</sup> and Responsible Care<sup>®</sup> initiatives.

## **Political donations**

In general, we do not make donations in the form of financial contributions or services to political parties or related organizations. Donations to holders of political office or candidates for such, as well as to political initiatives, must always comply with the statutes in force in the recipient's country. This approach is stipulated in our internal guidelines. In the United States, political action committees (PACs) have been set up through which our employees can donate money to support political candidates and organizations. Such donations are not made by or on behalf of the company; they are reported to the U.S. Federal Election Commission and publicly disclosed.

# materiality analysis



Part of the non-financial report

Which issues - in terms of our corporate responsibility are of particular significance to our long-term success? And what expectations do stakeholders have of our company? In an effort to answer these questions, we regularly conduct materiality assessments that aim to rate sustainability topics according to their importance to our company and external stakeholders. This allows us to align our business activities with their priorities. In applying this approach, we fulfill the requirements of the Global Reporting Initiative (GRI), the international framework on which we've based this CR Report, as well as meeting the obligation arising from the CSR Directive Implementation Act that was ratified in Germany in 2017. Consequently, in 2017 we reviewed the results of the comprehensive materiality assessment we conducted in 2016 to ensure they were still up-to-date and relevant.

# Validating material issues

In 2016, we conducted a comprehensive materiality assessment in which we evaluated media reports, inquiries from investors and sustainability ratings. We then weighted the issues based on the results of stakeholder surveys and interviews with experts. Both this process and the findings from the materiality assessment were reviewed by internal specialists and the CR Committee (p. 10).

In 2017, the 43 key issues identified in the 2016 materiality assessment were reviewed and validated by experts from the respective business sectors. In doing so, we took account of the latest developments, updating the analysis where necessary.

Our stakeholders rate product responsibility as very important, including product quality, the safety of chemical products, innovation, and research & development. In terms of issues relevant to our company, two additional topics were identified as a result of the validation process: capacity building was deemed an important component of increasing health awareness (p. 47) and our experts also identified genome editing as a key aspect of bioethics (p. 61). Both topics have been integrated into the relevant sections.

The topics rated as material form the focus of this CR Report. Since our stakeholders also expect information and transparency from us regarding less significant issues, we also report on these, albeit in less detail.

# Identifying issues for non-financial disclosure

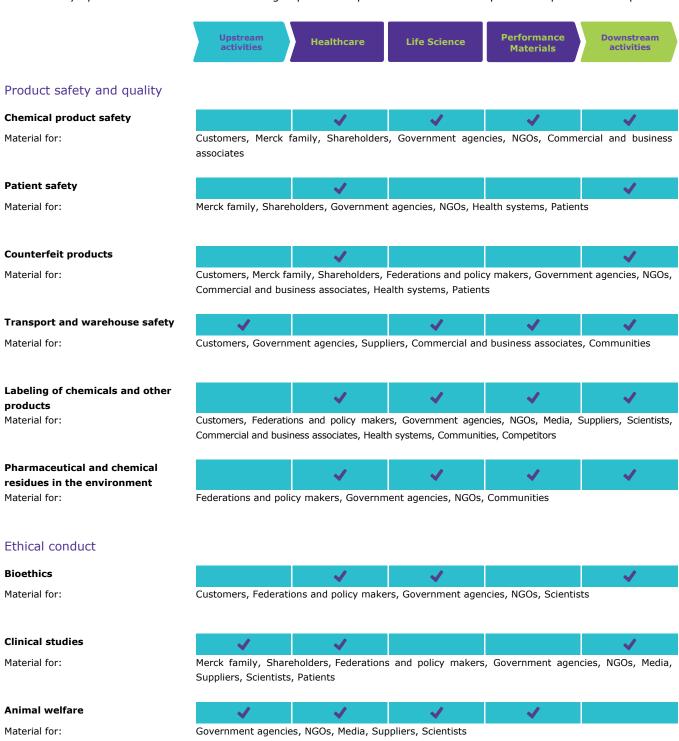
The German CSR Directive Implementation Act obliges us to review the "double materiality" of topics according to Section 289 (3) of the German Commercial Code. The principle of double materiality requires companies to disclose non-financial information when the following two criteria are met: Firstly, the information is necessary to understand the company's business performance, business results and financial situation. And secondly, the information makes it possible to understand how the company's business activities affect non-financial aspects. We have reviewed the double materiality of the issues validated in 2017, which were identified in the 2016 materiality assessment. The issues that fall within the scope of this definition are marked in the materiality matrix.

# **Material topics**

Supply chain standards	Ethical Conduct	Product safety and quality
☐ Supply chain standards	☐ Bioethics <b>②</b>	☐ Safety of chemical products <b>②</b>
	☐ Clinical studies <b>∅</b>	☐ Patient safety <b>⊘</b>
	Animal welfare	☐ Counterfeit products <b>勿</b>
		$\square$ Transport and warehouse safety $oldsymbol{arOmega}$
		$\Box$ Labeling of chemicals and
Health for everyone	Good Business Practice	other products 🕢
☐ Access to health	☐ Compliance <b>∅</b>	Pharmaceutical and chemical residues in the environment
☐ Prices of medicines <b>②</b>	☐ Responsible marketing <b>②</b>	Nanotechnology
Medicals to combat rare and	☐ Community involvement	<b>2</b> 1 1111 1 15,
neglected diseases	■ Interactions with health systems   ✓	
Health awareness	Governance	
	Advocacy	Sustainable products
Resource efficiency	Data security 🕢	
·		Sustainable product design
<ul><li>Waste and recycling</li><li>Water management</li></ul>		<ul> <li>Re-use and recycling of our customers' waste</li> </ul>
3 Water management		
Human rights	Climate Change	Attractive employer
☐ Human rights	☐ Energy efficiency and	Diversity and equal opportunity
	renewable energy	Attracting, recruiting and
	☐ Greenhouse gas emissions	retaining employees 🕢
		☐ Employee development <b>②</b>
		☐ Good leadership <b>②</b>
Technology	Environmental stewardship	☐ Employee engagement <b>②</b>
		☐ Safety and health <b>②</b>
■ Innovation and R&D <b>②</b>	☐ Process and plant safety  ☐ Process and plant safety	□ Work life balance ②
Digitalization	☐ Biodiversity	☐ Compensation <b>②</b>
<ul><li>Digitalization of the workplace</li></ul>	Other emissions	
■ Very high importance ■ High importan	nce Medium importance 🕢 Part of the	e non-financial reportipsum

### Material issues in our value chain

The following table shows where our main issues fall within the value chain: upstream in our supply chain, in the course of our own activities, or downstream with customers and patients. Moreover, we have listed the issues to show the breakdown of materiality by business sector and stakeholder group. These topics are linked to the respective chapters in this report.



# Good business practice



# Human rights

**Human rights** Material for: Customers, Federations and policy makers, NGOs, Media, Suppliers, Communities Sustainable products Sustainable product design Material for: Customers, Scientists Re-use and recycling of our customers' waste Material for: Customers Attractive employer **Diversity and equal opportunity** Material for: Employees, Employee representatives, Merck family, Media Attracting, recruiting and retaining employees Material for: Employees, Employee representatives, Shareholders, Competitors **Employee development** Material for: Employees, Employee representatives **Good leadership** Material for: Employees, Employee representatives **Employee engagement** Material for: Employees, Employee representatives **Health and safety** Material for: Employees, Employee representatives, Government agencies

# Technology

Material for:



Customers, Federations and policy makers, Government agencies, NGOs, Media, Suppliers

# products



- 29 Innovation and digitalization
- 32 Sustainable products
- 38 Access to health
- Prices of medicines
- **47** Health awareness
- Chemical product safety
- Patient safety

- Counterfeit products
- Transport and warehouse safety
- Responsible marketing
- Bioethics
- Clinical studies
- Animal welfare
- Interactions with health systems

# innovation and digitalization

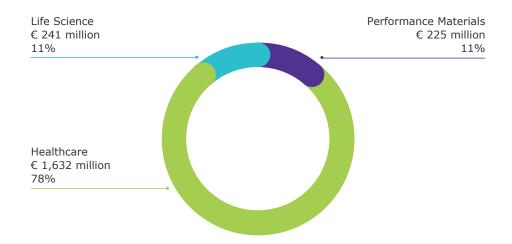


Part of the non-financial report

We develop products and technologies that enrich people's lives, and are constantly on the lookout for groundbreaking developments and trends. Research and development (R&D) as well as innovation are the cornerstones of our success. In 2017, we spent around € 2.1 billion on R&D. In particular new technologies and the advance of digitalization are

enabling us to create innovative products, services and pioneering business models. At the same time, digitalization is decreasing the time-to-market for new ideas, creating opportunities we intend to leverage.

### Research and development costs by business sector - 2017



### Our approach to innovation and digitalization

Our three business sectors Healthcare, Life Science and Performance Materials have established strategies to drive new product developments for the benefit of patients and our customers. The diversity of our business sectors provides us with a breadth of technologies and depth of market knowhow, giving us a competitive advantage in developing new products. In 2017, we established an organization to seize this opportunity by facilitating innovation between the individual business sectors and beyond our current strategy. Our **new Group function Strategy and Transformation** oversees an end-to-end process that ranges from setting the innovation direction, through ideation, incubation and growth of projects, to establishing long-term business models.

We are investing in forward-looking ideas. In deciding where to invest, we analyze current megatrends to determine the innovation fields in which we see potential for new business. We endeavor to identify innovation projects that transcend our current portfolio and develop them from the initial idea all the way to a functioning business model. This can only succeed if our business sectors work closely together— and if

we are open to external impetus. Our **end-to-end innovation process** seeks to achieve exactly that.

Based on this approach, we source and advance ideas and projects from the brainstorming stage onwards. Following the ideation phase, promising projects progress to an incubation and growth phase, where we provide project teams with a suitable environment in which to develop their business models. Project progress is monitored in a lean, gate-based process – applying strong criteria to evaluate the advance of the projects at each gate. All activities are **supported by experts** in business model design, business development and market research, as well as agile methodologies. The objective is that, after market launch, the new products or services will make a measurable contribution to our business success.

# Driving digital innovations

A major focus of our innovation efforts is digitalization. We want to leverage the opportunities this provides to boost our business performance and are therefore increasingly forming

new strategic partnerships with organizations that offer different perspectives. We expect to see progress in the following particularly promising areas:

- Research and development: Digital technologies enable us to access and quickly analyze large volumes of data, thereby accelerating our research and development activities. This is especially the case in our Healthcare business sector, where we are working to advance the development of new drugs to provide patients with faster access to effective medicines.
- **Supply chain management:** Digital technologies help us to better manage our supply chain. By collating all data centrally, we have access to crucial real-time data. This enables us to predict supply bottlenecks around the world and respond promptly, making sure medicines reach their destination.
- Interactions with customers: Thanks to modern data collection and analysis methods, we can make more efficient use of customer-relevant data. This information helps us to understand our customers more fully and facilitates our dialogue with them, allowing us to adapt our products and services where necessary.
- Digital product innovations: Digitalization enables us to broaden our existing product portfolio, for instance to include new digital services. Moreover, we intend to promote health awareness and improve patient treatment through innovative e-health offerings such as DORA (Diabetes Online Risk Assessment).

You can find more information on research and development in our Annual Report 2017.

# How we're driving innovations

The organizational set-up of our research and development activities reflects the structure of our company. In line with their individual innovation strategies, all three of our business sectors operate their own independent Research and Development (R&D) units. On top of that, our Group function Strategy and Transformation has developed a new end-toend process for innovation both within and beyond its current innovation strategy and is responsible for its implementation. This function reports directly to Stefan Oschmann, CEO and Chairman of the Executive Board.

Our Innovation Committee (IC) oversees the implementation of innovation projects both between and beyond our business sectors. It is tasked with ensuring that the **decision-making process** for selecting innovation projects is both **transparent and consistent**, and furthermore reviews the progress of ongoing efforts. The committee consists of senior executives from our Group functions and our three business sectors. If we participate in projects requiring larger-scale investments, the IC consults our Executive Board.

Even though we are **open to innovation** around the world, many potential partners for innovation projects are based in Silicon Valley, California (USA) – one of the key sites in the global high-tech industry. We are therefore currently building an innovation hub in Silicon Valley to be in closer proximity to the innovation partners there, be it companies or institutions. The head of our future hub is moreover building up a team of technology scouts to tap into the Silicon Valley innovation ecosystem. Also in 2017, we established the China Strategy and Transformation Group, which is responsible for driving our strategy, innovations and digitalization efforts between and beyond our business sectors in this fast-evolving market.

Our strategic Ventures Fund provides up to  $\in$  300 million for investments in start-ups. The fund is structured to enable us to invest in **external independent start-up companies** aligned with the strategies of Healthcare, Life Science and Performance Materials, as well as to invest in brand new businesses.

# Our commitment: Protecting innovative ideas

To ensure the fully confidential handling of sensitive information, especially intellectual property in digitalization projects, and to protect our innovative ideas, we adhere strictly to all data protection regulations. Our Policy for Data Protection and Personal Data Privacy defines the standards that govern how we process, save, use, and transfer data. You can find more information on data protection under Compliance (p. 11).

### **Spotlight on the Innovation Center**

Having started operations in the modular Innovation Center in May 2015, we completed the construction of our **new Innovation Center in Darmstadt** and moved into the new premises in early 2018. It will be officially inaugurated during our 350th anniversary celebrations in May. The Innovation Center offers our people and external partners an optimal environment in which to cultivate their ideas. We provide the infrastructure needed to advance cutting-edge projects, along with state-of-the-art methods and tools. Our work focuses on the following initiatives.

# Synergizing external ideas: Start-ups and crossindustry collaboration

Numerous start-ups are working on new technologies and innovative business models. Our global **Accelerator** program supports these enterprises in the early stages of their development, with a focus on projects in the fields of our business sectors and other current trends. In return, we gain insights into the innovative start-up scene and are able to identify emerging market trends early on. Moreover, we aim to link these start-up companies with our innovation projects or our business sectors for future collaboration.

Our Accelerator is complemented by **hackathons** that we supported in 2017 in countries such as Israel, the United States, Germany, and Italy, as well as a **Virtual Challenge** in Africa. A hackathon is an event at which students and young professionals from various disciplines collaborate to quickly develop solutions to specific issues. We ran Africa's first-ever hackathon in 2016, which led us to invite the start-up Peach Technologies to join our 2017 Accelerator in Nairobi, Kenya. At this event, they developed an electronic patient file and prevailed against 200 competitors.

The 198 participants of our Virtual Challenge, an online competition, tackled real-life problems in Africa in an effort to devise solutions. Examples included improving healthcare delivery and outcomes, safe food production and water sanitation. We provide six months of funding and support for the best idea to come out of the Virtual Challenge. In 2017, we selected Zelij Invent, a project that put forward a solution for producing flooring products made out of plastic waste. Its application will be fast tracked to the shortlist for the Accelerator.

We also supported the start-up program Highest 1877 run by the Technical University (TU) of Darmstadt. In March 2017, we teamed up with TU Darmstadt to organize a round-table for entrepreneurs at our Innovation Center, which was attended by around 50 start-up founders and other key actors in the field of innovation and entrepreneurship.

At the end of 2016, we entered into a **two-year partner-ship with the European Space Agency (ESA)** through which we hope to leverage synergies in areas such as innovation, digitalization and materials research. Within this framework, in 2017 we joined forces with Airbus to sponsor the Sustainable Exploration Challenge within the ESA Space Exploration Master's program. The competition is specifically aimed at start-ups and endeavors to find solutions capable of supporting human life in space – for instance by making use of special chemical and biological processes. Furthermore, we hosted the Space2Health hackathon at our Innovation Center in October 2017, where participants developed solutions for specific challenges using data from the health and aerospace industries.

# Channeling internal ideas to generate innovation projects

We want to maximize the innovative power within our company, which is why we give our employees around the world the opportunity to present their ideas to us via various channels. Our objective is to identify ideas between our business sectors and beyond our current scope that have the potential to become viable businesses. Within our **Innospire** (innovation and inspiration) initiative, we encourage our employees to submit ideas for new products, services and business models. The best suggestions are then developed into business plans in a multi-stage process. You can find more information on this topic under Employee engagement (p. 82).

Since 2015, our **Innovation Think Tank** has been analyzing current trends and technologies to generate new ideas for innovation projects. Here, we work closely with internal and external experts, research institutes and companies. Through **open campaigns**, we support idea-givers right from the initial idea through to the development of a business plan. Our employees can submit their ideas online and develop them to maturity with our support through resources such as online courses.

The most promising ideas sourced through these ideation channels become innovation projects. We offer employees the chance to focus on their innovation project by hosting them in the Innovation Center. In addition to financial support we provide a protected ecosystem and dedicated support, as well as clear governance and decision-making to efficiently grow and scale innovation projects into sustainable future businesses.

### Innovator Academy: Supporting innovation programs

Within our Innovator Academy, we run needs-based training sessions and workshops for idea-givers, internal project teams, members of think tanks, and start-ups. In May 2017, we launched "traintoinnovate.com", an online platform that provides the participants in our Innovation Center access to programs with additional information and methods for innovation. Employees can also use this platform for independent study and to share their ideas with others.

# **Second Displaying Futures Award**

The aim of our Displaying Futures Award, run by our Performance Materials business sector, is to support **teams from academic and institutional backgrounds**. In 2017, the target topic area was "flexible applications in the field of hybrid electronics". Submitted by creative minds from 22 countries, the number of ideas received rose from 31 in 2016 to 69 in 2017. The three winning teams focused on future-oriented technologies such as portable biomonitoring devices, soft robotics, electronic sensors, and packaging; they were evaluated on innovative value, business potential, and impacts on society and the environment. The Displaying Futures Award is worth a total of US\$ 150,000.

# Fostering young talent: An investment in the future

Well-trained talent is the best foundation for future innovations, which is why we endeavor to spark **young people's interest in science**. Students who are curious about chemistry and biology can use our Junior Lab and livfe BioLab to conduct their own research and experiments. We run both laboratories in partnership with the Technical University (TU) of Darmstadt.

Beyond youth labs, we also partner with various schools in the vicinity of our global headquarters in Darmstadt. For example, we provide STEM teachers with educational materials and organize annual teacher events such as Science Days, where they learn how to incorporate new technologies into their science classes. Moreover, we regularly invite groups of students to our company to explore our research activities and have been hosting the "Jugend forscht" student competition for over 30 years. You can find more information on our educational initiatives under Community (p. 114).

# Maximizing the opportunities of digitalization

In early 2017, we launched a strategic partnership with Palantir Technologies, a California-based company. We intend to use Palantir's **data analysis capabilities** to improve and accelerate the development, commercialization and delivery of new medicines.

To harness these capabilities, we have established three joint initiatives. Medical Research & Drug Development aims to accelerate the drug manufacturing process; Global Patient Intimacy intends to enhance patients' experience with our products, and Global Supply Chain focuses on improving demand-forecast accuracy in our supply chains. As well as these initiatives, we have built capacities for data analysis within our own company. In the future we hope to make use of Palantir technology in all three of our business sectors.

# Smart packaging processes and drug information in real time

Our Smart Packaging project allows us to make our drug packaging processes more efficient and flexible. We have connected our packaging machines via the Internet of Things and are currently assessing the potential of this technology to improve the accuracy and reliability of our machines while also increasing their output. Additionally, our new predictive maintenance capabilities will reduce machine breakdowns. By connecting systems across the entire organization and

using advanced analytics, we can decrease packaging waste and lead times when changes need to be made to product information. This means that we can pass newly discovered information on to our customers more quickly. We are also exploring options for active packaging that will allow patients to look up the latest information on their smartphones.

# Improving customer experience through artificial intelligence

We are currently developing **chatbots**, text-based dialogue systems that enable people to ask computer systems questions in natural human language – exactly as they would write messages to another person. This means we are available to answer our customers' questions 24 hours a day. In the future, for example, patients with multiple sclerosis will be able to order refills for their RebiSmart<sup>®</sup> injection device via chatbot. Future chatbots may even be capable of reminding patients to order extra supplies as soon as they run the risk of no longer observing the recommended dosage. Moreover, chatbots are more cost-effective for us than traditional customer services.

### Online diabetes campaign

In Africa, approximately 62% of diabetes cases go undiagnosed. To improve early diagnosis and promote awareness of the disease, we joined forces with various partners in March 2015 to launch a digital initiative known as DORA (Diabetes Online Risk Assessment). Thanks to this initiative, people in South Africa, Namibia, Kenya, Ethiopia, Ghana, Nigeria, Mozambique, and Mauritius can use their smartphones or computers to take an **online test**. In just a few clicks, they can ascertain how high their risk is of developing diabetes. Since its launch, the DORA website has received more than **740,000 hits**, with more than 100,000 coming from people who have taken the test.

# sustainable product design

Respect for the environment and natural resources is at the heart of sustainable conduct. As a major actor in numerous sectors, we see it as our duty to not only conserve resources in developing our own products, but also to help our customers increase the sustainability of theirs. For instance, our Performance Materials business sector manufactures liquid crystals that make displays more energy efficient, while our Life Science business sector develops technologies and solutions to make research and biotech production simpler, faster and more successful. Here too, we take sustainability into account right from the earliest stages of product development.

# Our approach to sustainable product design

Due to the different contributions of our individual business sectors to sustainability, sustainable product design is approached differently by each respective sector.

Performance Materials develops and produces numerous products that in turn help our customers manufacture sustainable and environmentally compatible goods. Our aim is to develop smart products that allow people to save energy in everyday life.

In our Life Science business sector, we particularly endeavor to reduce the impacts of our products on health and the environment. This applies to their **entire lifecycle**, from manufacture and use to disposal. At the same time, we seek to make our products more efficient and user-friendly, asking ourselves right at the start of product development how to best reconcile these requirements.

# How we include sustainability in product design

In Performance Materials, we have established the Performance Materials CR Committee with representatives from all four business units and other relevant internal stakeholders. The committee functions as a platform to discuss corporate responsibility issues and meets three to four times per year.

The CR group within our Life Science business sector is responsible for coordinating and driving **product-related sustainability**. This includes our Design for Sustainability (DfS) program for eco-friendlier life science products, and DOZN $^{\text{TM}}$ , a web-based tool for the quantitative assessment of greener alternatives.

The responsibilities described here likewise apply to packaging (p. 36) as well as reuse and recycling (p. 37).

# Our commitment: Chemicals and product policies

To meet the **product safety regulations** relevant to our company, our Regulatory Affairs Group Policy (p. 50) details our Group-wide processes for managing and implementing product safety, including the necessary management structures.

In addition, the following guidelines set out several requirements for sustainable product design within our Performance Materials business sector:

- Green Product Policy: This ensures that we adhere to all national and international laws and statutes (e.g. REACH and the European Union RoHS Directive), as well as to industry and customer-specific requirements.
- Our raw materials for the cosmetics industry fulfill the high standards of the Cosmetics Directive and are produced in line with Good Manufacturing Practices for Cosmetic Ingredients (EFfCI GMP).

### Our processes for sustainable product design

Within our Life Science business sector, a variety of approaches help our experts to drive sustainability improvement during product and packaging development:

- Through our Design for Sustainability program (DfS), we have developed a comprehensive approach to increasing the sustainability of life science products through the analysis of different sustainability criteria.
- Green chemistry assessment tool: In addition to our DfS program, our Life Science researchers are developing innovative solutions in line with the 12 Principles of Green Chemistry developed by chemists Paul T. Anastas and John C. Warner.
- Through our self-developed web-based tool DOZN™, we can assess the green alternatives of various chemicals, thereby creating transparency for our customers.

# **Current product examples from Performance Materials**

Our Performance Materials products help boost sustainability in a variety of ways:

### **Energy-efficient displays**

Liquid crystals ensure high picture quality in computer monitors and televisions, while also making them more power efficient. This is because our PS-VA technology (polymerstabilized vertical alignment) arranges the liquid crystals so as to make better use of the backlighting, the display component that consumes the most power. PS-VA equipped devices require significantly less energy than their predecessors.

Self-aligned vertical alignment (SA-VA) is the next-generation liquid crystal technology now in the pipeline, with the first SA-VA products expected on the market in 2018. **SA-VA helps conserve resources** and is even more environmentally sustainable because less energy and solvent are required to manufacture the displays. Moreover, its manufacture is more efficient as it requires fewer process steps. Since SA-VA technology can be applied at lower temperatures, it is also suitable for sensitive materials such as those used in premium products, or for forward-looking applications such as flexible displays.

Mobile-device displays have increasingly high resolutions, yet are still expected to be as energy-efficient as possible. This is where our liquid crystals for touchscreen applications come in. Based on ultra-brightness FFS technology (UB-FFS), these liquid crystals provide displays with 15% more light transmission. This can reduce the energy consumption of smartphones and tablets by around 30%, thereby prolonging battery life. UB-FFS furthermore enhances picture resolution. We are currently working to advance this technology for non-mobile applications such as high-resolution flat-screen LCD televisions, where UB-FFS can help boost energy efficiency.

### **Optimizing liquid crystal production**

By enhancing the standard C-C coupling reaction – where two hydrocarbon fragments are coupled via a new carboncarbon bond – during the manufacture of liquid crystals, we have considerably reduced production waste while also saving  $\in$  12 million in production costs. Moreover, this change means we used fewer **c**arcinogenic, **m**utagenic, and/ or **r**eprotoxic (CMR) substances.

### Switchable windows

Windows that can be darkened in a matter of seconds are now a reality thanks to **our liquid crystal window (LCW) technology**. The darkened windows also regulate the heat generated by direct sunlight while creating a certain sense of privacy. Commercialized under our licrivision brand, initial estimates show that this technology can lower the energy consumed by building climate control systems by up to 40%, thus replacing conventional sun shading. In 2017, we received the Frost & Sullivan Technology Innovation Award in the Smart Glass Industry category in recognition of our smart windows. We have invested  $\in$  15 million in the construction of a facility in the Netherlands to manufacture these switchable glass modules, which will start deliveries in 2018.

### **OLEDS**

Organic light-emitting diodes (OLEDs) likewise increase the energy efficiency of displays while also providing brilliant colors and razor-sharp images. Over the past several years, we've been collaborating closely with printer manufacturers to research **innovative printing processes** for the efficient production of large-area OLED displays. In September 2016, we opened a new production plant for OLED materials at our site in Darmstadt. Costing around  $\in$  30 million, this plant represents one of the largest single investments we've made at the Darmstadt site in recent years.

### **Innovations in photovoltaics**

We supply the photovoltaics industry with materials for the production of solar cells. These materials enable the realization of innovative applications for photovoltaics, such as flexible, semi-transparent and lightweight solar cells that can be used in buildings, on curved or straight surfaces, and even in clothing. Take for instance the solar trees that we've installed next to our Innovation Center in Darmstadt. The **organic photovoltaic modules** used in the trees were manufactured with our printable formulations of modern high-performance polymers. The energy generated is stored during the day and used to illuminate the trees at night.

### More natural-based cosmetics

In 2017, we teamed up with French company Agrimer to co-develop RonaCare<sup>®</sup>RenouMer, a skin care product that is extracted from a natural sea algae. Responding to the ever-growing popularity of natural cosmetics, we are working closely with our customers in the cosmetics industry to manufacture products such as RenouMer. We develop cosmetic formulations that comply with strict criteria. By the end of 2017, approximately one-third of our cosmetic raw materials met the criteria of Ecocert's Cosmos standard for organic and natural cosmetics.

### Alternative to plastic microbeads

We manufacture mineral-based pigments and functional fillers used by the cosmetics industry in formulations for various purposes. Our RonaFlair<sup>®</sup> functional fillers series provides an alternative to plastic microbeads contained in skin care products. Through this range, we are supporting initiatives such as the declaration of Cosmetics Europe, which advocates a phase-out of microplastics in rinse-off products by 2020. Microbeads are tiny, non-biodegradable polymer particles that cannot be filtered out by wastewater treatment plants. They end up in marine and terrestrial ecosystems, where they can harm the organisms living there.

### **Displaying Futures – Annual dialogue**

Pioneering advances are only possible through close collaboration with our partners. We seek to engage with trailblazers who look far into the future and conceive **groundbreaking technologies**. To encourage this dialogue, we instituted the annual Displaying Futures symposium, which took place in November 2017 for the eighth time.

Held in Tokyo (Japan), this year's conference was dedicated to the topic of "Digital Transformations". We examined digital transformation from various angles and explored current societal trends, asking ourselves how we as Performance Materials can advance various ideas and also serve as a source of inspiration for research and development efforts.

# Sustainable product design in the Life Science business sector

Through our Design for Sustainability (DfS) program, we have developed a comprehensive approach to increasing the sustainability of life science products. The DfS program provides our product developers with a range of tools enabling them to analyze the impact of the product on the following areas: materials, energy and emissions, waste, water, packaging, usability, and innovation. For each of these areas we have developed several sustainability criteria that are noted on a scorecard. When developing a new product, our aim is to improve on as many of these criteria scores as possible. We conduct product life cycle analyses to understand the potential environmental impacts within different product life cycle stages. The findings of these analyses show us how we can improve our products and are incorporated into subsequent development stages. During this process, experts from R&D, Product Management, Quality, Procurement, and other departments are in constant contact with one another.

# 35%

of our product development projects currently meet three or more product sustainability criteria thanks to our DfS process.

We intend to incorporate our suppliers into our DfS program as well. In 2016, we launched a pilot project to define the relevant requirements for our vendors. In particular, our objective is for our suppliers (p. 104) to become engaged in Together for Sustainability (TfS), a chemical industry initiative.

### Green chemistry assessment tool

In addition to DfS, our Life Science researchers are developing innovative solutions in line with the 12 Principles of Green Chemistry developed by chemists Paul T. Anastas and John C. Warner. These aim to make research **as environmentally compatible as possible** and to minimize negative impacts on human health. In total, we offer more than 750 products that align with the Principles of Green Chemistry, making them a greener alternative to conventional products.

Through our self-developed web-based tool DOZN™, we can assess the green alternatives of various chemicals, thereby creating transparency for our customers. Under DOZN™, the 12 Principles of Green Chemistry provide a framework for rating our products in three major stewardship categories, namely "Improved resource use", "Increased energy efficiency" and "Reduced human and environmental hazards". The system calculates scores based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as well as the Material Safety Data Sheet information on each substance. One score is given for each of the 12 principles, enabling an easy comparison of the products. The approach of the evaluation system has been verified by an independent body. To date, we have used this matrix to assess and improve more than 40 products. The DOZN™ processes and methods were validated by an environmental consulting company, and a peer-reviewed paper was published in March 2017.

# Wide range of solutions

Our Life Science portfolio comprises a broad array of products, each with different properties that are taken into consideration when applying our DfS approach and the Principles of Green Chemistry. The following examples illustrate the results.

### **Greener laboratory filters**

Under our DfS approach, we have significantly reduced the environmental footprint of our EZ-Fit™ Manifold laboratory filter. In comparison with its predecessor the Hydrosol Manifold, the EZ-Fit™ Manifold requires 47% less raw material. Its packaging consists of 100% recyclable cardboard, and overall, **99% of its parts are recyclable**. Because the heads can be easily removed for cleaning, it is no longer necessary to autoclave the whole device, which saves energy and results in a 91% reduction in the carbon dioxide emissions produced during cleaning. In 2016, we furthermore expanded our range to include a disposable filtration device used to determine the microbial count in liquid samples. Thanks to DfS, we have in particular improved the packaging of these products.

### **Greener chemistry**

In 2017 we received the European Bio-Based Chemical Innovation of the Year Award for our greener solvent Cyrene™. Bioderived from waste cellulose, this solvent is used as an alternative to dimethylformamide (formic acid), which has been the subject of increasing criticism in recent years due to its mutagenic effects. Through Cyrene™ and other greener solvents, we are helping our customers in the pharmaceutical and agrochemical industries make their production processes safer and more environmentally sustainable. We've teamed up with leading institutions and start-ups to co-develop further such green solvents. In contrast to conventional solvents, these are based on natural resources such as corn cobs and sugar cane bagasse, making them more eco-friendly, more biodegradable and easier to recycle. In 2017, we published the results of these R&D efforts in leading trade journals.

### **Eco-friendly lab water use**

In mid-2017 we launched Milli- $Q^{\circledR}$  IQ 7000, our new lab water purification and monitoring system. This product uses mercury-free UV oxidation lamps and has a hibernation mode to save energy while still preserving system water quality.

# packaging

Packaging protects our products from external influences and ensures that they reach the customer undamaged. It also prevents materials from leaking. Our packaging must therefore remain intact across the entire life cycle of our products – from transport and storage, through usage to disposal. Beyond safety, we also endeavor to design packaging that uses as few resources as possible. We are therefore working to reduce the amount of material required, as well as increasingly utilizing eco-friendly materials where possible. In the process, we ensure that the quality and safety of our packaging are not adversely impacted.

# Our new sustainable packaging strategy

We aim to deliver our products in packaging that is safe and easy for our customers to handle, and as sustainable as possible. The more than 300,000 products in our Life Science portfolio - ranging from biochemicals to lab chemicals, from filter materials and systems to instruments pose a variety of challenges when it comes to packaging. We strive to improve the sustainability of this packaging through measures such as reusable packaging systems or by avoiding the use of polystyrene. To achieve this goal, we are in the process of defining our new sustainable packaging strategy for Life Science to formalize our approach and set meaningful targets. This strategy is built on the three pillars of optimizing resources, choosing more sustainable materials, and recapturing post-use value. We are establishing priorities, goals, and specific initiatives to support them in the coming years. In doing so, we are continuing to position ourselves vis-a-vis our customers as an ambitious partner committed to the circular economy.

# Making packaging more sustainable

A great deal of our packaging is based on wood fiber. We are constantly working to increase the share of corrugated cardboard boxes certified to the standards governing **sustainable forestry**. These include the Sustainable Forestry Initiative (SFI), the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC). In adhering to these standards, we are doing our part to prevent deforestation.

# Cellulose and air cushions replace polystyrene and foam

In the past, we secured glass reagent bottles using expanded polystyrene (EPS) molded foam to prevent them from breaking during transport. While EPS, also known as Styrofoam<sup>®</sup>, is an excellent cushioning material, it is manufactured from non-renewable petrochemicals. It is also difficult to recycle and takes up a lot of space. By contrast, molded

pulp components can be easily recycled with other paper materials and compacted together for storage and transport. We have therefore initiated a substitution program in which we are developing solutions to replace EPS as far as possible with molded **components made of cellulose and recycled paper pulp**. In doing so, the safety of the packaging is always our top priority.

When shipping items from our major distribution centers in the United States and Germany, a large portion of our reagent bottles are secured using molded pulp components. Since 2017, we've been using molded pulp inserts to pack our 4X4 liter bottles in shipping boxes, thereby replacing around 350,000 EPS parts per year. We are currently conducting safety tests on new pulp designs for shipping other bottles of various sizes. As of 2018, our 6x0.5 liter and 1x4 liter reagent bottles are also to be secured using molded pulp. Overall, we use a total of 324 metric tons of molded pulp packaging material each year. In addition to these measures, in 2017 we replaced foam packaging with biodegradable air cushions at our distribution center in Allentown, Pennsylvania (USA).

As well as finding eco-friendlier alternatives to ship our products safely, we are working with Biogen, a specialist biotech company, to develop a more sustainable bulk-packaging design to transport our Millistak+® Pod Disposable Depth Filter. We are currently conducting a Life Cycle Assessment, with promising initial results. We expect a 21% reduction in used corrugated cardboard, which translates to a **19% decrease in greenhouse gas emissions** from the production of packaging materials. In addition to these savings, the large packages will cut down our delivery trips by 12%, thus further reducing emissions and energy use. Moreover, 70% less time is required in the processing of products and their packaging.

# More cardboard instead of plastic

The analytical technique of titration is utilized in laboratories to assure the quality of various products by verifying the purity of the raw materials. Although the necessary solvents are conventionally packed in plastic bottles, we use Titripac <sup>®</sup> because it offers an eco-friendlier alternative for supplying solvents to our Life Science customers. Using a cardboard carton and plastic liner with an integrated withdrawal tap, we have made the packaging more recyclable while also cutting its weight by more than half. As a result, the greenhouse gas emissions arising across the entire product life cycle are 61% lower than for plastic bottles. Because the withdrawal tap protects the product against contamination, the contents can be used to the very last drop, thereby reducing chemical waste. In 2016, Titripac<sup>®</sup> was recognized with the Green Good Design Award **for sustainable product design**.

#### Reusing EPS boxes

Many of our Life Science products need to be kept cool during shipping and are therefore packed in special EPS boxes. To mitigate waste, we offer our U.S. customers the option of sending us back these boxes. If they are still fully functional we reuse them – and with more than 20,000 boxes used per year, this significantly reduces waste.

#### Integrating stainless steel canisters in production

In Korea and Taiwan, our Performance Materials liquid crystal mixtures are delivered to display manufacturers in stainless steel canisters, an approach we extended to China in 2017. Our customers utilize these Standard Canisters from our company directly on their production lines without decanting. The empty canisters are then sent back to us and cleaned. In 2017, 1,512 standardized canisters were in circulation within this closed system, allowing them to be **reused over multiple years**.

#### Steel instead of glass

Thanks to our bulk product delivery system, our solvents are delivered to our U.S.-based Life Science customers in special

reusable steel containers such as the EMD ReCycler<sup>®</sup>. We started the program with containers of 18 and 50 liters in 2010. Since then we have filled more than 12,000 reusable containers annually. Over the years we have partly shifted to containers of 1,250 liters, which now make up roughly 10% of all containers filled.

Our customers can return the empty containers to us for refilling, enabling us to significantly reduce the consumption of primary packaging materials. Since the stainless steel containers are shipped without additional packaging, we also save a lot of the packaging material normally needed to ship glass bottles, which must be packed in boxes and cushioned by molded components.

In Europe, we also deliver solvents required in bulk for preparative chromatography in **reusable stainless steel containers.** Our customers send the empty containers back to us, where they are properly cleaned and then reused. Approximately 70,000 of our stainless steel containers are currently in circulation across Europe. The rate of return is at around 90%.

# Reuse and recycling

Many of the products we supply to our Life Science customers are used only once and then discarded. This is necessary in certain cases to minimize the risk of contamination and is thus common practice within the industry. Moreover, this approach helps reduce costs as our customers don't have to clean disposable products, thereby saving time and resources such as energy and water. However, these products do consume a great deal of material, so we've put recycling programs in place to help our customers properly dispose of and recycle our products and packaging.

#### Our Design for Sustainability program

Our Design for Sustainability (DfS) program encourages our Life Science business sector to design products with reduced life cycle impacts. This process focuses on utilizing **recyclable or reusable materials** that can be easily recovered or separated. Through DfS, we are continuously working to reduce the ecological footprint of our products and make disposal as easy as possible for our customers.

#### Recycling program updated

In cooperation with Triumvirate Environmental, a wastemanagement company based in Massachusetts (USA), we launched a comprehensive recycling program at the beginning of 2015 to serve our Life Science customers in the United States. Under this initiative, product waste from their research labs and biopharmaceutical manufacturing operations is collected, sanitized and **recycled into plastic lumber.** This material can be used in many industries, such as construction, landscaping, transportation, and marine construction. The program includes our Biopharma Recycling and Ech2o Collection and Recycling Programs.

We are continuing to expand this program throughout the United States and are exploring options for extension to other regions such as Europe and Asia. Since the program is dependent on the technology provided by Triumvirate, we would require new processing plants, as well as licenses, transportation and trained personnel in the respective regions.

Triumvirate's innovative process enables the recycling of biohazardous waste that contains multiple types of plastic and other materials. Our partner has developed a sterilization and shredding component that is combined with an extrusion process to make multiple plastic lumber products. Since launching the program, we have recycled 1,347 metric tons of waste generated from the use of our products, with 901 metric tons in 2017 alone. The program now serves 11 customers, almost twice as many as in 2016.

# access to health strategy

Across the globe, two billion people do not have access to medicines. The World Health Organization (WHO) and the World Bank have estimated that 400 million people lack access to effective and affordable health services, especially in low- to middle-income countries. However, according to WHO, these regions also bear approximately 90% of the world's disease burden. In cooperation with strong partners, we're working to tackle this complex challenge by researching innovative solutions, developing new approaches and improving existing programs to help people at the point of care. Moreover, we're striving to make health solutions affordable, raise awareness of diseases and teach people how to manage them.

### Our approach to help improve healthcare

We seek to improve **access to high-quality health solutions** for underserved populations and communities in lowand middle-income countries, a goal that underlies our Access to Health (A2H) approach.

To achieve this aim, we're leveraging our expertise from all our business sectors. However, we're aware that individual companies and organizations can only do so much to improve access to health, which is why we **collaborate closely with a wide range of partners**. To bolster the impact of our A2H efforts, we participate in industry-wide initiatives and work with other businesses to develop new approaches.

Our A2H strategy focuses on the following four areas:

- Availability: We research, develop and refine health solutions that address unmet needs, tailoring them to local environments
- **Affordability**: We seek to provide assistance to those who are unable to pay for the health solutions they require, including addressing challenges surrounding pricing and intellectual property. Further information can be found under Prices of medicines (p. 46) and Community (p. 110).
- Awareness: We help raise awareness for diseases and therapies (p. 47) by empowering medical professionals, communities and patients to make informed decisions.
- Accessibility: We promote initiatives that strengthen supply chains (p. 44) and develop localized health solutions. Medicines should reach the people who need them quickly and safely.

## How we're improving access to health

Our Access to Health unit investigates the factors that make it more difficult for underserved populations to receive healthcare, working with various partners to develop **ways** to reduce these barriers. Our A2H team is backed by a steering committee comprising representatives from our Healthcare and Life Science business sectors, along with representatives from our subsidiaries. The committee ensures that the programs developed support our business strategy and can be implemented locally in order to have the desired effect.

To support this objective, in 2015 we established the Open Innovation Committee, a body dedicated to overcoming access barriers in regions with major unmet needs. The committee helps to promote **intellectual property as an enabler of innovation**, allowing access to our knowledge and compound library to accelerate early discovery with leading partners in areas of high unmet need. For now, our efforts are focused on areas where we have no portfolio or competencies. The Open Innovation Committee is co-chaired by our the heads of our Access to Health and International Patents units.

# Our commitment: Our Access to Health Charter

Our Access to Health Charter sets out guidelines on the following:

- Our approach
- Pharmaceutical product donations
- Fake medicines
- R&D for neglected tropical diseases and priority communicable diseases
- Pharmaceutical product pricing
- Intellectual property rights

# Sharing and protecting intellectual property

When it comes to access to health, pharmaceutical manufacturers' approach to their intellectual property plays an important role. In most developing countries, we often do not file or enforce patents. In markets where we do register product patents, we are committed to **sharing data with researchers** and to improving public access to clinical study data. We report on the patent status of our products via publicly accessible databases. Furthermore, we support voluntary licensing agreements of all kinds, including non-

exclusive voluntary licenses, legally binding non-assertion covenants, and clauses that aim to widen access to health. Moreover, we support the concept of patent pools, but believe that these should be structured to improve access to medicines and prevent anticompetitive effects as well as geographic limitations. We consider joining patent pools when they are relevant to our portfolio and meet all our efficacy, quality, and safety requirements.

The responsible treatment of intellectual property does not pose a barrier to health, but rather guarantees safety and high quality for patients worldwide. Nearly all medicines that address the highest burden of disease in developing countries are **not protected by patents**. For example, approximately 95% of the 2013 WHO Essential List of Medicines are off-patent. Through our initiatives and partnerships, we provide access to patent information and in some cases also access to parts of our compound libraries for efforts such as open innovation research projects.

### Agreements and guidelines on intellectual property

A great deal of time and money is required to develop new drugs – without any guarantee of success. It can take ten to 15 years for an effective health solution to be market-ready. Pharmaceutical companies therefore need a **solid, transparent and reliable legal framework** to protect their intellectual property rights and enforce their patents, which provide a sufficient period of time and degree of protection to compensate for R&D costs.

We support TRIPS, an international agreement administered by the World Trade Organization (WTO) that addresses trade-related aspects of intellectual property rights, along with TRIPS addenda such as the 2001 Doha Declaration (Special Declaration on the TRIPS Agreement and Public Health). The Doha Declaration extends the deadline for least-developed countries to apply TRIPS provisions to pharmaceutical patents until 2033.



medicines provided by us are listed on the WHO Essential Medicines List and/or are classified as first-line treatments, such as bisoprolol/amlodipine, metformin (Glucophage $^{(8)}$ ) and praziquantel.

#### New initiative improves access to patent information

We are a founding member of the Patent Information Initiative for Medicines (Pat-INFORMED), which was established in 2017 by 20 leading research-based biopharmaceutical

companies. Pat-INFORMED will act as a global gateway to medicine patent information, offering new tools and resources to determine the existence of patents relevant to products sought by national and international drug procurement agencies. The transparency to be provided by Pat-INFORMED seeks to make it easier for drug procurement agencies to **access a basic body of patent information** necessary to implement disease management strategies, or other work addressing public health needs. The initiative is backed by the World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

#### Open innovation collaboration: WIPO Re:Search

We are one of more than 100 members of the WIPO Re:Search platform, whose goal is accelerating early discovery for infectious diseases as well as sharing members' knowledge and intellectual property. This platform is sponsored by the World Intellectual Property Foundation (WIPO). We initiated our first WIPO Re:Search partnership in 2015, joining forces with the University of Buea in Cameroon in a bid to use compounds from our library to develop a treatment for onchocerciasis (river blindness). In 2017, we reached the final phase of the initial screening of a variety of compounds. Also in 2017, we entered into a partnership with the University of California, San Diego (USA) to share compounds from our compound library under the WIPO Re:Search open innovation umbrella. This is part of our joint effort to identify potential cures for leishmaniasis, Chagas disease (American trypanosomiasis) and human African trypanosomiasis (HAT - sleeping sickness).

# Open innovation collaboration: Drugs for Neglected Diseases Initiative

In April 2017, we formed a partnership with the Drugs for Neglected Diseases initiative (DNDi) under which we're participating in the Drug Discovery Booster project for neglected tropical diseases. This project pursues an open innovation approach in which the various companies simultaneously search for **new treatments** for leishmaniasis and Chagas disease. We are joined in this project by five other companies (Eisai, Shionogi, Takeda, AstraZeneca, and Celgene).

### Alliances for better access to health

We are a member of the Business for Social Responsibility (BSR) initiative and have also endorsed the BSR Guiding Principles on Access to Healthcare, which provide a framework for us to refine and enhance our A2H efforts. In 2017, we collaborated within the BSR Healthcare Working Group to draft a new working paper on innovative financing models (p. 44). Moreover, we drove the development of the BSR working paper entitled "Advancing Access to Healthcare Metrics".

#### New initiatives for non-communicable diseases

At the World Economic Forum held in Davos, Switzerland in January 2017, we joined forces with 21 other leading pharmaceutical companies to launch Access Accelerated, a global initiative that seeks to improve both the treatment and prevention of non-communicable diseases in low- and middle-income countries.

# Best practices recognized by the Access to Medicine Foundation

In 2017, a report published by the Access to Medicine Foundation provided the first comprehensive landscape of company activities illustrating how 16 pharmaceutical companies are improving **access to cancer care** in lowand middle-income countries. We were included in the study, which mentioned our access initiatives in this area, including our intellectual property approach and patient access programs (p. 46) for improving access to cancer medicines.

In 2016, we were ranked fourth in the Access to Medicine Index, which assesses the degree to which companies have improved **access to medicines in developing nations**. The foundation highlighted several of our initiatives as being best practices, including our endeavors to combat infectious diseases (p. 41) and counterfeit pharmaceuticals (p. 55), strengthen transparency in the drug supply chain (p. 44), and boost health awareness (p. 47). They also recognized our efforts to align our access targets (p. 148) to the UN Sustainable Development Goals (p. 161).

#### **Engaging stakeholders**

Partnerships and dialogue are key instruments for improving access to health. Our partners include multilateral organizations, government agencies and NGOs, as well as academic institutions, health industry associations, companies, and experts from the private sector.

#### Our Access Dialogue Series

In 2017, our Access Dialogue event series put the spotlight on open innovation and intellectual property, as well as supply chain and delivery challenges in developing countries. We engaged our public and private stakeholders to discuss ways of eliminating access barriers to health. We initiated this event series in 2013 to provide a platform for publicand private-sector stakeholders to exchange information and share best practices on broadening access to health.

#### Discussions at a global level

In 2017, we participated in many other events, a selection of which are presented below:

- Two workshops hosted in Amsterdam in June and September 2017 by the Access to Medicine Foundation.
- "The Global Debate on Intellectual Property, Trade and Development: Past, Present and Future - A Conference in Honour of Pedro Roffe", held in Geneva in June 2017.
- "CAMP-N" (a coalition for access to medicines and products for non-communicable diseases) held on the eve of the UN General Assembly in New York in September 2017.
- Panel session at the World Health Summit to discuss supply chains and improving access to health, held in Berlin in October 2017, co-hosted with Roche and Novartis.
- Panel session on "Accelerating Innovation & Access to Vaccines" at the WIPO Global Challenges Seminar on Vaccines in Geneva in November 2017, including the launch of the new Global Challenges Report and the Access to Vaccines Index published by the Access to Medicine Foundation.
- Belén Garijo, CEO Healthcare, represented our company at the fifth anniversary of the London Declaration to Combat Neglected Tropical Diseases. You can find more information on the London Declaration under Infectious diseases (p. 41).
- Fourth Global Forum on Human Resources for Health under the banner of "Building the health workforce of the future": Attended by over 1,000 delegates from around the world, it was the largest open conference on human resources for health-related issues.
- You can find details on the Accessibility Platform dialogue series on local supply chain challenges under Supply chain (p. 44).

#### Activities at the local level

In 2017 we also actively engaged stakeholders on a local level, examples of which include:

- We continued our Unmasking Your Thyroid awareness and education campaign in the Philippines. You can find more information under Health awareness (p. 47).
- As part of our Prediabetes and Thyroid Care initiative, we partnered with the Mexican Society of Nutrition and Endocrinology to train 500 health workers in Mexico.

#### Employee events raise awareness

We seek to motivate and inspire our employees to actively engage in our access to health efforts. In this vein, in April 2017 the Access to Health team organized an event at which various internal and external experts presented our range of initiatives and efforts. Speakers included Peter Hotez from the National School of Tropical Medicine in Houston, Texas (USA), who discussed the topic of science and humanity, emphasizing how important it is to redouble efforts in neglected tropical disease drug discovery.

## infectious diseases

Many infectious diseases endemic to developing countries are barely known in industrialized nations. Referred to as neglected tropical diseases, these infections consequently attract little public attention and research funding. One poignant example is schistosomiasis, an insidious parasitic disease that still lacks a treatment suitable for children under six. Malaria, too, continues to pose a threat to public health. According to estimates by WHO, nearly half of the world's population is at risk of malaria. Although a large range of approved products and investigational compounds are available to treat malaria, the number of resistant pathogens is on the rise. New treatments and health solutions are therefore urgently needed. Bacterial infections and antimicrobial resistance also pose global challenges that are becoming increasingly acute. Urgent action is needed to prevent and control these issues.

# Our approach to preventing and treating infectious diseases

We seek to improve healthcare in developing countries by creating novel and integrated health solutions for infectious diseases and ensuring the sustainable implementation of these innovations. Our Group-wide initiatives and programs particularly address the **key unmet medical needs** of women and children, with a focus on schistosomiasis, malaria, bacterial infections, and antimicrobial resistance. Here, our integrated strategy is centered not only on developing and providing medicines, but also on improving diagnosis, countering disease transmission, and disease control, as well as strengthening local health systems.

Our comprehensive global health portfolio includes programs for the following:

- Development of a pediatric formulation to treat schistosomiasis
- 2. Development of a new active ingredient to treat and prevent malaria in children
- Screening of our compound library in search of potential new active ingredients to treat schistosomiasis and malaria
- 4. Development of diagnostic kits for schistosomiasis and malaria
- Development of products and technologies to enhance prevention

Our efforts to address bacterial infections and antimicrobial resistance concentrate on

- developing assets for antibiotic quality and laboratory capacity to detect antimicrobial resistance,
- improving the use of antibiotics by healthcare providers and patients,
- helping define industry-wide guidelines for the control of antihiotics.

Beyond these efforts, we also sponsor capacity building educational programs and initiatives to enhance research capability and infrastructure in African countries.

# How we structure our activities to fight infectious diseases

Our Global Health Institute is responsible for our Group-wide initiatives, programs and sponsorships pertaining to infectious diseases. Our experts there collaborate closely with our Healthcare, Life Science and Performance Materials business sectors to synergize their strengths and competencies. For instance, the internal collaboration with Performance Materials aims at introducing the malaria claim for our insect repellent IR3535<sup>®</sup>.

We also **cultivate partnerships with leading global health institutions and organizations** in both developed and developing countries. Take for instance the Pediatric Praziquantel Consortium, a public-private partnership that is working to develop pediatric formulations to treat schistosomiasis in children under six.

# Our commitment: Guidelines and voluntary commitments

Our programs and initiatives to fight infectious diseases are part of our efforts to improve access to health (p. 38). Our Infectious Diseases Research and Development guideline is particularly relevant here.

Our Global Health Institute acts in alignment with the United Nations Sustainable Development Goals (SDGs (p. 161)). In particular, the Institute's initiatives and programs aim to address SDGs 3, 4, 6, 9, and 17.

We were among the first organizations to endorse the **London Declaration** when it was launched in 2012 to fight neglected tropical diseases. Participating companies, governments and private organizations promise to help control or even eliminate the top ten most prevalent of these infections. We are particularly engaged in the fight against schistosomiasis.

### **Battling schistosomiasis**

In 2017 we continued our schistosomiasis research to combat this disease.

Around 10% of the approximately 220 million patients worldwide with schistosomiasis are younger than six years old. These children cannot be treated with praziquantel, the standard therapy for this parasitic disease. While clinical data is lacking, there is also no formulation of this drug suitable for children under six. This is a situation we intend to change. Since July 2012, we have been working within a consortium of partners from industry and science, as well as with funding organizations, to develop a pediatric formulation of praziquantel. In 2016, we initiated a Phase II study in Côte d'Ivoire that aims to assess the efficacy and safety of two different formulations for orodispersible tablets in schistosomiasis-infected children under the age of six. We expect to have the initial results by mid-2018. In 2017 the Japanese Global Health Innovation Technology Fund awarded the consortium an additional research grant in recognition of its efforts, the third time it has received this honor.

#### Partnering to find new solutions

Since 2017, we've been collaborating with the Australian Institute of Tropical Health and Medicine at James Cook University in Townsville, Queensland, and Baylor College of Medicine in Houston, Texas (USA) to research new biomarkers in order to develop **diagnostic tools for schistosomiasis**. Also in 2017, we established a drug discovery platform to search for new, long-lasting compounds to treat juvenile forms of schistosomiasis, improve efficacy and prevent reinfections. In addition, through academic collaborations, we aim to research a new genome editing method for vector control to combat schistosomiasis.

#### Fight against malaria

Malaria control also requires an integrated approach. As a science and technology company, we are well-positioned to help improve the treatment of malaria, as well as to develop and enhance diagnostics and prevention. In our efforts we closely collaborate with a wide range of partners.

#### Accurately diagnosing malaria

Sometimes malaria is hard to distinguish from other febrile infections. We are developing reliable diagnostics so that antimalarials are only administered to patients who are actually suffering from the disease.

Our Global Health Institute is currently developing a **novel malaria detection and typing assay** adaptable to the Muse<sup>©</sup> cytometry platform. It aims to accurately diagnose malaria and measure the type of malaria parasite as well as the infection level. In 2017 the project made progress in the preclinical phase, yielding promising results. We expect to register this new malaria diagnostic kit in 2020.

#### Enabling the treatment of children

In September 2017 we initiated the Phase I study of our anti-malarial drug program. We have been developing a new, **innovative drug** for the treatment of malaria since 2015. The new compound is intended to be developed as a single-dose combination treatment to treat and potentially prevent malaria in children. Performed in Australia, the Phase I study in healthy volunteers will allow us to assess the safety of the compound. A malaria human-blood challenge model will allow us to obtain an early read-out of the compound's antimalarial activity to confirm the potential for a single-dose cure. Phase I and challenge model results are expected in the second quarter of 2018. These activities are being supported by the Wellcome Trust, a biomedical research charity based in London.

#### Developing new lead programs

Initiated in 2015, our strategic collaboration with the University of Cape Town in South Africa has led to the development of a **new research and development platform**. It leverages our proprietary compound library to identify new lead programs for the treatment of malaria, targeting liver-stage forms and long-lasting compounds to improve post treatment prophylaxis. In a separate collaboration, we are in the process of developing a new cell model of liver-stage malaria infection.

#### Preventing and controlling transmission

To help prevent malaria from spreading, we are working to improve **access to insect repellent** as a vector control method. Through internal and external collaborations, we are working towards demonstrating the efficacy of IR3535® against malaria in Africa in a bid to foster the malaria claim for this insect repellent. IR3535® is already being utilized to help prevent the spread of the Zika virus and Dengue fever, and is particularly suitable for children and pregnant women.

# Dialogue and best practice sharing on infectious diseases

In 2017 the experts of our Global Health Institute continued to engage major stakeholders in a dialogue on infectious diseases, attending and holding meetings at around 30 international conferences and events, including:

- The Keystone Symposia conference on Malaria, held in Kampala, Uganda in February 2017
- The International Society for Neglected Tropical Diseases (ISNTD) Festival, held in London, United Kingdom in February 2017, where we received the ISNTD Award for Scientific Engagement
- The Towards Elimination of Schistosomiasis (TES) Conference, held in Yaoundé, Cameroon in March 2017

- The NTD Summit 2017, held in Geneva, Switzerland in April 2017. In the context of this event, Belén Garijo, Executive Board member and CEO Healthcare, represented our company at the fifth anniversary of the London Declaration. We also announced the Global Health Institute at this event.
- The Sixth International Conference on Vivax Research (ICPVR) in Manaus, Brazil in June 2017
- The World Health Summit in Berlin, Germany in October 2017
- The European and American Congresses on Tropical Medicine and International Health (ECTMIH & ASTMH), held in Antwerp, Belgium in October 2017 and in Baltimore, Maryland (USA) in November 2017

In 2017, our Global Health Institute furthermore joined advocacy initiatives such as the Worldwide Malaria Campaign and became a member of key stakeholder groups including the Swiss NTD Alliance and the Swiss Malaria Group.

### **Building capacities in the health industry**

Under our integrated approach to fighting infectious diseases, we have continued to enhance health capacities in and for the developing world.

We sponsor three PhD fellowships as part of a partnership

launched in 2015 with the University of Namibia. In support of governmental malaria control programs, these scientists are studying the extensive spread of malaria pathogens in Namibia, Botswana and Zambia, and are also working to characterize parasite subtypes that occur in the populations in these African countries.

In addition to doctoral fellowships, we also co-sponsor several international fellowship programs for postdoctoral researchers from developing and emerging countries via our collaboration with the European and Developing Countries Clinical Trials Partnership (EDCTP). As well as receiving training on clinical aspects such as clinical trial practices and clinical management, these research fellows are also given the opportunity to work for a period of up to 24 months at leading pharmaceutical enterprises, including our company. On returning to their home countries and academic institutions, they then have the **key resources** needed implement their research in line with international regulatory requirements and standards.

In 2017 our Global Health Institute provided the support needed to expand research infrastructure in several countries. For instance, we have been sponsoring a newly established gynecology ward in the District Hospital of Akonolinga, Cameroon, along with a clinical center in Côte d'Ivoire, where we're also conducting the Pediatric Praziquantel Program's Phase II study on the treatment of schistosomiasis in very young children.

# pharmaceutical supply chain

In many parts of the world, medicines are not always available where they are urgently needed. We want patients in low- and middle-income countries to have fast, safe and affordable access to medicines. We believe that efficient supply chain management is key to accomplishing this, as is support for local manufacturing in line with our high standards.

# Our approach to efficient supply chain management

Our pharmaceutical supply chains are organized efficiently to ensure that our products reach the right place in the right condition and quantity, at an affordable price and on time. **Modern supply chain solutions** allow us to monitor our inventory and current deliveries, as well as to predict expected demand for medicines, partly in real time.

Hand in hand with our partners we endeavor to improve supply chains, even in developing countries, and to guarantee **the targeted supply of medicines**. To this end, we partner with pharmaceutical companies and other supply chain stakeholders. We manufacture some of our products directly in the regions where they are needed, thereby shortening the distance to the consumer. Furthermore, thanks to local manufacturing we can offer medicines in these countries at considerably lower prices than in Europe.

### How we organize our supply chains efficiently

Global Planning is the unit responsible for our efficient medicine supply chains and is part of the Biopharma Supply Network Operations unit within our Healthcare business sector. Global Planning collaborates with our Access to Health unit (p. 38) and consults experts from other business sectors as needed.

# Our commitment: High quality standards for pharmaceutical production

All our pharmaceutical production plants operate to the same high standard of quality worldwide. We thus fully comply with the internationally harmonized guidelines set out in Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). This also applies to contract manufacturers.

Our **uniform quality assurance system** ensures that our quality standard is adhered to everywhere. It comprises training courses, quality control monitoring and technologies that are tailored to each site. The results of all audits conducted by health authorities are published Group-wide, allowing the respective units to share lessons learned and benefit from one another's improvements.

Through our Virtual Plant Teams, we provide our contract manufacturers with the support they need to comply with our quality standards. In Africa, Asia and Latin America, our external partners are each assigned a production expert from our company to act as a virtual site leader and provide guidance. Our Virtual Plant Teams were recognized as a best practice in the 2016 Access to Medicine Index.

# Leveraging organizational and technological possibilities

Accurate business forecasts are the foundation of **efficient supply chain management**. In 2017, we harmonized our Biopharmaceutical business planning processes across the Group and joined them together. We furthermore rolled out a special platform enabling us to plan specific demand for medicines centrally. This data is used to manufacture and deliver medicines according to demand, which allows us to prevent local inventories from running out or expiring. Our activities start with demand forecasts compiled at the local level, which are rolled out to the regional level and finally aggregated at the global level. All units involved coordinate with one another at least once a month.

In 2015, we rolled out a software-based solution for our customers in northwestern Africa. They can visit our e-shop at any time to quickly and easily order medicines that have been approved by the respective regulatory authorities. The system makes demand more transparent while also reducing lead times and miscommunications.

#### Working with partners to achieve more

Our collaborations and partnerships are founded on the Group-wide exchange of centrally stored information, which allows us to organize shared supply chains in a more efficient manner.

#### Shared data platform for medicine donations

In 2016, we launched NTDeliver, a digital information tool supporting **transparent supply chains for medicine donations**. This tool was developed under the auspices of the Neglected Tropical Diseases Supply Chain Forum, a public-private partnership. Forum members include the World Health Organization (WHO), the Bill & Melinda Gates Foundation, the logistics firm DHL, and six pharmaceutical companies that run donation programs: Merck KGaA, Darmstadt, Germany, MSD Sharp & Dohme, GlaxoSmithKline, Pfizer, Johnson & Johnson, and Eisai. NTDeliver transparently displays the deliveries from the donating companies – from purchase orders made by WHO through to delivery to the first warehouse in the destination country. Moreover, in 2017 we ran a pilot that also tracked the deliveries all the way

to the treatment point in the destination country, providing end-to-end visibility of our shipments. This improves coordination of our efforts on the last mile as well as providing us, the local experts and WHO with a more transparent overview of in-country inventory.

#### Further partnerships

In addition to these initiatives, we are also a founding member of the Accessibility Platform, which convened in 2017 to discuss local supply chains during our Access Dialogues (p. 40). This is an informal effort spearheaded by the private sector that aims to raise awareness of supply chain issues as part of the access to health challenge. It also seeks to increase knowledge-sharing and information exchange through open, multi-stakeholder dialogue, and to identify opportunities for collective action. We also share best practices with other companies and partners on **efficient, end-to-end, secure supply chains**.

### **Promoting local production**

At the end of 2017 we inaugurated a new production facility in Nantong (China) that will soon supply China directly with our pharmaceutical products. In India and Indonesia, too, we manufacture drugs for diabetes, cardiovascular conditions, and diseases of the lower respiratory tract. This allows us to supply medicines faster and more affordably to local markets, as well as to neighboring countries such as Sri Lanka and Myanmar.

#### Supporting regional vaccine manufacturers

In partnership with the Developing Countries Vaccine Manufacturers Network (DCVMN), we sponsor **educational programs for vaccine manufacturers** in developing and emerging markets and pass on our knowledge to ensure the safe, high-quality production of vaccines. Since 2014, we have conducted more than 12 training sessions as well as various technical workshops in the Asia-Pacific region and Latin America. In 2017, three seminars were held in Vietnam, India and China.

# prices of Medicines



Part of the non-financial report

The growing need to provide healthcare in aging societies poses major challenges to health systems. While reforms often focus solely on the price of medicines, it is important to consider the costs of medicines within the context of overall health systems. Medicine expenditures make up an important but still small portion of total spending. According to the OECD, spending on prescription medicines generally accounts for around 10%-16% of total healthcare spending in many OECD countries. Furthermore, science and innovative medicines are currently transforming care and allowing the treatment of many chronic diseases – the biggest cost-drivers – more effectively, thus achieving overall cost savings in health systems. At the same time, our commitment to creating a healthy society means that we must take a responsible approach to pricing our medicines.

### Our approach to pricing medicines

We want to ensure that all patients have access to the most effective medicines for their needs, which is why we're working to prevent cost from becoming a barrier to treatment. We therefore adapt our prices based on local market access and regulatory considerations such as health system capacity and financial standing, infrastructure, legal requirements, and unmet medical and treatment needs. Partnering with governments and other key stakeholders, we adjust our prices in different geographical or socio-economic environments to take account of **patients' ability to pay**. In addition, we continuously monitor the dynamic healthcare environments, pricing and reimbursement systems, and legal and regulatory guidelines, adjusting our prices as necessary.

Patients are at the very heart of our health solutions. We support patient access programs, flexible pricing, differential pricing, and risk sharing agreements. Moreover, we seek to improve data efficiency in health systems in order to achieve an optimal distribution of funds and resources. By following this approach, we balance our commitment to improving access to our products with our dedication to maintaining a sustainable medical innovation environment for future generations of patients.

## How we set medicine prices

Our Global Pricing and Market Access unit reports to the Chief Marketing and Strategy Officer of our Healthcare business sector. This team sets our initial prices in coordination with the respective businesses. Our subsidiaries are responsible for managing prices and continually adapting them to local environments.

# Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition, which includes increasing accessibility, availability, and awareness. As a key component of our overarching efforts to improve access to health (p. 38), medicine pricing adheres to the stipulations of our A2H Charter. Our approach is also informed by our Pricing of Medicines guideline. Furthermore, our Patient Access Programs Policy defines standards that enable us to offer medicines at reduced prices through our patient access programs.

### **Implementing our pricing**

We review our prices on an annual basis to ensure they meet patient access needs. To assist this process, we use a consistent, data-driven approach to monitor our local pricing. Based on the results, we define guidelines and, if necessary, adjust our prices to keep them affordable for patients. Our investment in enabling technology and our dedication to patient access allow us to make timely **strategic pricing and reimbursement strategy** decisions. We also make our products affordable to different patient segments within individual countries by participating in **government tenders**, establishing **second "lower-price" brands** or operating **patient access programs**.

### Innovative contracting models

We are committed to advancing value-based healthcare through innovative pricing and contracting mechanisms in full compliance with applicable local laws. In collaboration with payers such as health insurance companies, we have developed various product- and market-specific reimbursement and contracting models with the aim of providing patients **prompt access to our innovations**. Examples of such models include a shared-risk agreement recently established in the UK that will provide immediate access to Mavenclad® for MS patients, while the health service only has to pay for medicines for those patients that respond to the drug.

#### Government tenders to serve low-income patients

We work in partnership with governments and stakeholders on innovative, **differential pricing schemes**. Moreover, we regularly participate in government tenders for products that are used in public hospitals serving low-income patients. Many of these tenders take place in developing countries. For instance, we supply reduced-price products to governments in Africa, Asia, Latin America, and the Middle East.

### Second "lower-price" brands

We have established second "lower-price" brands of some of our existing brands. In South Africa, for instance, a second brand of our antihypertensive agent Concor® (named Ziak®) is available at discounted prices.

#### Patient access programs

Worldwide, we operate patient access programs that allow us to make our products **more affordable** to different patient segments within individual countries. These include programs in China to expand access to our oncology drug Erbitux<sup>®</sup>, which is used to treat conditions such as colorectal cancer. One example is our Erbitux<sup>®</sup> China Patient Assistance Program (ECPAP). Launched in 2012 in collaboration

with a local charity, ECPAP is geared primarily toward low-income patients, providing them with the drug free of charge. Since 2015 we have also been partnering with the China Charity Federation (CCF) and helping cover the costs of treating middle-income patients. In some cases, we split these costs with patients and a local insurance fund. To date, around 10,000 patients in China have benefited from our ECPAP donations.

We run similar assistance programs in other countries such as India, where we also offer  $Erbitux^{\$}$  at discounted prices. In South Africa, we support the Savanti Patient Access Program, which enables patients to be treated with  $Erbitux^{\$}$  at a lower co-payment rate.

# Health awareness

Many people are ill without realizing it. The result? Although effective medicines and therapies are available, these individuals do not receive treatment, or don't receive it in time. To prevent such an outcome, we conduct global campaigns to raise awareness and improve knowledge of diseases, their symptoms and treatment options. Ultimately, healthcare professionals, communities and patients can only make informed decisions if they possess the appropriate knowledge and information.

### Our approach to raising health awareness

Awareness plays a key role in our strategy to improve access to health (p. 38). We seek to empower communities, medical professionals and patients with appropriate tools, information and skills so that they can make high-quality, informed decisions on **prevention**, **diagnosis**, **treatment**, **care**, **and support**.

In our educational campaigns for prevention, early diagnosis and awareness, we often join forces with strong partners. We also seek to build the capacities of medical professionals working in the fields of research, technology and healthcare.

#### How we're building awareness

Our efforts and the strategic direction of our awareness activities are aligned with our respective businesses. Thus, our various business units plan and implement our diverse awareness projects either on a global level, or through their national and local offices, organizing local projects according to the specific needs of the area in which they operate. In our global campaigns they are additionally responsible for local mobilization.

In 2017 we launched a foundation, a philanthropic limited liability company (gGmbH) that consolidates key initiatives as part of **our efforts to support the community by building health awareness**. A Board of Trustees consisting of members of the Board of Partners and the Executive Board of Merck KGaA, Darmstadt, Germany monitors the foundation's activities and acts in an advisory capacity.

# Our commitment: Access to health through awareness

Awareness forms part of our A2H strategy, which is laid out in our Access to Health Charter. Our awareness campaigns are also subject to the responsible marketing (p. 59) principles set out in guidelines such as our "Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations". They are also governed by our internal policies and guidance for reviewing our interactions with health systems and by the review processes for communication materials.

## Global awareness campaigns

We regularly conduct campaigns to raise awareness of various diseases across the globe. Our efforts concentrate on those diseases that align with our **core competencies**, **expertise and experience** along the health value chain, in particular cancer (specifically colorectal, as well as head and neck cancer), thyroid disorders, diabetes, and multiple sclerosis (MS). In our awareness-raising activities we frequently collaborate with patient advocacy groups. In the 2017 period, we conducted or participated in multiple campaigns, enabling us to reach millions of people.

# Awareness and knowledge transfer for thyroid disorders

Throughout 2017, we worked to raise awareness of thyroid disorders. On the global level, we updated our Thyroid Aware website and joined campaigns in support of International Women's Day (IWD) and International Thyroid Awareness Week (ITAW). Within the ITAW we connected with more than 5,000 healthcare professionals (HCPs) and reached more than 2,500 people through our own events, of which more than half were directed at HCPs. Furthermore, over 158,000 people followed our own social media activities in 16 countries during the week.



million: During ITAW, we reached 13 million people through news coverage, social media and events. This was the ninth time we have participated in ITAW.

On the regional level, our National Endocrinology Congress in South Africa reached more than 2,000 people, including 300 HCPs. Other regional activities during ITAW 2017 included a public seminar held by our subsidiary in Indonesia in collaboration with the Ministry of Health, bringing together 100 HCPs and 250 members of local communities and nongovernmental organizations. Our subsidiary in Jordan sent a bus around the country to carry out testing and raise awareness of thyroid disorders in women (p. 50). It was approached by an estimated 1,100 women. In Saudi Arabia, we partnered with the Ministry of Health in a long-term awareness program named "Fly like a butterfly" and signed a memorandum of understanding to raise awareness of thyroid disorders. In Russia, our employees and endocrinologists shared their expertise on thyroid disorders and treatment options.

In the Philippines, we held our Unmasking Your Thyroid campaign for the third time in collaboration with the Philippine Thyroid Association (PTA) and the Philippine Ministry of Health. In its efforts to educate people on thyroid disease, this initiative utilizes a wide variety of media. It also offers training to health workers located in village communities, with approximately 250 people participating in 2017. Another integral feature of the campaign are **workshops for general practitioners**, which have provided 380 physicians with advanced training on the diagnosis and treatment of thyroid disorders since 2016. Furthermore, together with the PTA and healthcare provider Healthway, we've been offering training on accurately diagnosing thyroid disease since March 2017.

#### Awareness campaigns for cancer

In September 2017, we supported the fifth annual **Head and Neck Cancer Awareness Week**, an initiative of the Make Sense campaign. Under the banner of "Supporting Survivorship", teams from our Group came together in a global effort spanning nearly 30 countries to post more than 670 messages and pictures of themselves holding messages of support for head and neck cancer survivors. All images and videos were shared on our #SpeakUp wall microsite and our social media channels. Overall, our efforts generated more than 31,000 hits on social media.

On February 4, 2017, we joined **World Cancer Day** (WCD), an initiative driven by the Union for International Cancer Control (UICC) that aims to **bring the cancer community closer together**. We evolved the UICC's three-year campaign "We can. I can." and the 2017 motto "Support Through Sport" into our own call to action: "We can. I can. Jump in!" Participants were asked to submit images of themselves jumping in order to show their support in the fight against cancer. Our people worldwide provided over 500 photos from across 37 countries. The campaign was also opened to external audiences and received over 3,000 likes on social media.

In March, we recognized the colorectal cancer (CRC) **Awareness Month** 2017, an annual initiative to raise awareness of **CRC**, its symptoms and the importance of early diagnosis. As part of this initiative, we developed a multi-faceted campaign platform, as well as a website with an interactive pledge map, CRC quiz and factsheet. In total, we received pledges from six continents and over 60 countries.

#### World Multiple Sclerosis Day Activities

In May 2017, we supported World Multiple Sclerosis (MS) Day, an annual MS International Federation (MSIF) initiative. Under the banner of "Life with MS", the campaign reflected the need for better understanding and a clearer focus on the needs of care partners living with MS sufferers. Under this umbrella, we launched the global campaign "MS2020".

As part of the MS 2020 campaign, we announced a collaboration with the International Alliance of Carer Organizations (IACO). In partnership with IACO, we undertook a survey to deepen our understanding of the unmet needs of MS **care partners**. A preliminary analysis revealed that 41% of MS care partners suffer from anxiety, 38% from depression and 34% from insomnia. Additional data showed that many care partners suffer from chronic pain and worry about issues such as finances, intimacy, divorce, and parenting.

Also on World MS Day, we held a Tweetathon in which employees across 19 countries took part, sharing details of local awareness-raising activities under the hashtags #MS2020 and #LifeWithMS. Activities ranged from a sponsored run in the Netherlands to an outdoor photo exhi-

bition in Norway. The content was viewed over 70,000 times, and local events run by our teams involved more than 1,500 external participants from the MS community and beyond.

# Initiatives and programs from our Foundation

Launched in 2017, the Foundation sponsored by Merck KGaA, Darmstadt, Germany manages key parts of our efforts to support underserved communities by building healthcare capacities and raising awareness. The foundation is also driving many of our existing initiatives and programs.

#### Instigating cultural change

Through our "More than a Mother" initiative, we aim to empower infertile women through access to information, education and health, as well as by encouraging a change of mindset. Defining interventions to break the stigma surrounding **infertility and infertile women**, the campaign was launched in Kenya in 2015 and is still being conducted in many Asian and African countries today. To further this cause, the Foundation sponsored by Merck KGaA, Darmstadt, Germany is constantly seeking ways to engage government agencies and representatives in dialogue, leading it to take part in the 19th General Assembly of the African Union in 2017. Furthermore, we reached agreements with the several governments, including Uganda and Tanzania, to collaborate more closely on health awareness.

"More than a Mother" features an initiative called "Empowering Berna", which helps infertile women to start their own business and thus achieve financial independence. The project was rolled out across six African nations in 2016 and expanded to include three additional countries in 2017. To date, more than 1,000 infertile women from Central African Republic, Côte d'Ivoire, Ethiopia, Ghana, Kenya, Liberia, Nigeria, Sierra Leone, and Uganda have been enrolled in the project.

By the end of 2017, 23 embryologists and fertility specialists had taken part in our Merck KGaA, Darmstadt, Germany Embryology Training program, a three-month practical seminar on fertility management also offered within the "More than a Mother" campaign.

#### Building healthcare capacities

Through our Merck KGaA, Darmstadt, Germany Capacity Advancement Program launched in 2012, we're collaborating with academic institutions in various countries across Africa, Asia, Latin America, and the Middle East to train **medical professionals**. Through this effort, we are helping to build medical capacity and raise public awareness for diseases such as diabetes, hypertension and cancer, as well as infertility.

By the end of 2017, this program had reached more than 25,000 students from universities in Angola, Ethiopia,

Ghana, India, Indonesia, Kenya, Mozambique, Namibia, Uganda, Tanzania, and the United Arab Emirates, providing them with clinical diabetes and hypertension management training in a bid to equip them with skills to better treat and prevent these diseases. Our goal is to reach more than 30,000 students through this program by the end of 2018.

In 2017, we once again presented our Diabetes and Hypertension Awards to 37 medical students from over 30 universities in Africa and Asia. Through these awards, we have been building a platform of diabetes and hypertension experts across the globe and driving awareness in these fields since 2015.

To promote medical and scientific education, in October 2017 we hosted our fourth Africa Asia Luminary Congress in Cairo, which was attended by more than 450 African physicians, political decision makers and researchers. The event focused on contributions to socio-economic development in developing nations through sessions led by top international experts in diabetes, fertility, oncology, cardiology, family medicine, women's health, and research.

#### Raising local awareness

Our Community Awareness Program offers **easy access to information and educational materials** tailored to local needs. We disseminate this information through broad-based social media campaigns and use videos and posters to amplify the initiative's reach. By partnering with healthcare, policy makers, institutions, governments, ministries of health, and teams of interdisciplinary experts, we have successfully launched a wide range of targeted initiatives.

#### Bolstering STEM education

Through our STEM Program, we are seeking to encourage more young people, especially women, to pursue an **education in STEM fields**. The third UNESCO Africa Research Summit of Merck KGaA, Darmstadt, Germany (MARS) once more offered a key platform to pave the way for young researchers in Africa. Held in Mauritius in November 2017, the event focused on the role of scientific research in response to the latest developments in cancer management and vaccines. We use this annual conference as an opportunity to present the Best African Woman Researcher Award and the Best Young African Researcher Award. UNESCO-MARS Research Award winners go on to become ambassadors for our STEM Program within their home countries.

### Fighting cancer and its effects

Our Cancer Access Program was launched in 2015, with the specific aim of educating people about cancer and cancer treatment. Our "re than a Patient" initiative empowers African female cancer survivors to establish their own small business as a farmer or to open a shop. Thanks to the program's training and support, they are able to lead an independent and productive

life. To achieve this goal, we partner with cancer patient advocacy groups and cancer institutions across Africa.

Our Africa Oncology Fellowship Program focuses on increasing the number of oncologists in African nations and other developing countries. To this end, we have been offering various **fellowships** in collaboration with universities in Kenya, Egypt and India since 2016. By the end of 2017, 20 fellows had participated in this initiative.

# Su-Swastha in India: Providing healthcare to rural regions

In India, around 700 million people reside in rural areas and have no access to effective, affordable healthcare. This is because medical facilities are concentrated in India's megacities, which account for 80% of the country's healthcare professionals and 70% of its hospital beds. Through our Su-Swastha project we are working to improve healthcare in rural India. Our goal is to provide inexpensive medicines while also educating local patients and physicians on everyday health issues and their treatment. Medical professionals hold weekly community meetings on topics such as coughs, childhood ailments and prevention. Moreover, the program also provides patients with free check-ups and offers continuing medical education to help doctors advance their medical capacities. In 2017, a total of 482 community meetings were held, reaching 11,250 people directly. Every year around 70 workers from the health industry participate in our continuing education programs, with 346 people having received training since 2012. Due to its business model, the project is currently running self-sustainably. It was recognized as a best practice in the 2016 Access to Medicine Index.

### **Healthy Women, Healthy Economies initiative**

We aim to help women unlock their **economic potential** and in doing so create an impact for global economic growth. Nearly one in four women worldwide are held back from achieving their full economic potential due to preventable causes, such as a wide range of communicable and noncommunicable diseases. Healthy Women, Healthy Economies has taken up this challenge. In 2014, under the auspices of the Asia-Pacific Economic Cooperation (APEC), we collaborated with representatives of the United States and other governments to launch this public-private partnership (PPP). Comprising public and private sectors as well as non-governmental organizations, this initiative has developed a policy toolkit with recommendations to improve women's health.

Under this program, we have joined forces with the Philippine government and the Philippine Thyroid Association (PTA) to educate more than 2,000 health industry employees on thyroid disorders, a problem that disproportionately affects women. By the end of 2017, we had reached nearly eight million people in the Philippines through our campaign. In Jordan, we collaborated with the NGO Royal Health Awareness Society to likewise train health workers on thyroid disorders in women. Moreover, in 2017 we formed a partnership with the Wilson Center, Hand-in-hand with this U.S.based research institute we're gathering data and increasing awareness to illustrate how important women's health is to their participation in the economy. Furthermore, we are developing policy recommendations designed to support women in both paid and unpaid work in an effort to achieve greater work-life integration and improve their overall health and well-being. Another collaboration with the University of Miami's Department of Public Health Sciences is currently focused on women's unpaid labor in China, Canada, Chile, Mexico, and Peru.

# chemical product safety



Part of the non-financial report

Many of our chemicals are classified as hazardous substances and are therefore subject to an array of national and international regulatory requirements to ensure that they do not pose any risk to people or the environment. Fulfilling these statutes and guidelines is crucial to our business activities. In addition, we strive to meet the expectations stakeholders such as customers and employees have of a comprehensive risk management system.

#### Our approach to safe chemical products

Product safety is our top priority. Starting in the development stage, we investigate the potential impacts chemical

substances may have. Along the entire value chain of our chemical products – from import or production through commercialization, handling, recycling, and disposal – we fulfill all statutory requirements, often even exceeding them. We furthermore publish extensive information on our website so that both our customers and the general public can learn about our products and how to use them safely.

# How we ensure the safety of chemical products

Our Life Science and Performance Materials business sectors each have their own Product Safety units. Working in close collaboration, these units are responsible for all product safety activities such as registering chemical products, classifying hazardous substances and communicating risks through safety data sheets and labels. In addition to these activities, they also assume similar duties for our Healthcare business sector.

Our Group Product Safety Committee (GPSC) monitors regulatory requirements worldwide to check for relevant changes, initiating and reviewing the measures needed to integrate these changes into our processes.

Our Group-wide governance unit Regulatory Affairs (EQ-R) ensures that steps are taken to address gaps in regulatory compliance as soon as these arise. Reporting directly to the head of our Group function Corporate Environment, Health, Safety, Security, Quality, EQ-R is independent of our business sectors and is not subject to any operational commitments. Any necessary corrective or preventive action is carried out by the operating units within each business sector. EQ-R further supports individual units in implementing and harmonizing efficient processes.

# Our commitment: Observing statutory regulations and Group-wide guidelines

We have implemented Group-wide guidelines that guarantee compliance with national and international regulatory requirements, and have also endorsed general voluntary commitments of the chemical industry such as the Responsible Care<sup>®</sup> Global Charter.

To meet the product safety regulations relevant to our company, in 2017 we adopted the Regulatory Affairs Group Policy, which details our Group-wide processes for managing and implementing product safety, including the necessary management structures. The statutory requirements applicable to our operations include the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and its implementation in regional and national legislation (such as the CLP regulation in the European Union and HazCom 2012 in the United States), the EU chemicals regulation REACH, the amended U.S. Toxic Substances Control Act (TSCA), and the German federal law on protection from hazardous substances (ChemVerbotsV). Our Group-wide policy also incorporates legal norms concerning the transport of hazardous chemicals, biocides, cosmetics, and products used in food and animal feed.

### REACH registration on schedule

We are working to register all our chemical substances under REACH. We successfully completed registration phase 1 in 2010 and registration phase 2 in 2013. The next step, part of phase 3, is due by June 2018 and requires us to evaluate and register all substances produced or imported in quantities ranging from one to 100 metric tons annually. This process now also includes the substances added to our portfolio through the acquisition of Sigma-Aldrich and is on schedule.

In line with the Strategic Approach to International Chemicals Management (SAICM), a global policy framework overseen by the United Nations, **requirements for registering and licensing chemicals** are being recognized in a growing number of countries. Thanks to our experience in implementing REACH, we are well prepared for such a procedure and have already initiated the registration process for select substances.

#### Transcending laws

In an effort that transcends statutory requirements, we support the goals of the Global Product Strategy, an international initiative of the chemical industry. In this vein, we publish product safety summaries for all lead substances we've registered under REACH on the website of the International Council of Chemical Associations (ICCA).

# Safety analysis during product development

We believe that product safety starts during the development stage. By conducting hazard, exposure and risk assessments, we seek to ensure that our chemical products can be safely used later down the road. All our product innovations undergo a formal **EHS analysis**, which examines aspects such as their impact on human health and the environment. Before launching a new product, we evaluate all relevant hazardous substance data and classify it accordingly. In conducting these safety assessments, Regulatory Affairs provides advice and support to employees in our Life Science and Performance Materials business sectors.

#### Safe nanotechnology

Nanotechnology is a highly innovative field of development that researches and uses structures 50,000 times thinner than a human hair. This technology makes it possible to produce materials with completely new properties and functions for a myriad of applications.

Nanotechnology opens up many opportunities for our Group. In our Life Science and Performance Materials business sectors, we can use nanoscale materials to develop **products with new functions and properties** – meaning, for instance, that resources and energy can be used more efficiently. In our Healthcare business sector, we partner with research institutes and other European companies to explore the use of nanomaterials to improve therapeutic options. Under the auspices of European research partnerships, we are also investigating the suitability of nanoparticles as vehicles to deliver active pharmaceutical ingredients to the required site of action.

However, the special structure of nanoparticles can also entail risks, which we assess in line with statutory requirements such as REACH. Moreover, we only utilize this new technology with the greatest care, abiding by the precautionary principle and taking nanomaterial safety issues very seriously. In doing so, we consider Group-wide requirements for safety as well as environmental and health protection, employing our existing processes and systems for product safety. Whether using nanomaterials in pharmaceutical and chemical laboratories, production plants, filling plants, or warehouses, we abide by our Group-wide Policy for Use and Handling of Nanomaterials.

In the manufacture and processing of our products, we adhere strictly to all statutory regulations and other applicable standards, such as the guidelines of the German Federal Institute for Occupational Safety and Health (BAuA), as well as the German Chemical Industry Association (VCI). We also provide our customers safety data sheets containing information on the proper handling of nanomaterials, during transport, processing, storage, and disposal.

#### Consolidating knowledge of nanotechnology

Over and above our internal efforts, we continuously engage other companies, associations and regulatory agencies in a dialogue on the **opportunities and risks of nanotech-nology**. We also participate in committees and working groups such as the Nano-coordination group of the VCI's Technology and Environment committee, as well as Responsible Production and Use of Nanomaterials, a joint technology working group of DECHEMA (Society for Chemical Engineering and Biotechnology) and the VCI. Under the auspices of the VCI, we furthermore help to review current scientific literature in order to glean new findings on nanotechnology.

## Standardized product safety information

As part of our efforts to communicate the potential dangers of our products, we provide our customers with in-depth informational material on all our chemical products. These brochures contain instructions for use and handling to prevent them from posing a danger to people and the environment. Our goal is to give our customers product safety information that has been standardized worldwide.

We issue all chemicals classified as hazardous with **safety data sheets**, which, in accordance with UN regulations, follow a globally harmonized format. These sheets contain

information on the physicochemical, toxicological and ecotoxilogical properties of the agent, and reflect the relevant regulatory requirements of the countries in which they are published. We therefore produce country-specific safety data sheets in 41 languages for our Performance Materials business sector and in 37 languages for our Life Science business sector. Although not mandated by law, we also provide safety data sheets for the non-hazardous materials and finished medicinal products manufactured by our Healthcare business sector.



million safety data sheets in total are made available to our customers.

Since all these documents must be kept up to date and consistent, in 2017 we automated the majority of our Group-wide hazard communication processes. Now the aim is to centralize the creation of safety data sheets in our business sectors. Within Performance Materials, for instance, we began drafting all safety data sheets Group-wide using a single system this year.

#### Informing customers and increasing awareness

All information on the safe use of our products is also available on our website, where our customers can additionally access the ScIDeEx $^{\circledR}$  program. This tool allows them to check whether they can use a chemical agent safely in line with the EU chemicals regulation REACH.

We aim to increase awareness for the safe handling of hazardous chemicals, providing users with best practice advice and information. To this end, we regularly conduct seminars and information sessions worldwide that teach basic lab safety rules such as the handling of flammable solvents and the storage of chemicals in safety cabinets and warehouses.

# patient safety



Part of the non-financial report

The safety of patients treated with our medicines is a critical priority. That is why we consistently monitor risks and adverse effects as they arise, and take the necessary action to minimize them. Through rigorous benefit-risk assessments, we ensure that the benefits of our drugs always outweigh the risks for patients.

### Our approach to ensuring patient safety

Our pharmaceutical products need to be effective in treating the respective disease while also posing as little risk as possible to patients. To ensure their safety, every new medicine passes a series of precisely defined development stages. Prior to using a drug in humans, we first conduct extensive preclinical testing both in vitro and in vivo. Through toxicological testing, we determine whether an active pharmaceutical ingredient is toxic to living organisms and if so, at what dose. This also helps us determine the dose that humans can safely tolerate. Only once this is complete do we perform clinical studies (p. 63) to investigate the safety and efficacy of the drug when used in humans. During clinical development, we diligently use all collected data to continuously evaluate the drug's benefit-risk profile. We only submit an application for marketing authorization to the regulatory authorities if the medicine has a positive benefit-risk profile.

### Continual monitoring

After a drug is launched, the number of patients being treated with it increases significantly. In certain circumstances, rare adverse effects that go undetected during clinical development may occur, which is why we continually monitor and update the benefit-risk profiles even after market launch. For new products approved in 2017, we introduced educational materials for patients and healthcare providers on potential risks.

**Pharmacovigilance** is the process of continuously monitoring a drug to detect, assess and understand adverse effects in an effort to take appropriate action to minimize risk.

We always provide physicians and patients with the latest information on the safety of our drugs. This applies to the entire life cycle of a product, ranging from development, market launch and commercialization to expiration of the marketing authorization.

### How we monitor patient safety

Our Global Patient Safety unit is responsible for pharma-covigilance; it continually collects current safety data from a wide variety of sources across the globe, including clinical studies, spontaneous reports on adverse effects, and articles published in medical and scientific journals. In 2017 we launched a new methodology and technical system providing effective, state-of-the-art capabilities for signal detection and management using data collected worldwide and big data analytics.

Our experts ensure that all information on the potential risks and adverse effects of our medicines is properly documented, tracked and reported to the respective health authorities in accordance with regulatory requirements. Global Patient Safety analyzes all data and uses this as required to **reassess the benefit-risk profile**. We then inform regulatory authorities, physicians and patients about potential risks and changes in the benefit-risk balance.

To meet the growing demands of our innovative R&D pipeline, Global Patient Safety underwent a strategic reorganization and specialization process in 2017. This resulted in two dedicated units specializing in the co-development and benefit-risk management of our investigational pipeline products, and in the global pharmacovigilance of our broad portfolio of products marketed worldwide. This specialization has already created new capabilities in advanced benefit-risk management, big data analytics, advanced signal detection technology, and pilot processes in patient-centric adverse effects collection.

Our Product Quality unit (MBQ) processes quality complaints relating to our products. When quality defects may have an impact on patient safety or lead to adverse effects, Global Patient Safety gets involved.

### Our Medical Safety and Ethics Board

Our Medical Safety and Ethics Board (MSEB) oversees the safety and benefit-risk evaluations of our drugs throughout clinical development and commercialization. As required, it initiates appropriate **measures to minimize risk**, such as package insert updates. This board is chaired by our Chief Medical Officer (CMO) and consists of experienced physicians, scientists and experts from our company. Throughout a drug's entire life cycle, the MSEB reviews and assesses important medical safety risks and benefit-risk issues, and reviews ethical issues if necessary.

# Our commitment: Guidelines and statutory requirements

To evaluate benefits and risks, we have introduced a **Benefit-Risk Guide** to our Global Patient Safety unit. This manual builds on the results of a joint initiative of the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in which we are involved. We benefited from the recommendations when compiling the documentation for marketing authorization of the drug cladribine. Subsequently we made use of these learnings for the documentation required for the marketing authorization of avelumab.

In producing pharmaceuticals, **quality assurance** is a key aspect. The Current Good Manufacturing Practice (CGMP) regulations ensure that pharmaceuticals meet the standards set for identity, purity, potency, and safety. Compliance with these regulations is mandatory for pharmaceutical companies and is closely monitored by health authorities. As a pharmaceutical manufacturer, we have appropriately trained employees, as well as suitable facilities, processes and procedures in order to meet all requirements.

We want our pharmaceutical products to be readily available to physicians and patients and always arrive on time. For this to happen, our **distribution processes** must function reliably all over the world. By continually auditing our distribution network, we ensure that both our subsidiaries as well as our partners and contractors adhere to our quality and safety requirements. All distribution activities must comply fully with Good Distribution Practices (GDP).

### Meeting statutory requirements

We always adhere to all statutory pharmacovigilance regulations in force in those countries where we market our products and are continuously working to incorporate requirement changes in our Group-wide standards and processes. In 2017, for instance, we upgraded our safety database and the associated reporting processes to meet the new requirements of the European Medicines Agency (EMA).

# Collecting information and checking processes

In March 2017 we rolled out agReporter, a mobile app for reporting adverse effects from the use of our products. This tool was initially intended for use by field nurses and our sales representatives. Furthermore, we plan to add a **patient-friendly interface** to the app, thereby putting patients center stage in our efforts to consistently collect adverse effects data.

### Supervising drug safety

Regulatory authorities conduct regular inspections to verify that we are complying both with statutory requirements as well

as our own internal standards for drug safety. In Germany, these are handled by the German Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (the German Federal Institute for Vaccines and Biomedicines (PEI)) on behalf of the European Medicines Agency. In 2017 **pharmacovigilance inspections** were conducted in Canada, Colombia, France, Japan, and Switzerland. All inspections have continually confirmed the proper functioning of our Pharmacovigilance system.

Furthermore, we perform our own audits to ensure that all our departments, subsidiaries, vendors, and licensing partners involved in pharmacovigilance consistently meet all requirements across the globe. In 2017, we found no significant deviations from these requirements. Such audits help us hone our pharmacovigilance processes so that they surpass statutory requirements.

#### **Labeling of products**

**Package inserts** inform physicians and patients on how to properly use the respective drug. In accordance with statutory regulations, the insert contains all relevant information such as ingredients and dosage, storage, mode of action, instructions for use, warnings, precautions, and possible adverse effects. Should the medicine contain ingredients that may impact the environment, the package insert may also contain information on the proper disposal of the product.

We review and update all package inserts as necessary, ensuring that they contain the latest information about our medicinal products. These leaflets also reflect changes initiated by our MSEB, such as new warnings. In accordance with statutory requirements, all modifications to the inserts are submitted to the respective regulatory authorities for approval.

#### Internal and external training

All employees involved in the **safety and quality of pharma- ceutical products** are trained according to our global training standards. We verify compliance with these requirements by performing regular audits. In addition, all our Biopharma employees receive basic pharmacovigilance training once a year that covers how to report adverse effects from our products.

Through such training, all employees are kept consistently up-to-date. This includes their professional expertise and training on internal standard operating procedures and other relevant requirements. In this way, we ensure adherence to Good Pharmacovigilance Practice (GVP) requirements. We provide our training via a global e-learning platform.

In 2017 we initiated a pharmacovigilance campaign in Mexico to raise awareness for adverse effect reporting. This effort is targeted at both patients and health workers (such as health authorities, physicians and nurses) along with our own Marketing

& Sales people. To ensure the campaign's success, we offered a special training program for our Marketing & Sales staff, who also receive additional informational material every two months. Moreover, we are conducting a poster campaign to make health sector employees more aware of the importance of reporting adverse effects.

#### Sharing expertise with other countries

We also work to transfer our drug safety expertise to other countries, especially those where health workers still lack the necessary **knowledge regarding pharmacovigilance**. In November 2017 we launched the "Africa kommt!" project in an effort to educate trainees from Africa on the safe use of pharmaceutical products, with the ultimate goal of them subsequently implementing the educational content in their home countries.

# counterfeit products



### Part of the non-financial report

According to the World Health Organization (WHO), a considerable proportion of the medicines in developing countries are illegal, counterfeit or substandard. In industrialized nations too, however, such products are becoming increasingly available on the market through unlicensed internet pharmacies and underground business-to-business (B2B) platforms, ultimately posing a risk to public health. Chemical products can furthermore be used for illegal purposes such as the manufacture of illicit drugs.

### Our approach to anti-counterfeiting

Our company develops and manufactures products of the utmost quality. In order to protect both customers and patients, we secure our products against counterfeiting and are deeply committed to fighting product-related crime. For instance, we collaborate with regulatory and law enforcement agencies at the regional, national and international level. When cases of product crime are identified, we also cooperate with customs authorities in the respective countries, along with Interpol, the World Customs Organization, various health authorities, and our peer industry. Our guidelines, standards and processes apply to all our business sectors and markets worldwide, thus protecting our reputation as a supplier of quality products.

#### What we mean by product crime

1. Counterfeit products: In line with the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and WHO standards, we define a counterfeit product as "a product that is deliberately and fraudulently produced and/or mislabeled with respect to its identity and/or source to make it appear to be a genuine product."

This includes products

- with incorrect active ingredients or concentrations thereof
- without any active ingredients
- with dangerous impurities
- with modified/altered packaging and/or incorrect brand names
- with an authentic active agent, but not one produced under GxP conditions
- that have expired
- that were removed from the legal supply chain (e.g. through theft).
- **2. Illegal diversion of products**: This term refers to the diversion of either chemical or pharmaceutical products from within the legitimate supply chain for illegal export, for use in the production of illegal drugs, weapons or explosives, or for any other illegitimate purpose.
- **3. Black market crimes**: This refers to the sale of counterfeit and/or diverted products via illegal channels such as the Internet, or for illicit purposes.
- **4. Misappropriation of products**: This refers to theft from production sites and warehouses, or while in transit.

### How we're tackling product crime

Our Group function Corporate Security coordinates all our anticounterfeiting activities. All such efforts are carried out under the supervision of our Chief Security Officer and the Head of Environment, Health, Safety, Security, Quality (EQ). Furthermore, all our sites have a Product Crime Officer who investigates potential cases of counterfeiting, acting as the interface between local regulatory and law enforcement authorities, national associations, our Group functions, and our facilities. Depending on the type, violations are first investigated by the unit in charge.

#### Group-wide anti-counterfeiting network

Our Anti-Counterfeiting Operational Network (MACON) is responsible for globally monitoring and implementing **all anti-counterfeiting measures** for our products. Along with coordinating preventive measures and the development of security systems, this organization is also responsible for investigations. Comprised of experts from various units such as Legal/Trademarks, Product Security, Export Control, Supply Chain, Patient Safety, and Quality Assurance, MACON is coordinated by our Corporate Security unit. All MACON activities are now overseen by the new Global Anti Product Crime unit, created in 2016.

To investigate suspected cases, MACON collaborates with the appropriate law enforcement agencies and regulatory authorities. This network has allowed us to identify more cases of counterfeiting and take decisive action, especially in high-risk countries. In 2017, MACON reviewed and investigated approximately 128 cases, including inquiries from authorities that arose during backtracking investigations. We furthermore uncovered four underground laboratories that were counterfeiting several of our products.

# Our commitment: Group-wide guidelines and standards

Our Crime Relating to Products guideline of Merck KGaA, Darmstadt, Germany describes our goals and strategies for combating counterfeiting. Our Group-wide Product Crime Investigation Standard sets out binding requirements and defines the knowledge sharing process within our company in an effort to provide a solid legal footing for dealing with illicit products.

# **Enhanced monitoring and reporting systems**

We analyze and document all counterfeit product incidents using a Group-wide reporting system. This approach provides us with a **complete picture of the security situation** and enables us to identify possible links between different cases, thus equipping us to combat similar future incidents more effectively. Implemented at the end of 2017, our "Data and Documentation Quality Management" SOP details the associated process.

#### Tracking system for chemical substances

We monitor chemicals that could be misused to produce illegal weapons, explosives or narcotics. These are tracked through an **internal tracking system** that flags suspicious orders and/or orders of sensitive products, which are only released once we've confirmed the existence of a (verified) end-user declaration.

In addition to fulfilling the duties stipulated by statutory provisions on export control, we also report suspicious orders, inquiries and requests to the competent authorities. Through these efforts, we are honoring a voluntary commitment of the German Chemical Industry Association (VCI) and meeting the terms of the Guideline for Operators published by the European Commission.

#### Reviewing our efforts

We evaluate the effectiveness of our measures according to the number of reported, investigated and solved cases, as well as their severity.

### Supporting customers and patients

We believe that patients should be able to determine the identity and authenticity of a pharmaceutical product themselves. We are therefore rigorous in meeting the requirements of the EU Falsified Medicines Directive, for instance by applying a **unique serial number** to our pharmaceutical packaging. In the United States, this practice has been required by the Food and Drug Administration (FDA) since the start of 2018. We were the first company to have complied with this requirement by the end of 2015. As an EU company, we are likewise legally mandated to label all pharmaceutical packaging with a unique product identifier by February 2019. We are in the process of implementing this provision.

# In parallel to meeting these provisions, we are also pursuing our own initiatives:

- We apply Security M, a security label containing our color travel pigments, to some of our products, taking a riskbased approach to identifying those products that should be labeled in this manner. The Security M enables users to easily verify the authenticity of our products and is considerably harder to counterfeit than the holograms commonly used.
- Through our Track & Trace system, pharmacists and distributors of our products can trace the supplier of the medicine to verify its authenticity. Having implemented this system for all our pharmaceutical products in the United States and China, in 2017 we expanded it to Colombia as well. We intend to furthermore include Europe, the Middle East, Egypt, and Russia by the end of 2018
- Our free Check My Meds app for smartphones allows patients in the United States and since 2017 also in Colombia to scan the serial number of their medicines and quickly verify their authenticity.
- In our Mobile Anti-Counterfeiting System (MAS) project in Nigeria, we are working closely with one of our suppliers on a text message-based identification system. Patients scratch off a barcode that is printed on the product packaging and then send this code via text message to an assigned number. They immediately receive back a response telling them whether their code is authentic.

- We sponsor the non-profit Global Pharma Health Fund (GPHF), which supplies **GPHF Minilabs**® to test the quality of 90 different active ingredients. With this compact test kit, counterfeit medicines can be detected quickly, easily and inexpensively, a tool that especially benefits developing and emerging countries. You can find more information on this project under Community (p. 111).
- We offer our customers in the pharmaceutical industry Candurin® pearl effect pigments, which feature unique color properties that make tablets and capsules more difficult to counterfeit.

### **Industry-wide exchange**

In an effort to fight product crime, we have joined forces with organizations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and the German Association of Researchbased Pharmaceutical Manufacturers e.V. (vfa). We also support industry-wide initiatives. For instance, we work particularly closely with the Pharmaceutical Security Institute (PSI), a non-profit organization dedicated to protecting public health by sharing information on pharmaceutical counterfeiting and initiating enforcement actions through the appropriate authorities. Our Chief Security Officer is the Vice Chair of the PSI Board of Directors. Furthermore, we are a member of Rx-360, a consortium of global pharmaceutical manufacturers and suppliers that aims to prevent counterfeit products through the introduction of a global quality assurance system.

# **Educating our employees and business partners**

We endeavor to raise awareness of product crime among our employees and business partners, educating our people worldwide on the subject. In the countries where we don't have our own subsidiaries, we offer training for our business partners.

All staff involved in security, such as Product Crime Officers, participate in **onboarding and training programs** aimed at building their capacities and promoting idea sharing. We are constantly refining these programs and adapting them to new trends. In 2017, for instance, we held incident reporting & intelligence systems training for our Product Crime Officers.

# Security audits for contract manufacturers and distributors

We regularly check whether our distributors and contract manufacturers are complying with GMP and GDP (Good Manufacturing Practice/Good Distribution Practice). In doing so, we also ascertain the extent to which our **security requirements** are being implemented. In general, our contract partners meet these requirements. However, special security audits are conducted if significant deviations are identified. Such audits are also conducted when we certify external service providers for our Security M label. This applies to both pharmaceutical contract manufacturers as well as print companies that print packaging. This auditing system is based on the EMA ICH Q10 pharmaceutical quality assurance standard. In 2017, we conducted ten security audits of our partners worldwide, who have since taken the necessary corrective action.

# transport and warehouse safety



Part of the non-financial report

We transport and store products and materials worldwide such as chemicals and pharmaceuticals, raw materials, intermediates and waste, as well as technical materials and packaging, all of which could pose a hazard if handled incorrectly.

### Our approach to safe transport and storage

We strive for all our shipments to reach our customers and sites safely, undamaged and with the required safety information. Several of the materials we store and transport are classified as hazardous. To prevent danger to people and the environment, we therefore adhere to **extremely strict safety regulations** across our Group. The storage of such

hazardous goods and the corresponding transport involved – whether by road, rail, plane, or ship – are governed by regulations applicable worldwide. We ensure safety and compliance with these rules through our standards, regular audits of our sites and employee training.

# How we achieve transport and warehouse safety

Transport and warehouse safety falls under our Group function Environment, Health, Safety, Security, Quality (EQ) (see Environmental stewardship (p. 87)), which sets Group-wide standards and guidelines. In addition, our individual sites are subject to various national and international **regulations** 

**governing environmental stewardship and public safety**, which local site directors are responsible for implementing.

Each of our sites around the world has an EHS manager and a dangerous goods manager, a position that equates to the "dangerous goods safety advisor" required by EU regulations. Both of these advise the site director on issues regarding the safe storage and transport of hazardous goods while also monitoring compliance with statutory requirements and our own internal standards.

Our EHS managers are also responsible for monitoring our third-party warehouses. Before signing a contract with a warehouse provider, we assess whether they properly adhere to national and international storage and transport regulations and if they are able to implement our additional requirements. The findings from this audit are summarized in a statement issued by EHS. If off-site warehouses employ additional subcontractors, these are also included in our audit.

# Our commitment: Internal standards and international rules

Our **Group-wide safety concepts and standards** govern the safe storage of hazardous substances. The Warehouse Safety standard, for instance, defines measures to prevent substances from leaking or igniting. According to this standard, risk evaluations must be conducted on all stored substances, and it also sets out special rules of conduct that apply to all warehouse employees.

To ensure third-party warehouses also adhere to our strict safety requirements, our Group standard Warehouse Requirements for Third-party Warehouses defines specific **structural and organizational requirements** for a facility. Before we sign a contract, warehouse providers must submit a statement detailing how they plan to meet our stringent safety standards.

In Germany, the Technical Rules for Hazardous Substances (TRGS) govern the storage of hazardous substances in non-stationary containers. Across all our warehouse and distribution centers worldwide, we have implemented this regulation's requirements for storing various hazardous materials together and in 2017 we began rolling out **software** that will help us keep track of everything. We also comply with the current requirements of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) at all our sites, with the sole exception of India, where the GHS system has not yet been fully transposed into national regulations.

Our Group Transport Safety standard defines the safety levels for our sites and is based on the United Nations Recommendations on the Transport of Dangerous Goods. This is especially important for facilities in those countries with no local regulations on the transport of hazardous mate-

rials. We update our Group standard to reflect current requirements every two years and support our site directors in implementing the relevant changes at the local level.

### **Enhancing transport and warehouse safety**

In addition to the inspections conducted by our EHS and dangerous goods managers, we regularly perform **risk-based** audits across our company to ensure that our sites are complying with warehouse and transport safety regulations. We generally conduct these audits every five years, performing them more frequently at facilities that pose a potentially higher risk. If major shortcomings are identified, we re-audit the respective site the following year. Conversely, we may decide to extend the period between audits at facilities where, based on the findings from previous audits, we deem the risk potential to be low.

In 2017, we audited 37 of our warehouses for compliance with our Warehouse Safety and Transport Safety standards. In response to the deficiencies identified by this audit, we are currently optimizing our Group-wide packaging selection process with a focus on our portfolio of acquired Sigma-Aldrich products.

Third-party warehouses and contract transportation companies are also regularly audited by our EHS managers. In 2017, we audited 15 third-party warehouses and external logistics providers, developing corrective action plans where shortcomings were identified. Along with implementing individual corrective measures, we also intend to optimize packaging and disposal processes at our third-party warehouses. In this vein, we are therefore currently compiling **information for off-site warehouses in Asia and Latin America**. Using real-life examples, this brochure will describe and explain our safety concept and guidelines. This is one of the ways we support our providers in meeting our strict requirements.

As a member of the Logistics & Distributors User Group of SQAS, a service provided by the European Chemical Industry Council (Cefic), we receive additional audit reports on our logistics service providers. In 2017 we developed criteria to evaluate these reports, which we subsequently make available to the relevant units in our company.

In 2017, no incidents that could have significantly impacted the environment or community were recorded at our company, our third-party warehouses or logistics providers, **nor were there any infringements** of international regulations.

#### Continuously improving safety concepts

Our local EHS and dangerous goods managers regularly review and evaluate our transport and warehouse activities, informing site directors of shortcomings and opportunities for improvement. Based on a **strength and weakness**  **analysis of each site**, we calculate key performance indicators for transport and storage safety, which help us determine where to institute additional improvements. Rolled out in 2017, our in-house e-learning concept for basic management courses on the transport of dangerous goods is mandatory for all logistics, EHS and dangerous goods managers; additional courses on transport safety and storage are currently under development.

# **Employee training and best practice sharing**

Several times a year, our warehouse workers and all employees involved in the transport of goods undergo training on our standards and procedures, as well as on changes to international requirements and incident management. All our truck drivers hold a dangerous goods driving license, while in Germany they complete additional training in line with the German Professional Driver Qualification Act (BKrFQG) and on securing cargo. Across the globe, every year we conduct around 1,000 internal and external training seminars on transport and warehouse safety. In some cases, the managers of third-party warehouses also participate in these sessions.

Furthermore, our EHS managers meet regularly at the EHS Conference in Darmstadt (Germany), where they have the opportunity to share lessons learned and best practices, as well as participate in transport and warehouse safety training. These topics are also covered in the mandatory three-day orientation seminar for all new EHS managers.

Such meetings also provide a platform to discuss current issues, for instance transport and warehouse safety during natural disasters such as Hurricane Harvey, which hit the United States at the end of August 2017.

### **Ensuring correct transport**

Our products are primarily delivered to our customers by logistics providers. In Germany, we transport the majority of our hazardous waste ourselves, but do sometimes also enlist the services of other companies if necessary. Furthermore, we participate in the **German Transport Accident Reporting and Emergency Response System** (TUIS) operated by the German Chemical Industry Association (VCI). Within this system, we exchange expertise and best practices on chemical transport with experts from other chemical companies and also provide hands-on assistance in the event of a chemical transportation accident. When a transport or warehouse accident occurs, we can use our "TUIS Messkonzept Südhessen" to quickly calculate the rate at which hazardous substances are spilling and spreading.

### Making transport vehicles safer

The safe transport of dangerous goods requires safe vehicles, another area we pursue. In the past few years, for instance, we have been constantly improving our **SafeServer truck body technology**. In this design, the aluminum panels integrated into the side walls of the truck render the walls extremely stable, making it largely unnecessary to secure cargo.

# Responsible Marketing



Part of the non-financial report

We commercialize both prescription medicines and over-the-counter products. Pharmaceutical marketing is regulated by legislation worldwide. In Germany, for instance, manufacturers are only permitted to advertise prescription drugs to medical professionals such as physicians and pharmacists. In doing so, they must always disclose the active ingredients, adverse effects and contraindications of the advertised drug. In marketing our pharmaceuticals, the wellbeing of patients is always our primary consideration - because they deserve effective, high-quality treatment.

### Our approach to responsible marketing

We adhere strictly to all regulations on pharmaceutical marketing. All guidelines pertaining to marketing and advertising are part of our Group-wide compliance program, which requires us to always conduct business in compliance with the law and **in line with the highest ethical standards**. Our compliance program is complemented by our internal guidelines and various voluntary commitments that, in many cases, exceed the applicable statutory regulations. We regularly review all our internal guidelines, adapting them to new developments.

#### How we conduct ethical marketing

Our Group Compliance unit is responsible for setting up internal compliance policies and procedures to ensure that our business activities adhere to the statutory regulations applicable to our sales and marketing activities. Our Global Regulatory Affairs unit has also established a dedicated policy and complementary process document on the review and approval of our promotional materials. The necessary training and communication are carried out by each policy owner. On the operational level, the businesses and every

employee involved in our sales and marketing activities must carry out these activities in adherence with our internal policies and procedures. Our Internal Audits unit regularly conducts risk-based reviews of our sales and marketing activities. You can find more details on how we ensure compliance with statutory regulations worldwide under Compliance (p. 11).

# Our commitment: Code of Conduct and industry-wide regulations

Our Group-wide "Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations" defines the relevant standards for our ethical marketing practices. It also governs our interactions with physicians, medical institutions and patient advocacy groups. Due to specific regulations in the United States, our pharmaceutical activities there are subject to a specific guideline entitled "Pharmaceutical Operations of Merck KGaA, Darmstadt, Germany and the biopharmaceutical business sector in the United States".

Through our "Principles of Review and Approval of Promotional Materials and Other External Communications", we ensure that **all promotional materials conform to our rigorous standards**. In 2017, we updated these principles along with the associated standard process, focusing particularly on our requirements for scientific communication with health workers. All employees involved in creating promotional materials worldwide have received training on these updates.

Beyond national laws and our own standards, we furthermore comply with the codes of conduct of various industry organizations, such as the Code of Practice and Code of Pharmaceutical Marketing Practices published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). Moreover, we are a member of the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), which has defined its own code of conduct regarding collaboration between physicians and the industry.

### **Reviewing marketing material Group-wide**

Our aim is to review all promotional material end-to-end to ensure that it meets our standards, which is why we apply a **Group-wide review and approval system**. In 2016, we updated this system and harmonized a variety of locally used tools. Since the beginning of 2017, approximately 2,200 Healthcare employees have been using a centralized platform that allows us to streamline the review and approval process more efficiently, while also providing a better overview of global marketing data. This helps us identify opportunities for improvement.

#### Addressing violations of standards and regulations

A **variety of channels** has been established so that wrongful marketing practices can be reported to the industry associations to which we belong. For instance, when members of the FSA or third parties suspect a violation of the FSA Code, they can file complaints directly with the respective Arbitration Board. In 2017, **no such complaints** were lodged against our company.

In addition to external reporting options, we have also established a SpeakUp Line that allows our employees to anonymously report potential compliance violations. If our marketing or advertising rules of conduct are violated, we have a committee in place to take immediate countermeasures. Appropriate corrective action is taken to deal with violations as required.

We have not identified any significant cases of non-compliance regarding regulations and voluntary codes.

### Regular employee training

Employees responsible for our pharmaceutical advertising receive regular training on current guidelines. This particularly applies to individuals working in sales, marketing and drug registration. These seminars are conducted locally in a classroom setting, but are also offered online and as e-learning courses. In 2017 for instance, more than 1,100 employees took part in the training course on the "Review and Approval of Promotional Materials and Other External Communications". Additionally, the **employees in charge** can also access our compliance guidelines on the marketing and promotion of pharmaceuticals via our Intranet.

#### **Direct marketing only in certain countries**

Direct-to-consumer (DTC) advertising for prescription drugs is allowed in some countries such as the United States. We only pursue **DTC campaigns** in these jurisdictions. Through direct advertising, we hope to increase people's awareness of certain diseases as well as available therapies, empowering consumers and patients to make informed decisions about their own treatment.

#### **Marketing chemicals**

We approach the marketing of our chemical products with the deepest sense of responsibility. For instance, we only supply our chemicals to commercial customers with proven expertise and furthermore provide them with detailed information on the safe handling and use of our products. We have an extensive safety and security network in place to prevent the **misuse of dual-use products**. This network features standardized export control guidelines for these products, which are monitored by our central Export Control & Customs Regulations unit, as well as by trade and export control officers at our local subsidiaries. If we suspect misuse, we terminate our business relationship with the respective customer. In 2017, too, there were attempts to obtain our products for illegal purposes. In questionable cases, we additionally engage the responsible authorities to prevent illegal use.

# **Bioethics**



### Part of the non-financial report

Bioethics are foundational in guiding how we use the rapidly advancing power of life sciences and technology responsibly and ethically to the ultimate benefit of society, humans, and other living beings. However, factors such as diverse cultural backgrounds have led to heated debates, with controversy surrounding certain bioethical issues arising from the explosive progress in science and particularly molecular biology. In light of this situation, we believe it necessary to clearly state our position on these issues.

### Our approach to ethical business conduct

In the course of our activities, we encounter various bioethical issues, including stem cell use, animal testing, the use of genetically modified microorganisms, the potential impact of new genome editing techniques such as CRISPR/Cas, and our own clinical research. We are strongly committed to conducting research in an ethical manner. In treating patients with our drugs and supplying academic researchers and the biopharma industry with our products, patient benefit and wellbeing are always of utmost importance. When faced with **controversial topics**, we carefully evaluate all relevant positions to ensure we make informed decisions in line with the highest ethical standards.

#### How we assess bioethical issues

Our Bioethics Advisory Panel (MBAP) of Merck KGaA, Darmstadt, Germany convenes once a year and also provides support when urgent bioethical issues arise. Co-chaired by our Global Chief Medical Officer (CMO) and the head of our Global Health Institute, the MBAP provides clear guidance on bioethical questions, which we take as a basis for our entrepreneurial conduct. For the benefit of our employees, we publish summaries from MBAP meetings on our Intranet.

In 2017, we adapted the organizational structure of the MBAP to reflect the current requirements of bioethical issues so that it now advises on bioethical questions pertaining to all three of our business sectors. Moreover, by appointing external experts from Africa and Asia to the panel, we have also integrated the views of these regions more strongly in bioethical discussions. Our Dedicated Guidance Panels for Genome Editing and Stem Cell topics are also now operating under the overarching MBAP. These panels are responsible in particular for the operational implementation of our positions and are empowered to make decisions regarding specific questions on individual projects. Formed in 2011, the Stem Cell Research Oversight Committee (SCROC) verifies in advance all internal research proposals employing human stem cells, compliance with our ethical guidelines,

and legal requirements pertaining to stem cell research. This also includes collaboration with external partners. The SCROC works under the quidance of the MBAP.

## Our commitment: Identifying issues early on

As a global company, it is crucial for us to promptly identify and address new developments concerning bioethical issues in order to define our own stance. Although we align all our business activities with international and national legislation, many bioethical discussions raise questions that far exceed the current purview of legislators, which is why we also seek the advice of external experts.

#### **Bioethics Advisory Panel discussions**

In 2017, in addition to organizational changes, the MBAP discussed the establishment of our new Global Health Institute, as well as fertility research (p. 62), stem cell research (p. 62) and genome editing (p. 62). We have submitted the panel's advice and scientific recommendations for publication in a peer-reviewed journal.

Our Global Health Institute aims to improve access to healthcare, particularly in developing countries. Its focus areas are addressing the unmet needs of women and children, as well as infectious diseases (p. 41) and antimicrobial resistance. The panel has suggested developing a guideline for the Global Health Institute that would define aspects such as collaboration with partner organizations and research priori-

### **Biotechnology and genetic engineering**

We utilize genetically modified organisms (GMOs) in our research and development work and have been manufacturing biotech products using GMOs since the 1980s. Without this technology, **the major medical advances** of past years would not have been possible.

Our most important research hubs for medical biotechnology are Darmstadt, Boston (MA, USA), Beijing (China), and Tokyo (Japan). Major biotech production sites are located in Martillac (France), as well as Aubonne and Corsier-sur-Vevey, Switzerland, the latter of which is one of the largest biopharmaceutical production facilities in Europe.

Across our Group, we manufacture our biotech products according to the highest standards, and all our biotech activities are subject to strict statutory regulations worldwide. Compliance with these regulations is monitored by our biological safety officers. We continuously track regula-

tory changes pertaining to biotech products and adapt our processes accordingly, thus ensuring we adhere to all statutory requirements.

#### Using genome-editing applications

We are a leading supplier of technologies such as CRISPR/ Cas9, which can be used to target and modify specific genes, a process known as genome editing. CRISPR/Cas9 opens up new possibilities in genetic engineering research that could bring about major advances in the treatment of serious diseases or in "green genetic engineering", the use of genome editing techniques in plant cultivation. Statutes in different countries allow for a varying degree of latitude in applying this technique, which is why in 2017 the MBAP once more thoroughly discussed the current possibilities and ethical boundaries of genome editing systems. The results of this discourse have been incorporated into our new Genome Editing Technology Principle, which took effect at the end of October 2017. This principle provides our employees with background information and explains our current stance on such technology. It thus defines a mandatory ethical and operational framework - firstly for us as a supplier of custom targeted nucleases and genetically modified cell lines, and secondly as a user of genome editing technologies for scientific research.

#### Stem cell research

At present, we neither participate in clinical programs that utilize human embryonic stem cells or cloned **human cells** for the treatment of diseases, nor do we pursue such approaches ourselves. However, we do make use of stem cells in our research. In addition, we offer our customers several select stem cell lines. Our updated Stem Cells Principle, which was discussed by the Stem Cell Research Oversight Committee in 2017 and took effect in October 2017, ensures compliance with our ethical approach. The panel further recommended a new Informed Consent form for the use of induced pluripotent stem cells (iPSCs), which are identical to embryonic cells and can generate every type of cell in the human body.

### **Fertility research**

Because we develop treatments for infertility and seek to improve the success rate of in vitro fertilization, we are frequently confronted with various bioethical issues relating to such treatments. For instance, may embryos resulting from artificial insemination be screened for genetic disorders and then selected on this basis? In such questions, the German Embryo Protection Act is our legislative point of reference. Developed based on guidance from the MBAP, our new Fertility Principle came into force at the end of October 2017. Further discussion topics on the MBAP's 2017 agenda included various issues pertaining to **medical technology and products for fertility research**. We have the support of the panel in establishing a data pool of clinical evidence regarding fertility technologies.

### **Biosampling and biobanking**

Biological samples obtained from patients within clinical studies are indispensable to the development of new precision treatments and advanced diagnostic methods. We handle these samples in a responsible and ethical manner, in compliance with all regulatory requirements, and according to the consent given by patients for the use of their samples.

When conducting clinical studies in which biological samples are collected, we inform study participants upfront about the purposes for which we use their samples. On this basis **participants may consent to the use of their specimens**, thereby enabling us to learn more about the study drug, the disease, or other medical questions. Participants can withdraw their consent at any time.

In addition, study participants are given the opportunity to authorize the use of their biosamples for further medical research beyond the clinical study. This way they help to address future scientific questions and ultimately support medical progress. In 2017 we implemented a policy and a standard operating procedure defining the principles and processes of human biosample management during and after clinical studies.

Biological samples, including tissue samples and body fluids, are permanently stored in biobanks together with the corresponding encrypted patient and specimen data. While these are extremely important to our research, their storage and use for research purposes requires us to adhere to stringent ethical standards. In 2017 we implemented new rules governing biobank operation and the use of stored samples.

#### **Clinical studies**

We discover and develop **innovative medicines** that meet patient needs. In doing so, we adhere to all relevant statutory and regulatory requirements, as well as scientific and ethical standards. For clinical studies, these standards particularly include the Declaration of Helsinki, in which the World Medical Association has formulated ethical principles for medical research involving human subjects, and the Good Clinical Practice (GCP) of the International Council for Harmonisation (ICH). More details can be found under Clinical studies (p. 63).

#### Off-label use

We endeavor to **drive scientific and medical progress**, often doing so in close collaboration with medical professionals. We regularly receive inquiries about the off-label use of our products, i.e. indications for which the drug was not originally approved. While each medicine is authorized for specific indications, cases do arise in which a physician wishes to prescribe a drug to treat a disease for which it is not approved. Such applications can benefit patients. However, to use a drug in this way, solid evidence must

exist showing that it can be effective in the treatment of the specific disease.

Our principles for disseminating information regarding the off-label use of our products are set out in corresponding globally applicable policies. In particular, we only market our medicines within the scope of the drug's marketing approval. We never share information on off-label use for commercial

ends and provide such information to healthcare professionals only for medical purposes and only upon direct, unsolicited request. The information must be backed by scientific evidence and factually balanced. Our employees are not permitted to make any sort of treatment recommendations for individual patients.

# clinical studies



#### Part of the non-financial report

Our company develops medicines that help people with serious diseases. Before obtaining regulatory approval, we conduct clinical studies with patients and, if necessary, also with healthy subjects to test the safety and efficacy of these products. These trials generally run for multiple years. Prior to doing so, extensive preclinical testing must first be performed to demonstrate that the drug poses no unacceptable risks. This preclinical test phase typically includes procedures such as animal testing. We only test medicines in patients if the compounds show great therapeutic promise and have a positive benefit-risk ratio.

# Our contribution to safe and transparent clinical studies

We conduct high-caliber clinical research that always complies with applicable laws and regulations. When performing clinical studies, we adhere to the highest **ethical and scientific standards** worldwide.

We only conduct clinical studies to investigate issues that are relevant to patients, healthcare professionals or society as a whole. In addition to this prerequisite, a sound, established scientific methodology must be available to investigate these scientific or medical questions. We only enroll the number of participants required to answer the respective questions.

Protecting the safety, wellbeing, dignity, and rights of the patients and healthy volunteers participating in our clinical studies is of utmost importance to us. We do not intentionally expose study subjects to undue risk or irreversible harm. Personal data privacy is extremely important to us, and the confidentiality of all data and information collected is ensured in compliance with statutory regulations.

#### Clinical studies in developing countries

We conduct all our clinical studies in accordance with local laws and regulations. In addition, we also adhere to all relevant international scientific and ethical standards at all times. We are intentionally expanding our medicinal product development to more diverse markets in order to address the healthcare needs in various regions and countries and to support the development of their healthcare systems.

In performing clinical studies in developing countries, where there is usually a lower level of healthcare and less developed healthcare infrastructure, we adhere to the same principles that apply when conducting such trials in industrialized countries. When we perform studies in developing countries, we also:

- only do so in an environment in which the principles of Good Clinical Practice can be upheld; particularly in those places where ethics committees and well-trained Clinical Investigators are present.
- only investigate diseases and innovative medicines that are relevant to the local population.
- only conduct clinical studies in countries where we expect that the drug tested will be submitted for marketing authorization and made available to patients after we have proved its efficacy and safety.
- assure that no subject enrolling in a clinical study is discriminated against on the basis of ethnic origin, gender or socio-economic status.

### How we govern clinical studies

Overall responsibility for pharmaceutical development as well as the related governance process is borne by our head of Global Research and Development, who, hand-in-hand with the Chief Marketing & Strategy Officer, co-chairs the Development Operations Committee (DOC). This top-ranking Biopharma committee ensures a cross-functional approach to the governance of drug development.

Under the umbrella of the DOC, two further committees oversee our clinical studies. The Integrated Clinical Study Committee (ICSC) is responsible for studies in pharmaceu-

ticals that are under clinical development, while the Global Medical Affairs Decision Board is responsible for studies involving approved medicines. Both bodies consist of medical scientific **experts and executives with long-standing experience** in clinical research. Each committee meets regularly to conduct a comprehensive review of the proposed clinical study concepts to verify that our studies are scientifically sound, have a legitimate scientific purpose, and are performed according to the latest standards and best practices. Our therapeutic area review boards support the ICSC by conducting thorough scientific assessments of new drug/ pharmaceutical study concepts.

Before administering a new drug to human subjects, there must be sufficient evidence that it offers a potential therapeutic benefit, is sufficiently safe for use in humans, and has a positive benefit-risk profile. Only after diligently **conducting extensive preclinical testing** do we take the critical step of a first-in-human clinical trial. This important step of exposing humans to an investigational drug is governed by the Human Exposure Group chaired by our Global Chief Medical Officer.

Potential risks for subjects are carefully and continuously analyzed before and during the course of our clinical studies. Our Medical Safety and Ethics Board (MSEB) oversees the safety of subjects participating in our clinical studies and, as necessary, reviews the benefit-risk profiles of investigational drugs. You can find further information on the MSEB under Patient safety (p. 53).

# Our commitment: International guidelines and agreements

Our Clinical Research policy provides the framework for conducting clinical studies and ensures that we adhere to all legal, ethical and scientific standards. In addition to the relevant national laws and regulations, these standards also include:

- The Good Clinical Practice (GCP) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- The Declaration of Helsinki published by the World Medical Association
- The Belmont Report from the Office for Human Research Protections, USA
- Good Pharmacovigilance/Laboratory/Manufacturing/ Distribution Practices (GVP/GLP/GMP/GDP)
- The International Ethical Guidelines for Health-related Research Involving Humans published by the Council for International Organizations of Medical Sciences (CIOMS)

- The "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" and the "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature", published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japan Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA)
- The "Principles for Responsible Clinical Trial Data Sharing" published by EFPIA and PhRMA

#### Regular supervision of clinical studies

Our clinical study procedures are regularly inspected by health authorities to ensure compliance with the applicable laws and guidelines. We also conduct our own internal quality assurance audits. In both cases, we respond immediately to any issues found by defining and implementing corrective and preventive actions to improve our processes accordingly.

### **Conducting clinical studies responsibly**

Prior to enrolling subjects, every clinical trial must first be assessed and approved by a qualified independent ethics committee. Furthermore, all regulatory authorizations required in the respective country must be obtained. In accordance with Good Clinical Practice guidelines (ICH-GCP), all subjects must give their explicit informed consent before enrolling in a clinical study. Subjects are fully informed about all aspects of the clinical trial in a language that they understand; this includes the potential risks and benefits from participating in the study. All participants are given ample time and opportunity to inquire about details before deciding whether to participate. All questions are answered by the clinical investigator or another qualified healthcare professional familiar with the study. As far as possible, non-interventional (observational) studies are also assessed by an ethics committee. The subjects are further provided with thorough information.

Every study follows precisely defined procedures to ensure that studies are conducted to the **highest quality standards** in line with good working practices for the development and manufacture of drugs (GxP), the ethical principles of the Declaration of Helsinki, and other international guidelines and regulations. This approach ensures in particular that studies are designed, conducted, recorded, and reported in line with all applicable requirements. In 2017, no significant issues regarding these clinical study procedures were raised by third parties or regulatory agencies.

We continuously collect and communicate safety data for our investigational drugs and promptly provide clinical investigators with important new findings relevant to the safety of subjects. In this way, we ensure the safe use of our phar-

maceuticals. Potential adverse effects and risks are taken into consideration in an effort to evaluate the benefit-risk ratio of our products and manage risk. Product information, including the Investigator's Brochure and Subject Information, is updated accordingly. You can find more information under Patient safety (p. 53).

### Conducting clinical trials in vulnerable populations

The implementation of clinical studies in vulnerable populations requires **special attention and care** in order to comply with the highest ethical and scientific standards. When a drug is intended for use in vulnerable populations, such as children or people with mental disabilities, in some cases clinical studies must be conducted in these populations. Their wellbeing is our utmost priority as, in general, these groups are relatively (or absolutely) incapable of protecting their own interests. We therefore only conduct studies with patients from vulnerable populations if there is no other way to achieve conclusive results. When performing such studies, especially when informing study participants and obtaining their consent, we comply strictly with all statutory regulations.

One example of a trial involving vulnerable populations is our praziquantel study in Africa to develop a formulation for children under the age of six. Praziquantel tablets are only suitable for adults and children older than six. Due to a lack of clinical data and no suitable pediatric formula**tion** of praziquantel, pre-school aged children must currently go untreated. Within a public-private partnership, we are working to develop, register and provide access to a pediatric formulation of praziquantel that is suitable for children under the age of six. To this end, a Phase II study is currently ongoing in Côte d'Ivoire, and Phase I trials have been completed in South Africa and Tanzania. This clinical program was designed in line with U.S. Food and Drug Administration recommendations for pediatric development. It was planned and implemented with the support of regulatory authorities and a panel of international experts, including clinicians from endemic countries. Further details can be found under Infectious diseases (p. 41).

### Teaming up to get results

To provide a broad, in-depth basis for the development of new medicines, we frequently conduct clinical studies in collaboration with external partners in academia and industry, as well as with medical scientific advisory boards, service providers and vendors. We expect all our partners to abide by the same set of high standards when conducting clinical research. This applies especially to **contract research organizations** (CROs) performing studies on our behalf.

Our CROs, partners and suppliers are subjected to regular audits within our quality assurance strategy to verify their compliance with Good Working Practices (GxP, for example ICH GCP), other international guidelines and regulations, and

the Declaration of Helsinki. This also applies to study centers (for example hospitals) involved in our clinical studies. In 2017, these audits did not reveal significant non-compliance with the above-mentioned standards.

# Close dialogue with patients and advocacy groups

We want to ensure that **patients' voices** and needs are adequately taken into consideration when planning and carrying out clinical studies. To this end, we established Patient Advisory Boards (PABs) in 2014. Our Patient Advisory Boards Charter describes the process on how to involve the Patient Advocacy Groups in our clinical research. During Advisory Board meetings, caregivers and representatives from patient advocacy groups are invited to provide feedback on clinical study matters. This advice and wealth of valuable insight applies to both the design of the clinical trial as well as its operational implementation. Cumulatively, we use this information to render clinical development and clinical studies more patient centric.

Furthermore, we are involved in the European Patients' Academy on Therapeutic Innovation (EUPATI), a public-private partnership within the Innovative Medicines Initiative (IMI) that initially ran from 2012 to 2017. In 2017, we extended our participation in EUPATI for an additional three years. EUPATI is a pan-European project led by the European Patients Forum (EPF); it features partners from patient advocacy groups, universities and not-for-profit organizations, along with a number of pharmaceutical companies. This project focuses on helping patients better understand pharmaceutical research and development while also offering them a way to incorporate their needs into the development of clinical studies. EUPATI furthermore aims to improve the availability of objective and reliable information for the public.

### Responsible data sharing

We support professional circles in advancing **medical and scientific knowledge**, thereby allowing for informed healthcare decisions for the benefit of patients. To this end, upon request we provide qualified researchers with study protocols, anonymized patient data, study data, and clinical study reports. In doing so, we share data and information in a manner that is consistent with the following joint Principles for Responsible Clinical Trial Data Sharing of the EFPIA and PhRMA:

- Safeguarding the privacy of patients
- Respecting the integrity of national regulatory systems
- Maintaining incentives for investment in biomedical research

#### Disclosure of clinical studies and publication of results

We are obliged to disclose information from our clinical studies, which we do publicly in a complete, accurate, balanced, transparent, and timely manner, as laid out in our Clinical Trial Disclosure Policy. Our clinical study designs and results are made public in the international Clinical-Trials.gov database run by the U.S. National Institutes of Health (NIH), which can also be accessed via the World Health Organization's International Clinical Trials Registry Platform (ICTRP). Furthermore, in accordance with EU regulations, we publish results from our clinical studies in the European Union Drug Regulating Authorities Clinical Trials (EudraCT) database, which is run by the European Medicines Agency (EMA). If required by local laws and regulations, we publish study results on other publicly accessible platforms. In 2017 we started providing our study participants with Lay Patient Summaries, which explain clinical study results in plain language.

We make sure that results from our clinical studies are published in medical journals in line with applicable laws and industry codes. In doing so, we adhere in particular to the current version of the Good Publication Practice (GPP3) and follow the recommendations of the International Committee of Medical Journal Editors (ICMJE). Our Medical Publications Policy ensures compliance with all relevant standards. Furthermore, we have defined standard procedures for scientific publications on our products.

# Immuno-oncology: Major clinical research milestones

Immuno-oncology investigates the extent to which the body's immune system can be activated or strengthened to mount an immune response against cancer. As part of a strategic alliance with the U.S. pharmaceutical company Pfizer, we are studying **avelumab**, an investigational anti-PD-L1 (programmed cell death ligand 1) antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany, as a potential treatment for a broad spectrum of tumor types. Under this collaboration, in 2015 we launched JAVELIN, our comprehensive international clinical study program in which we are investigating the potential therapeutic benefit of avelumab in multiple tumor types. By the end of 2017, more than 7,200 patients had been evaluated within this program.

In 2017, avelumab was granted its first marketing authorization in several countries (including the United States and Japan) and the European Union for treatment in patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive form of skin cancer. Subsequently, avelumab was granted regulatory approval by the U.S. Federal Drug Administration for the treatment of patients with locally advanced or metastatic urothelial carcinoma (a malignant tumor of the urothelium that lines the urinary tract) that had progressed following platinum-containing chemotherapy. Meanwhile, avelumab continues to be evaluated in several ongoing registrational Phase III studies across multiple different tumor types, including lung, gastric, ovarian, renal cell, and head and neck cancers.

### **Enabling early access to new medicines**

Not all patients can take part in a clinical study and so must wait for a new pharmaceutical product to be approved. Through our Early Access Program, we are, under specific circumstances, enabling patients to gain early access to new, potentially life-saving medicines. The offer is aimed at people with serious conditions who have already used all available therapies without success. It allows them to obtain medicines that have already been clinically tested but not yet obtained marketing approval. Here too we meet stringent statutory, ethical and scientific standards. By performing a thorough assessment of all available data, we ensure that the potential benefits outweigh the potential risks for patients. We have published a position paper on the Early Access Program on our website.

### Coming to terms with the past

In the 1950s and 1960s, drugs from various manufacturers were tested on children living in institutions in Germany. The majority of such clinical studies were performed in collaboration with (university) hospitals and general practitioners. By making files in our historical archives at our global headquarters in Darmstadt available, we are now supporting efforts to understand and come to terms with this episode in the history of science. As part of these efforts, we opened our archives to researchers in 2015. It is important that the findings and completion of their work be awaited before making a final assessment of this complex issue. We guarantee full transparency and will do everything necessary to help the affected institutions come to terms with the past.

# animal welfare

From both an ethical and scientific perspective, animal research is indispensable and is furthermore mandated by law. Through animal studies, we test both the safety of our chemical and medicinal products, and the efficacy of our pharmaceuticals. We enforce stringent animal welfare standards that exceed applicable laws and extend these high expectations to our suppliers, contract research organizations and other partners. We conduct animal testing within our Healthcare business sector as part of the official drug approval process. However, animal welfare is also a prominent issue for our Life Science business sector, which keeps laboratory animals for the production of antibodies, for instance. In addition, our subsidiary Bioreliance conducts animal testing as part of contract research work for third parties.

### Our approach to animal welfare

Our Group-wide Use, Care and Welfare of Laboratory Animals Policy sets forth our commitment to consistently uphold the highest ethical standards regarding the housing, care and feeding of laboratory animals. When conducting animal research, we pursue tried and tested methods that ensure high-quality results and furthermore strive to replace animal testing with alternative methods wherever possible and permissible by law. We therefore subscribe to the internationally recognized **3Rs for animal-based research**:

- Reduction using the minimum number of required animals
- Refinement minimizing distress or discomfort before, during and after testing
- Replacement replacing animal studies with non-animal systems

We promote the 3Rs outside our company as well. Under the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium), for instance, we have joined forces with other companies to support the Global 3Rs Awards Program. In partnership with the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International), this initiative recognizes innovative contributions to the 3Rs of animal research to advance ethical science in academia and industry.

## How we ensure animal welfare

As head of Corporate Animal Science and Welfare (EQ-A), our Chief Animal Welfare Officer is responsible for creating uniform animal welfare standards. This individual also initiates EQ-A audits, sometimes performing these himself within

our company or on our partners. Moreover, all our animal science and welfare experts regularly interact through our **global laboratory animal science network**. A platform for sharing best practices and lessons learned, this network supports the animal welfare units at our sites along with all projects and processes related to animal science and welfare.

Our Group Animal Welfare Council convenes twice a year. Comprising representatives from all our business sectors, this council discusses relevant developments and makes decisions regarding our Animal Welfare Strategy. In 2017, our efforts focused on creating various guidelines and certifying contract research organizations, other partners and suppliers. To accomplish this, the council is developing a risk-based approach that will also apply to the procurement of products of animal origin.

In most cases, our sites are subject to additional national regulations. In order to assess the quality of animal husbandry practices and ensure compliance with our standards as well as all statutory requirements, we appoint animal welfare officers and establish animal welfare councils across our Group, even where not required by law. In 2017, for instance, we appointed an animal welfare officer for our Life Science business, who is greatly involved in conducting audits and identifying potential animal welfare risks in our supply chain.

#### Work with committees and associations

As part of our efforts to improve animal welfare, we are involved in several organizations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), the German Association of Research-based Pharmaceutical Companies (vfa), and Interpharma, a federation of research-based pharmaceutical companies in Switzerland. Our Chief Animal Welfare Officer has an active role in various committees to advocate our position on animal welfare. Moreover, he represents EFPIA on the AAALAC International Board of Trustees, where he ensures adherence to European standards. At the end of 2016, he was appointed to the Executive Committee of AAALAC International for a term of three years. In addition to these positions, he is a member of the German Federal Animal Welfare Commission.

# Our commitment: Group-wide methodology and standards

Through our Group-wide Use, Care and Welfare of Laboratory Animals Policy, we have made a commitment to global animal welfare principles and the highest possible ethical standards in animal research. In 2017, we updated this policy to establish a basis for the work of our Group Animal Welfare Council. The policy further sets out principles on the

housing, care and feeding of laboratory animals. We strive to provide our animals with high-quality living conditions and consistently seek ways to make improvements. This ethos applies equally to the contract animal research services we offer third parties. In addition to our policy, our Group-wide Animal Science and Welfare manual describes the requirements for implementing, maintaining and improving animal welfare practices. Moreover, in 2017 we created a new guideline entitled Housing and Husbandry Practices for Common Laboratory Animals, which applies to our external partners as well. We also drafted a Standard on Vendor Qualification, which describes our criteria for evaluating the quality of our suppliers' and partners' animal welfare practices. This standard took effect in March 2018.

#### Legal requirements

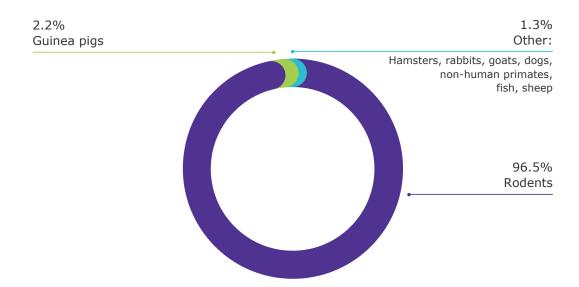
Animal research is only permitted if there are no recognized alternative methods available. In many fields, however, animal studies are indispensable and legally mandated by ICH guidelines or REACH, which place priority on the safety

of humans. Laws and regulations govern all aspects of animal research, such as the housing conditions of laboratory animals, the conduct and approval of studies, and the reliability and expertise of all involved individuals.

# The majority of laboratory animals are rodents

Approximately 97% of the laboratory animals we use are rodents (mice and rats). Other animal species are only used if specified by statutory regulations or if deemed necessary for scientific reasons. For example, regulatory agencies sometimes require investigational drugs to also be safety tested on a non-rodent species such as monkeys, dogs or pigs. Guidelines such as REACH also require testing on non-rodents under certain circumstances. This allows researchers to identify potential **adverse effects with the necessary accuracy** and include them in the risk assessment (p. 53) of a substance. In performing tests on non-rodents, we must meet additional requirements pertaining to animal care and study design.

#### **Animal types**



### **Auditing our research facilities**

We perform regular audits on our animal research facilities to ensure adherence to our animal welfare standards. In 2017, for instance, our Corporate Animal Science and Welfare unit conducted two internal audits at our Healthcare sites in Billerica, MA (USA) and Ivrea (Italy). We have initiated the relevant corrective measures where necessary. No critical shortcomings were identified during these audits.

It goes without saying that we adhere to the **highest inter-national animal welfare standards** at all times. All our Healthcare laboratory animal facilities have been certified to the standards of the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). Furthermore, one of our Life Science laboratory animal facilities has also received AAALAC accreditation.

### Collaborating with partners and suppliers

We perform the majority of animal studies ourselves and for the most part procure our animals from specialized breeders or, in very few cases, from our own breeding colony. Sometimes, however, we also hire contract research organi**zations** (CROs) to conduct animal research on our behalf. Furthermore, we work with both the private sector and academic institutions. When collaborating with such organizations, we expect them to adhere to the same high standards as we do, as set out in our Use, Care and Welfare of Laboratory Animals Policy. We verify compliance with this policy through a risk-based qualification procedure and, where necessary, also conduct audits, generally every three years. In order to harmonize animal welfare efforts within our company, in 2017 we created a Group-wide standard entitled Housing and Husbandry Practices for Common Laboratory Animals, which also applies to our partners and vendors.

#### Regularly auditing our partners

We perform regular audits on our animal breeders and contract research organizations to ensure compliance with our animal welfare standards. As part of our work with Interpharma, we have developed a cross-company audit concept that concentrates on those partners that are relevant to the maximum number of companies involved. In 2017, two audits were conducted in Europe. The results are shared among Interpharma member companies and treated confidentially. If critical defects are not corrected, we reserve the right to terminate our collaboration with the respective vendors.

#### Comprehensive employee training

We regularly train all employees who work with laboratory animals, thereby ensuring that animal studies are conducted according to the latest scientific standards and that animals receive the best care possible. The nature and scope of this training is based on national and international legislation, as well as local requirements. The respective regulatory authorities monitor our activities to ensure compliance. In addition to this training, our employees regularly participate in **external continuing education programs** such as accredited laboratory animal science courses offered by the Federation of European Laboratory Animal Science Associations, the American Association for Laboratory Animal Science, the Laboratory Animal Science Association, and the Interessengemeinschaft Tierpfleger (Community of Animal Caregivers).

### How we implement the 3Rs

To minimize the discomfort and distress to animals before, during and after testing (refinement), in 2017 we introduced our own innovative group housing concept for rabbits and rats at one of our sites. By keeping animals together in groups, they are generally healthier and less stressed.

Moreover, we actively support the development of alternative testing methods and their official recognition at an international level. There is a serious need for action here because animal research can only be truly reduced if a new methodology is internationally accepted. Without this **global recognition**, both animal studies and alternative testing have to be conducted in parallel when developing pharmaceuticals intended for worldwide distribution.

To help rectify this situation, we support the European Partnership for Alternative Approaches to Animal Testing (EPAA). This collaboration between the European Commission, European trade associations and companies from various sectors seeks to pool knowledge and resources to accelerate the development of alternative approaches to animal use in regulatory testing. Through our membership in the German Association of Research-based Pharmaceutical Companies (vfa), we also support the set Foundation, which seeks to reduce and replace animal testing. To achieve this objective, the foundation funds projects that conduct research into alternative methods. Our Chief Animal Welfare Officer is currently Vice Chairman of the set Board of Trustees. Our own scientists are also working on developing alternative methods and have received numerous accolades for their efforts:

- 2014: The Hessian Animal Welfare Research Prize for Alternative Methods to Replace or Reduce Animal Testing
- 2010: The IUTox Bo Holmstedt Scientists Award for Alternative Test Strategies according to the 3Rs
- 2009: The Eurotox Gerhard Zbinden Young Scientists Award
- 2008: The Eurotox Bo Holmstedt Young Scientists Award for Alternative Test Strategies according to the 3Rs
- 2007: The Hessian Animal Welfare Research Prize for Alternative Methods to Replace or Reduce Animal Testing
- 2006: The German Animal Welfare Research Prize awarded by the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) for alternative methods to replace or reduce animal studies
- 2005: The Eurotox Gerhard Zbinden Young Scientists Award

# interactions with health systems



Part of the non-financial report

We want all patients to receive the best possible medical treatment. To achieve this, it is essential that research institutes, physicians, patient advocacy groups, and other key actors in health systems have access to detailed and upto-date information on diseases and treatments. We help facilitate this access by sponsoring independent initiatives and medical capacity advancement programs, as well as by donating money and supplies. In addition, we promote outstanding research projects. In all our endeavors, transparency is our number one priority.

# Our approach to interacting with health systems

We support health systems by providing information, making monetary contributions, and donating supplies to professional medical associations, university clinics and other hospitals, as well as to patient advocacy groups. These contributions are expressly not intended to influence decisions regarding treatment, prescriptions or purchasing. Consequently, we have committed ourselves to providing complete transparency. We prepare detailed reports on our donations that align with industry-wide codes and with statutory requirements such as those governing data protection. Every year we disclose all transfers of value to healthcare professionals, healthcare organizations and patient organizations. We also report on transfers of value made by our R&D activities in every country where our company operates within the region covered by the European Federation of Pharmaceutical Industries and Association (EFPIA). Furthermore, we fulfill the relevant voluntary commitments of our industry.

# How we're ensuring transparency and compliance at an organizational level

In all interactions with health systems, Group Compliance establishes internal policies and related **review processes** to ensure adherence to statutory requirements and transparency obligations. Group Compliance also provides the necessary training and communication to all employees involved. Furthermore, the Global Transparency Operations team of Group Compliance serves as a center of excellence, providing support for transparency reporting and our end-to-end management process for interactions with healthcare professionals, healthcare organizations, patients, and patient advocacy groups.

Our Internal Audits unit monitors the implementation of these initiatives locally. Before entering into a partnership or collaboration with third parties, we also involve our Business Partner Risk Management unit in the respective selection process. The Compliance (p. 11) chapter of this report provides more details on how we implement legal requirements across the Group.

# Our commitment: Group-wide guidelines and industry standards

Our "Interactions with Patients, Patient Opinion Leaders and Patient Organizations" policy provides a comprehensive framework for our prescription medicines business. For our over-the-counter product business we have a comparable policy that was revised in 2017 and is now in effect throughout the Group. Supplementing this, our guideline "Good Practice and Process Guidance: Engagement with Patients, Patient Opinion Leaders and Patient Organizations" provides additional guidance for our interactions with patients and patient advocacy groups. It furthermore ensures that patient wellbeing is always our top priority. Through this policy, the supplementary guideline and specific local policies, we provide a robust compliance guidance structure to support our employees in conducting compliant interactions with patients, patient opinion leaders and patient organizations.

In all transfers of value, we comply with the principles set forth by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in its "Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations". Furthermore, our efforts are aligned with the Code of Conduct of the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA).

In addition to complying with these codes, we adhere to all statutory transparency requirements worldwide, such as the stipulations of the Sunshine Act in the United States and the Loi Bertrand in France. Specific national laws and requirements are implemented by our local units. In doing so, we consistently adhere to the applicable data privacy legislation and make a best effort to ensure our partners also comply fully.

Through mandatory online training and classroom seminars, the relevant employees are kept up-to-date on our interactions guideline and policy, as well as on important changes to reporting requirements for transfers of value.

#### **Transparent reporting**

In 2017, we continued to publish all financial and non-financial contributions made to European medical professionals

and organizations in the health industry. As required by the EFPIA Disclosure Code, this information includes the names of individual recipients and their addresses, as well as the purpose and amount of the transfer. Before publishing, we secured all necessary informed consent forms as required by applicable data privacy regulations. In 2017, as part of the EFPIA transparency initiative, new laws were adopted in several European countries including Greece, Spain, Belgium, and Turkey. These changes have already been incorporated into our 2017 reporting processes. Other than disclosing monetary transfer of value on an individual level, we also published our overall spending on our research & development activities as required by the EFPIA Disclosure Code.

### Partnering with patient advocacy groups

Patient advocacy groups support patients, family members and caregivers, providing them with information on disease management. Just like these organizations, our company has also made it our goal to **improve patient quality of life**, which is why we endeavor to support their vitally important work. We provide the highest level of transparency on our donations by publishing the details of contributions to European patient organizations. Updated annually, the 2017 report includes all donation amounts, recipients and the purpose of each donation, thus fulfilling our obligation as a member of EFPIA.

# Transparently promoting research and education

We sponsor research and continuing medical education around the world in order to contribute to medical advances that will benefit patients. Through our Grants for Innovation, for example, we support research projects in fertility, multiple sclerosis, oncology, and growth disorders. Through our Global Medical Education unit we also provide grants to continuing medical education providers, enabling them to develop and deliver advanced medical training to scientists, physicians, nurses, pharmacists, and other healthcare professionals. We take an entirely transparent approach to this collaboration as well. All direct and indirect financial aid aligns with the principles of EFPIA. According to our internal "Medical Education Funding Policy", all requests for medical education funding are channeled through an evaluation process under the responsibility of our R&D and Compliance functions. This process ensures that all funds for medical education programs are granted according to established internal guidelines and criteria while also complying with all applicable laws and industry codes.

In 2017, we partnered with other experts belonging to a sub-group of the International Pharmaceutical Alliance for Continuing Medical Education (iPACME) to write a joint position paper setting out suggestions for improving and harmonizing quality standards for continuing medical education (CME) in Europe. We explicitly invited our stakeholders to take part in this discussion. The position paper was published in July 2017 in the Journal of European CME and is supported by the European CME Forum and the Global Alliance for Medical Education.

# **Employees**



- Attractive employer
- Diversity
- Health and safety

- Employee engagement
- Good leadership

# attractive employer



#### Part of the non-financial report

We recognize that our employees are crucial to our success. To secure our future viability, we seek to attract people who have the potential to take on greater future roles. Demographic change is heating up the competition to hire top talent, especially in Europe, the United States and parts of Asia. By contrast, in several emerging countries, filling leadership positions is one of the greatest challenges.

Owing to the ever-faster pace of technological progress, the bar on professional requirements is constantly being raised. In response to this situation, we constantly work to advance our employees' career development and help them build their skills. In doing so, we as an employer must also meet the growing expectations for work-life balance.

# Our approach to recruiting and retaining talent

Our aim is to attract **qualified employees** and retain them over the long term. In our quest to offer our people a career that is both professionally and personally enriching, we are committed to facilitating professional paths that align with their individual ambitions, skills and talents. Especially when it comes to new challenges and development opportunities, we encourage them to take on responsibility.

In 2017, we introduced a new Group-wide job architecture called Expanding Horizons that provides leaders with greater flexibility in making employee-related decisions while also empowering them with more responsibility. Through this initiative, we are promoting strategic objectives such as empowering our leaders, engaging our employees and creating multifaceted development opportunities for our talent. Expanding Horizons combines personnel development with other HR processes such as compensation and guidelines for organizational development. This initiative builds on the Global Role Framework, a catalog of positions and functions in which all employees have been remapped from Global Grades into Roles. The Expanding Horizons job architecture defines three fundamental career types - managers, experts and project managers - which all have equal opportunities. Those who wish to advance their careers and attain a top position within the company can also do so as an expert or project manager. The job architecture thus creates greater transparency for individual employees regarding their development opportunities and the requirements of their particular Role, providing a solid framework to effectively develop human resources.

In addition to implementing this new job architecture, we have made it our mission to discover high-potential individuals at an early stage in their career and develop their talents. Within our Succession Management Process, we work with leaders and our HR unit to systematically prepare candidates for leadership positions, allowing us to fill vacancies quickly and efficiently.

# How we structure our personnel management

All global HR expert and business partner roles are organized in one global structure, serving all businesses and functions. Our "Talent, Development & Recruiting", "Rewards", and "Engagement & Inclusion" expert units focus on strategies to advance and promote our employees, organization and culture, coordinating the implementation of the necessary measures. At our sites around the world, our HR staff implements these measures in collaboration with leaders from our business sectors. In doing so, they comply with global HR guidelines and requirements, which we monitor by means of internal audits that are conducted every two or three years.

In September 2017, Executive Board member Belén Garijo assumed responsibility for Group Human Resources, a function previously performed by Kai Beckmann. Our Chief HR Officer reports directly to Belén Garijo and is in charge of the various expert and business partnering HR activities. In 2017, HR Services were combined with other Group Function services into one Business Services unit. Executive Board member and Chief Financial Officer Marcus Kuhnert assumed responsibility for this Business Services unit.

#### Digital HR tools

To harmonize our HR processes around the world, in 2012 we introduced HR4You, an online platform accessible to all employees. It is used to manage all key HR functions, such as development and succession planning, recruitment, continuing education, and employee performance assessments. Moreover, it helps calculate compensation and bonus payments.

# **Our commitment: People Development Policy**

Our People Development Policy provides a Group-wide framework for employee development and succession planning and contains guidelines pertaining to our development opportunities, as well as roles and responsibilities. The corresponding processes are set out in the People Development process descriptions.

### Group-wide labor and social standards

Our company is dedicated to appropriate labor and social standards, working hard to uphold them. Our Code of Conduct is a compulsory set of rules for our company's entire workforce. All

employees receive a copy with their letter of offer. The Code of Conduct explains the principles for dealings with business associates, general partners, co-workers, and employees, as well as the communities in which we operate. Thus, it supports all employees in choosing the ethical path. Our Human Rights Charter supplements the Code of Conduct with global human rights principles such as the fundamental conventions of the International Labour Organization (ILO), which cover topics such as freedom of association, the right to organize, collective bargaining, forced labor, child labor, anti-discrimination, equal opportunity, equal pay, working hours, occupational health & safety, and the prevention of abuse and harassment. These principles describe our commitment to respecting fundamental labor standards and are reviewed during our internal audits to check that our local subsidiaries are complying with them.

In 2017, we furthermore decided to draft a Group-wide set of guidelines on adherence to additional ILO core labor standards. Our intention is to make global occupational and social standards an integral pillar of our organization.

# Providing feedback and supporting development

We regularly provide our employees feedback on their performance through our **Performance and Potential Management Process**, which ensures that, in addition to the feedback, a meeting is held once a year to evaluate their overall performance. This process is applicable to all employees Group-wide with a Role of 2 or higher, and additionally to all non-exempt staff employed by either Merck KGaA, Darmstadt, Germany or any other subsidiary based in Germany.

The process involves leaders and subordinates working together to define individual objectives and create a detailed **development plan** that reflects each employee's core tasks as well as current strategic priorities. In drafting the development plan, all employees have access to the Development Advisor. Building on our competencies (p. 84), this webbased tool provides a selection of development opportunities that employees can tailor to their own needs. Thanks to a 2017 upgrade to our electronic HR4You platform, employees can now create their development plan easier and faster.



of our people took part in the Performance and Potential Management Process in 2017, and 61% submitted a development plan.

Every three years, employees can additionally have their performance assessed by select colleagues and external

partners. This 360-degree feedback helps to identify personal strengths and advancement opportunities. Using a new feedback tool we launched in 2017, it's now easier for employees to receive and submit feedback.

#### Employee learning and education

Our **Group-wide advanced training and continuing education program** ensures that our employees develop the skills needed to help us realize our company strategy and continue down the path of success. Our employees can use our My Learning online tool to sign up for suitable activities such as seminars and online training courses.

In 2017, a total of 5,700 employees took part in our global classroom training. These courses are flexible, meaning that while the core curriculum is uniform around the world, there is still room for adjustments, for instance to reflect specific local change projects. As well as classroom training, more than 3,500 employees also signed up for global e-learning courses and more than 380 completed online language classes.

#### Performance-based pay

We endeavor to reward the performance of all our employees and maintain a competitive edge in attracting qualified professionals, which necessitates commensurate compensation. At our company, compensation is based on the requirements of each position and employee performance. In making compensation decisions, direct supervisors always consult with their respective superior. In addition to competitive remuneration, we offer attractive fringe and social benefits. Our benefits4me package, for instance, encompasses three pillars, namely company-funded benefits including our company pension, health & well-being, and services. To meet the multifaceted needs of our workforce worldwide, we offer a variety of benefit packages.

To ensure a **competitive compensation structure**, we regularly review our compensation policy based on data analyses and benchmarks. In doing so, we take internal factors and market requirements equally into account. In making adjustments to this policy, we involve key stakeholders such as employee representatives (p. 83) in the early stages of the process. The reward structures at Merck KGaA, Darmstadt, Germany are gender-neutral and based on defined criteria such as job requirements and performance. Our analyses on Group level show that there are no significant gender-based compensation inequities.

#### Attracting qualified university graduates

We endeavor to attract the top university graduates. As part of our efforts, for instance, we partner with the German online network "careerloft". Furthermore, we regularly attend job fairs to reach out to potential applicants, informing them about job opportunities and career tracks

within our company. In countries outside of Germany, particularly the United States and China, we likewise use career fairs as a way of making **personal contact with university graduates**.

In addition to recruitment, we also provide financial assistance to talented students. That's why we collaborate with organizations such as the German National Academic Foundation and the Foundation of German Business, and furthermore support the Deutschlandstipendium (German national scholarship program).

University graduates can apply for a position with our company directly or complete one of our trainee programs. Our trainees acquire international experience in various business sectors and functions, and take part in tailored continuing education offerings.

#### Sparking student and graduate interest

We employ trainees in units such as Inhouse Consulting, Finance and Production. In 2017, we launched trainee programs in Marketing, Sales, Human Resources, and Research & Development. All **trainee programs** named "GOglobal" provide graduates experience in various units, international assignments, tailored continuing education, mentoring, and coaching, while also offering participants a high level of visibility within the company. Although the programs are largely centered around Germany and the United States, we also employ trainees at our sites in Ireland and France. In 2017, the first two trainees in China started our vocational training program. In 2017, we employed 90 trainees.

Beyond trainee programs, we also offer internships to high school and university students. Through our **Keeping Ties to Students program**, we stay in touch with talented individuals who perform particularly well during their internship. Furthermore, every year we invite students from German, Austrian and Swiss universities to our company, where they learn about the various career tracks and job opportunities we offer. Going forward, we intend to step up contact with students.

#### The foundation: Vocational training

For us, **vocational training** is one of the most important ways to meet the current and future need for qualified professionals. In Germany, Austria and Switzerland, we offer numerous apprenticeship positions for various professions, as well as **dual vocational training programs**. We continuously invest in new technologies and integrate these into our vocational training. We also give young adults the opportunity to complete their vocational training on a part-time basis. If, after completing their apprenticeship, they wish to continue studying while working, we will cover up to 100% of the costs and also allow them to take special leave. Furthermore, apprentices can take part in community outreach projects.

# Impressive hiring rate and new dual vocational training programs

In 2017, 588 people were enrolled in vocational training programs at our sites in Germany, with 205 beginning their apprenticeship at our company. In total, we offer apprenticeships across 23 occupations, primarily in production, laboratory work and office administration. Furthermore, 18 young adults embarked on vocational training courses in the fields of business administration, business IT, process engineering (chemical engineering), and mechanical engineering. Apprentices in the Laboratory group begin their training as chemistry or biology lab technicians and, subject to suitability, may receive the opportunity to start a dual study program after six months. Since 2014, we have been offering permanent employment contracts to all apprentices and graduates of dual study programs working in occupations for which we have long-term demand. In 2017, the hiring rate for graduates of these programs - taking voluntary terminations into account - was over 90%.

#### Special vocational training opportunities

In Darmstadt, our "Start in die Ausbildung" program helps young people who have a high school diploma but have been searching for an apprenticeship for at least one year without success. We offer them the opportunity to complete an 11-month program with our company, providing **insight into professional life** and improving their chances of gaining an apprenticeship. In 2017, 20 participants aged 16-25 started this program. Since its launch in 2006, 204 young people have already taken part in the program; 103 of them have successfully completed an apprenticeship, while 37 are still in a vocational training program.

In October 2016, we established a similar program for refugees. Having entered its second round in 2017, the "Integrating refugees through training" initiative prepared 12 young people for vocational training, thereby opening the door to the German labor market. The project comprises language, technical, cultural, and career-related training. In 2017, we hired three of the participants from the 2016 program as apprentices and placed two others in apprenticeships with other companies. The seven remaining participants are now pursuing further studies at schools or academic institutions.

# Leveraging the opportunities of digitalization

Our work is becoming increasingly digital and flexible, a development described by the terms "Work 4.0" and digitalization (p. 29). This trend is also impacting our vocational training and continuing education programs, where we are integrating instruction on using new technologies such as 3D printing and trying out **novel learning and innovation methods** such as design thinking. Moreover, since 2017 we've been providing all new apprentices with hybrid laptop/tablets to teach them how to navigate our company's soft-

ware landscape and to educate them on data protection. In 2017, members of the Production Engineering group partnered with employees from Organic Polyproduction to implement damage simulation software. In addition to simulation software, apprentices also utilize augmented reality technology to learn how to operate plants and machinery, accessing useful additional information via a display.

Our EVA collaboration platform is another example of an innovative, cutting-edge working environment. EVA stands for "Expertise everywhere, Virtual teams, Access to information" and brings our employees from across the globe together. It allows virtual teams to collaborate and communicate across departmental boundaries and national borders. In total, approximately 50,000 people have access to the platform, which has won an array of international awards. A dedicated project team is continuously working to improve and optimize this tool.

## Good standing in employer rankings

Our company is one of the world's best employers, a fact now officially verified by the Global Top Employer 2017 certificate awarded by the Netherlands-based Top Employers Institute. Every year, this independent institute organizes an international assessment involving an external audit as well as a detailed survey to determine the processes and structures that make up a company's human resources environment.

Rolled out in 2017, our **newly developed employer brand** sums up what it means to work for Merck KGaA, Darmstadt, Germany. It is built on the passion, creativity and curiosity of the employees who have helped us become a global science and technology company. We believe that curiosity always leads to positive outcomes, something we hope to make clear both through our employer brand and the accompanying campaign. We are aspiring to become the employer of choice for all inquisitive individuals, which is why this campaign centers on our promise to "Bring your curiosity to life".

The success of our efforts is also confirmed by our **ranking among the 100 top employers** for students and experienced scientists in Germany. This index is published annually by the research and consulting firm Universum and involves a survey of more than 5,000 people. Among scientists, in 2017 our Group ranked fifth in the student survey and seventh among experienced professionals.

In addition to this recognition, we were also ranked fourth among the world's top employers by Science, a leading peer-reviewed scientific journal. Almost 7,000 employees as well as managers from biotech and pharmaceutical companies took part in the magazine's online survey.

#### Finding work-life balance

We recognize how important **work-life balance** is for a productive and motivated workforce, which is why in many

countries we allow our employees the flexibility to organize their own work schedule. Our people make use of more than 30 different part-time models. In Germany and the United States, where around 45% of our workforce is based, we offer parental leave conditions that go beyond the statutory minimum requirements. Moreover, in Darmstadt we hold special seminars and offer referral services for employees who provide care for family members.

#### Expanding flexible working models

We offer our employees various flexible and innovative working models. The mywork program was implemented in 2013 at the Darmstadt and Gernsheim sites in Germany and is now open to all exempt and non-exempt employees. Since 2017, this model has been available in many countries across Asia and Europe, and also in Australia. In agreement with their teams and supervisors, employees can freely choose their working hours and location. Employees can decide for themselves, together with their respective supervisors, when and how often fixed physical presence in the office is necessary for all team members. Working hours are no longer recorded or monitored. This approach aims to strengthen the **culture of performance and trust** within the company. At the end of December 2017, a total of 5,267 employees were making use of this model.

In 2017, 4.6% of our employees worldwide worked parttime, 10.7% of whom were men. We believe that with these flexible working models, we are on the right track to achieving a better balance between the expectations we set as an employer and the home life demands of our employees. Ideally, such a balance should lead to greater employee satisfaction and increase our appeal as an employer.

#### Supporting parents

We endeavor to make it easier for our employees to return to work following parental leave, which is why in 2016 we launched a program for parents in Darmstadt and Gernsheim (Germany). By the end of 2017, 101 employees had signed up for this program, which gives mothers and fathers on parental leave the opportunity to talk and interact while also helping them keep in touch with the company. Moreover, they can make use of the various **training and networking offerings**. We have established a similar program in the United States.

In the United States, we offer the female employees in our Life Science and Healthcare business sectors eight weeks of paid maternity leave. In Life Science, fathers are eligible for two weeks of paid paternity leave, which also applies when adopting a child, while Healthcare staff are given five weeks of paid paternity or adoption leave. By contrast, the statutory minimum only provides for 12 weeks of unpaid parental leave per year. Furthermore, we also reimburse up to US\$ 5,000 in adoption fees.

At our sites in Germany (around 25% of our workforce), 452 employees were on parental leave at the end of December 2017, 51% of whom were fathers. In other key countries, we go beyond the legal requirements to offer other kinds of new parent support such as extended leave for employees in Brazil. In India, too, we offer five days of paid paternity leave to fathers, even though it is not a legal entitlement. In offering these benefits, we do not differentiate between full-and part-time staff or employees with fixed-term contracts. The latter may apply for parental leave until the end of their term of employment.

#### Daycare support

For 50 years, a **daycare center for children** aged 1-12 has been operating at our global headquarters in Darmstadt. This facility is funded by the Merck family and offers 150 slots. Since 2013, we've been providing year-round care from 6:30 a.m. to 7 p.m. For the children of our employees in Gernsheim, five places are available at a public daycare center.

Our Darmstadt site also offers **provisional daycare services** to cover times when an employee's regular childcare falls through. During school breaks in the German Federal State of Hesse, we host a variety of vacation camps focused on sports, art, research, and nature for up to 450 children. Since June 2016, we have also been providing

temporary care for sick children. For up to two days, parents throughout Germany can engage the services of an education specialist free of charge to look after their children at home.

Our facility in Mumbai, our main site in India, also features a **daycare center** for the children of our employees. In the United States, parents can go to www.care.com to find external childcare. Furthermore, we offer up to ten days of provisional childcare, as well as daycare center slots at special rates and home childcare. We are currently considering the possibility of introducing measures at our other sites as well to help our staff reconcile work and family life.

#### Family and elderly care: Better informed

Twice a year, we offer our employees in Germany **family care seminars** on a range of topics. An external associate provides advice on all issues relating to family care and guides people in their search for suitable options. In Darmstadt, our company health insurance fund also puts people in touch with nurses and, in the United States, our employees can use the online portal care.com to locate family care services.

# **Diversity**



## Part of the non-financial report

We are an international company with employees who represent a varied cross-section of nationalities, cultures, religions, and age groups, as well as different gender identities, different sexual orientations and an array of professional backgrounds. We believe that a diverse workforce – paired with a respectful corporate culture – strengthens our ability to innovate and contributes significantly to our business success. With this in mind, we work hard to foster a culture of diversity and inclusion.

# Our approach to diversity and equal opportunity

Our goal is to further drive diversity across our workforce and offer all our employees **equal opportunities** for advancement. In particular, we endeavor to promote greater opportunities for women, cultivate an international working environment and form teams with a balanced age structure. To this end, we offer our employees global development opportunities and are working to increase the percentage of leaders from international growth markets across the Group

to leverage their knowledge of local markets. To support these efforts, in 2017 we developed a detailed diversity policy for the Executive Board and Supervisory Board of Merck KGaA, Darmstadt, Germany. The policy is published in our management report.

The strategic competencies that guide our employees and leaders in their tasks are set out in our Competency Model (p. 84), a fundamental element of HR processes such as recruitment, feedback and training for supervisors and leaders. We have software in place that allows our leaders to quickly and reliably analyze their personnel and team data. Select data on topics such as diversity are also presented in this report.

## Women in leadership roles: Requirements and targets

Our target for 2021 is to maintain a 30% representation of **women in leadership roles**, and we are working to further increase the representation of women in leadership positions and business units where they are still underrepresented. To achieve this objective, in 2017 we formed special teams

that are responsible for developing goals and measures at a departmental level to help us move female candidates into positions in different areas and hierarchies. At the end of 2017, women occupied 30.3% of leadership roles Groupwide. Although these figures are increasing steadily across the company, this is not the case within certain business units, Group functions and hierarchical levels.

# How we're making diversity a pillar of the company

Our Chief Diversity Officer is responsible for overseeing our Group's diversity strategy and reports directly to Belén Garijo, the Executive Board member whose responsibilities include Group Human Resources. Consisting of executives from all our business sectors and select Group functions, our **Diversity Council** performs four key tasks:

- It is responsible for implementing our strategy for greater diversity.
- It evaluates and further develops proposals to increase diversity submitted by our business sectors and functions as well as employee-organized networks.
- The council members ensure implementation of the Diversity Strategy in their respective areas, monitoring the progress of the initiatives.
- Members act as direct points of contact for the employees in their respective areas.

Group Human Resources (HR) has also implemented a number of programs and processes in order to further enhance diversity within the company.

# Our commitment: Industry-wide initiatives and regulations

In an effort to promote further diversity and underscore our **commitment to fairness, inclusion and tolerance** in the workplace, we support industry-wide initiatives:

- In 2017, we adopted the new Inclusion Action Plan of the German Mining, Chemical and Energy Industrial Union (IG BCE), which sets out concrete measures and provides guidance for creating a more inclusive workforce for employees with disabilities. In endorsing this plan, we are meeting the requirements of the United Nations Convention on the Rights of Persons with Disabilities.
- In 2015, we furthermore signed the IG BCE Equal Opportunity Charter, thereby promising to do everything in our power to achieve gender equality within the company.
- In 2013, we endorsed the German industry-wide "Charta der Vielfalt" (Diversity Charter).
- In 2011, we joined other DAX® 30 companies in signing a declaration committing to advance women in leadership roles.

#### Meeting statutory requirements

The German Law for the Equal Participation of Women and Men in Leadership Positions in the Public and Private Sector has been in effect in Germany since 2015. Owing to our legal form as a KGaA (corporation with general partners), this law also applies in part to us.

Consisting of 37.5% women (6 out of 16 members), our Supervisory Board already meets the stipulations of the German legislation on the **gender quota**. Owing to our legal form as a KGaA (corporation with general partners), we are not required to set targets for our Executive Board. For the two management levels below the Executive Board, however, the Executive Board set the following targets in 2016:

- 21% women on the first management level below Executive Board
- 26% women on the second management level below Executive Board.
- We've set a deadline of December 31, 2021 for reaching these targets.

## **Increasing diversity awareness**

We seek to raise awareness for diversity and inclusion among our employees. In a bid to educate people on unconscious bias, in 2017 we conducted pilot projects Group-wide involving a variety of training seminars and webinars. 192 employees took part. These seminars help participants recognize unconscious thought patterns and stereotypes, thereby preventing any unfair treatment resulting from such a mindset. In addition to raising diversity awareness, we also support our business units in their efforts to advance a greater number of women into leadership roles. Launched in 2017, our Gender Balance Toolkit enables them to identify gaps in recruitment processes and develop a custom-tailored course of action to increase the percentage of female employees in their ranks. In 2017, we also started looking into ways to leverage the Healthy Women, Healthy Economies toolkit, whose guidelines help identify methods of promoting worker health.

In 2017, for the sixth year running, we dedicated the entire month of September to the topic of diversity and inclusion. Under the banner of "Different Perspectives", we hosted a variety of activities around the globe. The approximately 11,100 employees participating across 32 countries showed how important the issue is. Our Diversity Council sponsored the campaign, supporting it through media articles and by participating in roundtables and employee events.

### **Networks to bolster diversity**

Creating an inclusive work environment that promotes mutual respect is a particular focus of our diversity strategy. We support specific employee networks in order to foster **exchange among like-minded individuals**. Apart from our internal women's network in various countries, we also promote networks that further the interests of the LGBTIQ (Lesbain, Gay, Bisexual, Trans, Intersex, Queer) community, Afro-American employees, and international staff.

Owing to the acquisitions we have made in recent years, there has been a steady increase in the number of our employee networks. Going forward, we intend to better leverage the potential of these networks to benefit our business activities. Networks with similar objectives are to be merged and expanded internationally. Moreover, we want to help establish leadership structures within these networks and define their goals. To this end, we invited leaders from all networks Group-wide to a first-ever leadership summit in 2017.

Through our Rainbow Network for homosexual, bisexual and transsexual employees, in 2017 we supported Christopher Street Day in Frankfurt and Darmstadt (Germany). As well as taking part, we were the official corporate sponsor of the event in Darmstadt. Since 2016, the Rainbow Network has also been active in the United States and Canada.

Our U.S.-based Black Leadership Network is dedicated to advancing and developing African American employees, offering its members advanced training and continuing education programs, tailored career advice and networking opportunities.

### Tapping into external networks

We are a corporate partner of the Healthcare Businesswomen's Association (HBA), a non-profit organization committed to furthering the advancement and impact of women in the healthcare industry. We encourage our female employees to get involved in this network because it gives them access to mentoring programs as well as the opportunity to attend various seminars and conferences at our global headquarters in Darmstadt (Germany), as well as in Lyon (France), or Boston, MA (USA). In autumn 2017, several of our employees participated in the HBA's European conference in London (United Kingdom) as well as its annual conference in Philadelphia, PA (USA), not to mention regional events held in cities such as Darmstadt. Furthermore, three of our female employees are board members of HBA Europe.

As well as supporting the HBA, we were also a primary sponsor of the 2017 Women's International Networking (WIN) Conference in Oslo (Norway), which was attended by 15 of our employees, some of whom gave talks. The network connects **women in leadership roles** with the aim of helping them gain more influence. As a member of the Center for Talent Innovation, we benefit from their research on diversity and inclusion. In 2017, two of our female employees participated in the Task Force Summit held in New York City (USA).

## Taking action against discrimination

As stipulated in our Code of Conduct, we do not tolerate any form of discrimination within our company. If an employee feels they have been discriminated against, they can report the issue via **various channels**. Their first point of contact is their supervisor, but they can also contact Human Resources, Legal or Compliance. Alternatively, employees can call our SpeakUp Line anonymously from anywhere Group-wide. Group Compliance (p. 11) is responsible for investigating alleged cases, a process coordinated by the Group Compliance Case Committee. In confirmed cases of discrimination, a subcommittee provides a recommendation for disciplinary action that is implemented by our management team. In this way, we ensure that similar cases are dealt with consistently across the company. In 2017, **no suspected cases of discrimination** were reported via the SpeakUp Line or other channels.

# Successfully integrating international employees

Our company is becoming increasingly international. We currently employ people from a total of 131 nations, 23% of whom are German citizens. Our leadership (Role 4+) includes representatives of 65 nationalities. In 2017, 64% of leadership positions were held by non-German employees. As of the end of 2017, 8% of our employees were working outside their home countries.

To best facilitate this **international collaboration**, we offer intercultural seminars for all employees along with suitable online tools. For instance, our Cultural Navigator helps prepare our staff for international projects and business trips abroad. We also provide the majority of our company-related documents in English, and support employees posted to other countries through language courses and international networks to help them adjust more quickly to their new country. For instance, around 600 expatriate employees are members of the International Community, which meets regularly in Darmstadt.

### Addressing demographic change

Another issue we're tackling is demographic change. We expect the average age of our workforce to continue to rise in the coming years. In Germany, we are responding to this trend with various initiatives including our corporate health management program. Take for instance BELS, the tool for strain evaluation that we use to design ergonomic work spaces that boost performance. BELS takes demographic change into consideration by assessing a range of stressors through the lens of age. This approach allows us to adapt our workplaces to suit the needs of older individuals. In addition to modifying physical working environments, in 2015 we developed new shift models and introduced a prevention program for shift workers. In 2017, our company health insurance fund partnered with our health management organization to conduct a yearlong campaign entitled "Time for me - Building resources". Under this campaign, we hosted health and safety days that were attended by over 1,200 employees.

# Health and safety



Part of the non-financial report

We take responsibility for the health and safety of our employees, doing everything in our power to safeguard them against work-related illnesses and accidents. When it comes to office work, issues such as stress prevention, nutrition and mobility are top priorities. Here, we focus our efforts on helping our employees prevent temporary or long-term health problems.

# Our approach to preventing accidents and promoting health

We seek to promote the health of our employees and maintain their ability to perform over the long run, which requires a **safe workplace**. One of our Group-wide objectives is to step up our safety culture. Our goal for 2020 is to keep our lost time injury rate (LTIR) under 1.5. Furthermore, we are working to make workplace health management a greater part of our corporate culture and leadership.

# How we manage occupational health and safety

Our Environment, Health, Safety, Security, Quality (EQ) Group function is responsible for our Environment, Health and Safety (EHS) management system. This unit reports to Executive Board member Walter Galinat, setting objectives, overseeing global initiatives and conducting internal audits. Local EHS managers ensure that each individual site adheres to occupational safety laws and regulations.

We collect **workplace accident data** from our sites on a monthly basis. Every facility is required to immediately report relevant accidents to EQ, where the cases are investigated and assessed. If necessary, we implement additional safety measures at our sites.

Furthermore, our Life Science business sector holds monthly safety calls with local EHS officers to share lessons learned and discuss recommended actions for comparable situations.

At our Darmstadt and Gernsheim sites, our Health Management unit helps weave health awareness into our corporate culture. The strategy necessary, individual focal areas and measures required are developed by an interdisciplinary steering committee consisting of various senior leaders such as the Head of Occupational Health & Safety, the Chairman of the Works Council, and the Head of Health Management. Topics include workplace health fundamentals, good leadership and tailored health programs.

## **Our commitment: Policies and bylaws**

Our approach to occupational health and safety is detailed in our Corporate Environment, Health and Safety Policy. This is an integral part of our EHS management system, which undergoes an external OHSAS 18001 audit every year.

Our Group Health Policy defines how we ensure workplace safety for our employees while also promoting their health and welfare. This document details our **Group-wide approach to safety and health management** as well as our comprehensive behavioral modification program to prevent workplace accidents and occupational diseases. One component of the policy is our Global Wellbeing and Health Promotion Framework, which describes the differing requirements in a wide array of countries. Our individual sites are responsible for performing local workplace risk assessments and hazard analyses.

At most of our sites in Germany, we work in partnership with employee representatives to craft bylaws on occupational health and safety. Our Employee Care bylaw defines processes such as employee care conversations, which help our managers promptly identify health risks and mental stress in their employees. In 2017, this bylaw was extended by an additional three years. Introduced in 2017, our Occupational Integration Management bylaw governs the procedure for protracted employee illness and applies to nearly all our facilities in Germany. This bylaw aims to help keep the employee's position open while also helping prevent adverse health impacts after their return to work.

### Safety certification expanded

By the end of 2017, all Performance Materials production sites had been certified to the international standard OHSAS 18001. In 2017, the Healthcare facilities at our Darmstadt site were certified, along with those of other units. Our Life Science facilities in Bangalore (India), Buchs (Switzerland), Irvine and Haverhill (both in the United Kingdom), and Jerusalem and Rehovot (both in Israel) are now OHSAS 18001 certified. The certification process helps us pinpoint weak areas, **identify opportunities for improvement** and take suitable measures. Other sites have also been required to apply this standard.

### Reducing our accident rate

The lost time injury rate (LTIR) is the indicator used to assess the success of our safety efforts. This figure measures the accidents resulting in at least one day of missed work per one million man-hours. We track the LTIR for both employees and temporary workers. After having achieved our 2010 target of a 2.5 LTIR, in

2015 we set a new ambitious goal of sustainably lowering the LTIR to 1.5 by 2020. In our view, nothing is worth an accident. In 2017, our LTIR was 1.5. The majority of incidents resulting in lost time were slips, trips and falls, along with accidents involving the operation of machinery and equipment. In 2017, there were no fatal accidents

#### Clear rules of conduct

Experience shows that most workplace accidents can be prevented by proper conduct. Through our "BeSafe!" **safety culture initiative**, we are working to raise employee awareness of dangers in the workplace and provide them with rules of conduct that help keep them safe. All production and warehouse sites have now been incorporated into the program. Eight former Sigma-Aldrich facilities have likewise implemented BeSafe! since being acquired by our company in 2015. The rollout at these newly acquired sites will continue until 2020.

In 2017, we conducted initiatives, campaigns, and awareness efforts across the Group as part of our BeSafe! program. For instance, by means of a safety video we increased employee awareness in a bid to further bolster our safety culture. In addition, several subsidiaries held safety competitions. To underscore the importance of safety, we launched the Safety Excellence Award in 2010, which is presented annually to all production sites that have no workplace accidents on record for the year. In 2017, 59 of 97 facilities achieved this honor. Furthermore, we conducted refresher training on key content from our BeSafe! program.

### Workplace health management

At our Darmstadt and Gernsheim sites, our Health Management unit conducts numerous campaigns and programs to promote the health of our workforce. These activities are based on health indicators derived from sources such as our employee surveys, the health report issued by our company health insurance fund and evaluations from our Site Medical Center. We utilize the analysis findings in the creation of **prevention programs tailored to specific target groups or facilities**.

Moreover, our Health Management unit offers individualized health programs such as awareness courses and workplace ergonomics consultation. Along these lines, we have a standard procedure in place for continuously assessing the working conditions and environment, making state-of-the-art updates wherever needed. If other sites express interest, our Health Management unit will advise on potential improvements or health programs. When requested, we provide local consultation and promotional activities by means a service contract.

Since 2013, our Darmstadt site's restaurant & catering services have been certified with the "Job&Fit Premium" certification from the German Nutrition Society e. V. (DGE). For our healthy and sustainable employee food service in Darmstadt, we were nominated in 2017 for the Dr. Rainer Wild Prize, which recognizes outstanding projects, individuals and initiatives in support of healthy nutrition.

Our employees have access to a health catalog detailing our Health Management offerings. Available in English and German, it contains information on ergonomics, nutrition, stress, and mental health issues.

In 2017, we were granted the "Excellence" certification for our Germany-wide health management efforts, presented under the auspices of the 2016/2017 German Corporate Health Award sponsored by BKK Dachverband e. V. This organization recognizes companies that have implemented exemplary health management programs and met the quality criteria of the European Network For Workplace Health Promotion (ENWHP).

Launched at the end of 2016, our program to minimize chronic back pain has become an integral component of our workplace health management activities in Darmstadt and Gernsheim. This initiative, which also takes mental health factors into account, is offered in units with demonstrable need, such as a relatively high number of employees suffering from these sorts of symptoms.

Throughout Germany, we also regularly offer our employees services such as our company's fitness program, which provides them with up to  $\in$  195 per year towards **health prevention classes**. In Darmstadt and Gernsheim, we furthermore run a company athletics program that currently features 25 different sports.

In an effort to improve our workplace, we analyze the ergonomics of individual workstations and then implement any measures required. Our workers also receive training on occupational ergonomics tailored to specific areas such as manufacturing, office work or the laboratory. Moreover, we conduct programs at many sites, doing so either ourselves or in collaboration with external providers. Our Life Science employees at our Bedford (MA), Danvers (MA) and Jaffrey (NH) sites in the United States, for instance, have access to the Early Symptom Intervention and Prevention Program (ESI), which saw 59 people participate from January to April 2017. In early 2018, we replaced the ESI program at the Jaffrey facility with a pilot of the Industrial Athlete Program (IAP). While ESI focused on individuals with pre-existing conditions, IAP is open to all employees who wish to improve their physical and general wellbeing through exercise in small groups.

### **Testing and supporting our employees**

Our Physical Ability Test and Health Preservation process ensures that all employees meet the health requirements for their particular tasks. This test helps us implement targeted intervention as necessary.

Our Travel Health & Medical Advisory Service assists employees who spend a lot of time abroad on business for Merck KGaA, Darmstadt, Germany, providing them with recommendations on necessary vaccinations and advice on hygiene risks.

# Employee engagement



As a science and technology company, we are always looking for new solutions and working to continuously evolve our approaches. Engaged, curious employees are key to our ability to innovate, and therefore also to our success. We need a corporate culture that broadens the knowledge base of our employees, one that creates exciting opportunities and motivates them to take a proactive role in shaping the development of our company. Candid feedback from every individual helps show us where we have room for further improvement.

## Our approach to engagement

We strive to create a work environment that empowers our employees to think outside the box and seek new solutions, opening the door to creative ideas and the discovery of new market opportunities. To better engage employees, we have set clear goals and defined the steps necessary to accomplishing them.

We seek to understand the needs of the people who work for us and therefore regularly conduct employee surveys that show where we can do better. Following each survey, we plan improvements that are implemented by the respective units.

#### How we engage our employees

Engagement and Inclusion, a unit within our HR organization, creates and oversees our employee surveys.

In addition to conducting employee surveys, we regularly include local employee representatives in our decision-making processes. Within Germany, 14 of our subsidiaries have employee representation. These local works councils as well as a Germany-wide Group works council represent the interests of our employees, discussing topics such as compensation, working hours, and organizational realignment. The Senior Executives Committee represents the interests of senior executives, while the Euroforum of Merck KGaA, Darmstadt, Germany represents our employees at the European level, focusing on the economic situation, employment rates and significant changes within our company.

### **Understanding our employees**

In response to a 2016 employee survey, in 2017 we initiated a series of measures to **improve our employees' working environment**. In terms of our IT structure, we improved the performance of programs such as Skype and Outlook, updated networks and optimized IT support. Moreover, we enhanced our employee recruiting and integration processes, optimized the search function and mobile access to our Intranet, and even launched an initiative to cultivate an in-house community of scientists. To give us a

better sense of the situation within our company as a whole and to better benchmark against our competitors, all employee surveys are conducted Group-wide on an annual basis. This provides a platform for employees, leaders and executives to engage in a regular dialogue, sharing ideas and experience.

### **Rewarding innovative ideas**

In 2017, our employees submitted approximately 2,000 suggestions for improvement via our **Germany-wide idea management program**. These ideas are expected to yield around  $\in 4.6$  million in cost savings in the first year. In exchange for their proposals, our employees received roughly  $\in 585,000$  in bonuses. This concept aims to inspire our employees to think creatively and encourage them to contribute to the continuous evolution of our procedures and processes. We reward any ideas that are successfully implemented by offering employees a bonus based on how much the suggestion improves our processes or cuts down our costs.

In addition to rewarding good suggestions, we also regularly hold a **Group-wide innovation competition called Innospire** that allows employees to submit ideas for new products, services and business models. Through this competition, we target ideas in specific areas such as biointerfaces and biosensing, enablers of precision farming, and artificial intelligence. However, we also welcome ideas outside of these target areas.

In 2017, nearly 900 ideas were submitted. We chose the top 18 proposals at the end of 2017, and teams have until May 2018 to further develop them, at which point the winners will be announced.

In addition to Innospire, we annually present the company's awards in recognition of outstanding ideas, teamwork and projects. In 2017, the Executive Board presented four teams consisting in total of 40 employees with the awards in the categories of Performance, People, and Technology, along with a special CEO Award. Projects were submitted Group-wide by 70 teams from our Healthcare, Life Science and Performance Materials business sectors, as well as our Group functions. With submitters representing a variety of countries worldwide, some of the proposals even spanned multiple businesses.

### Making room for ideas

Over the last several years, we have undergone a major evolution and grown through acquisitions. We are now transforming our site in Darmstadt into a global headquarters that will bolster our ability to innovate, enabling us to respond flexibly to growth while also reflecting our corporate identity. This transformation is supported in part by our ONE Global Headquarters strategic initiative.

Opening its doors in early 2018, our **new Innovation Center** (p. 29) is the heart of our global headquarters. Replacing the previous modular Innovation Center, this new facility will give our employees room to explore their creativity by joining interdisciplinary teams and collaborating on pioneering projects – all with the aim of cultivating new businesses that transcend our existing ones.

Within the walls of our Innovation Center, 15 project teams are currently pooling their creative energy in the pursuit of new ideas. We have also invited numerous external startups to take advantage of the center as part of our Accelerator program, an initiative that supports fledgling enterprises. These start-up teams take up residence at the Innovation Center for three months at a time and receive financial assistance, training and access to our experts worldwide. In 2018, we shall be expanding our Accelerator with a focus on Africa, specifically in places with a thriving or burgeoning start-up culture. In addition, we will be modifying the platform of our first offshoot in Nairobi (Kenya), and opening small satellites in Lagos (Nigeria) and Cape Town (South Africa). In March 2018, we'll be increasing the number of startups in our Darmstadt Accelerator to 12, the first time we've had this many teams in the program.

The Innovation Center creates a fertile ground for discourse, which serves to benefit not only the startups, but also our own project teams. Here, for instance, all teams are provided a "maker space" that allows them to quickly develop prototypes. They additionally receive access to our scientific library and a web-based platform that contains tutorials, useful project tips and online courses, and provides users the opportunity to share ideas and experiences.

Beyond facilitating cross-collaboration and creativity, the Innovation Center team regularly conducts events, workshops, seminars, and webinars. Through these channels, we introduce our employees to new innovation methods such as design thinking, which has generated great interest. We also hope to accelerate the exchange of innovative ideas within the company and build a Group-wide network of ambassadors for this facility.

### Innovating with young scientists

Our company's Biopharma Innovation Cup is targeted to science and business graduates, graduate students or postdoctoral researchers from around the world. This competition seeks to spark the interest of young talent in our company, while also offering a forum for new ideas. During a one-week summer camp, 30 participants learn first-hand how research and development works in the pharmaceutical industry, collaborating with current and retired employees to create new, innovative project concepts. The team with the best concept receives a prize of € 20,000.

To mark our 350th anniversary in 2018, we will be hosting a larger anniversary edition of our Innovation Cup that will feature 75 talented post-graduate students and cover all three of our business sectors. All participants will also be invited to attend Curious2018-Future Insight, a conference we are launching in 2018 as part of our 350<sup>th</sup> anniversary celebrations. In 2017, the winning Innovation Cup team submitted an innovative project proposal on the role of natural killer cells (NK cells) in immuno-oncology. NK cells are lymphocytes that target both tumors and virally infected cells, killing them. Overall, more than 1,400 scientists from across the globe competed for the prize.

# Keeping employees informed and encouraging dialogue

We keep our employees up to date and encourage exchange through a number of formats tailored to specific target groups. Take, for instance, our international collaboration platform EVA (p. 75) and our international employee magazine "pro", which is published in seven languages and is available in a digital format as well an app. Through "pro", we reach more than 90% of our approximately 52,000 employees worldwide in their local language. Several subsidiaries also publish local editions of "pro", for example in Germany, Korea, Mexico, and Russia. In addition to these formats, a variety of newsletters is also published by our businesses.

Our collaboration platform EVA encompasses our global Intranet for all subsidiaries and business sectors and furthermore consolidates numerous collaboration applications in one central location. EVA ranks as one of the most important internal communication media – second only to e-mail – receiving approximately 1.7 million hits per month. Moreover, we publish articles on EVA and host various events to raise employee awareness of corporate responsibility issues.

## Deepening employee engagement

SPARK is a global volunteer program in which our Life Science employees conduct scientific experiments with school children around the world in an effort to ignite a passion for science in the next generation. Benefitting both urban and rural schools, this initiative also gives our employees the opportunity to pass on their knowledge. You can find more information on SPARK as well as the diverse range of education projects in the community in and around our global headquarters under Community involvement (p. 114).

# good leadership



Part of the non-financial report

We think it's essential for our leaders to develop and grow so that they can address the diverse needs of their team members. Within our company, teams collaborate across sites and international boundaries. Their members bring a variety of skills, strengths and experience to the table that our leaders can leverage. We in turn support them in fulfilling their responsibilities. Since global collaboration plays an increasingly important role in the development of our next generation of leaders, our management processes fundamentally follow an international approach.

### Our approach to good leadership

Our strategic **competency model** describes core competencies that should underpin the conduct of employees at all levels. Our six core competencies are Purposeful, Future-oriented, Innovative, Results-driven, Collaborative, and Empowering. In our day-to-day work, they play an important role in our success. This model provides the foundation for all development activities within our HR work – for employees, but in particular for our leaders, who act as role models and are therefore key to building employee buy-in for the competency model. In addition, the model defines the leadership culture through which we intend to grow our business.

#### **Our competency model**



We use our Performance and Potential Management Process (p. 74) to gauge the impact of our development initiatives. Furthermore, our employees also take surveys (p. 82) to rate the quality of leadership within our company.

### How we facilitate good leadership

Our leaders are attuned to the needs of our diverse workforce and receive support in the form of resources and data. At the same time, they can access transparent feedback through specially developed tools to track the impact of their decisions.

#### **Management programs**

In recent years, we have initiated three programs to enhance the skills of our people managers. The Managerial Foundation Program imparts the basics of leadership, such as communication techniques, leadership styles, conflict management, motivation, and emotional intelligence. The Advanced Management Program covers topics such as change management, self-reflection and resilience. In addition, it teaches coaching methods that help leaders transition from their first management role to positions managing cross-functional and international teams. The third initiative is our Global Leadership Program, which focuses on competencies needed to ensure successful international collaboration. In 2017, the Managerial Foundation and Advanced Management programs were offered at several of our sites worldwide, while the Global Leadership Program was held in Germany, the United States and Dubai.

By the end of 2018, we want at least 50% of our people managers rated Role 3+ to have taken part in one of these programs. By the end of 2017, all our top 400 executives (Role 6+) had completed the Global Leadership program. Since the launch of the three programs, a total of more than 4,000 people managers have taken part.

# Expanding the range of the company's University courses

Since 1999, we have partnered with top international universities to offer a university program that is **multi-regional and modular**. Over a period of ten months, senior executives take classes on management techniques and strategic business development. In 2017, we partnered with the U.S.-

based Stanford Graduate School of Business to offer a new module on leading innovation and digitalization, in which 23 of our executives took part. The module features an eightweek online course entitled "Innovation Process for Entrepreneurs" and also requires participants to attend classes on campus in Stanford over the course of three and a half days. To date, a total of 373 executives have completed the company's University program.

Another initiative we've been offering our up-and-coming executives since the 1990s is our International Management Program, where participants work on an interdisciplinary project over a period of nine months. The results are then presented to the Executive Board. Moreover, we partner with universities across the globe in an effort to help our employees obtain qualifications such as an Executive MBA.

## Leveraging growth market potential

In the development of our leaders, we also want to include our growth markets. In 2017, for instance, we again conducted our Growth Markets Management Program for local leaders in the Asia-Pacific (APAC), Latin America, and Middle East, Africa, Russia, Turkey (MEART) regions. The training covers a range of business administration topics such as marketing and financial analysis, along with content specific to our business, for instance our strategy and corporate culture. In 2017, we integrated a digital marketing module into this program for the Asia-Pacific region, similar to the program we introduced in 2013 in China and in 2016 in the Middle East and Latin America. To date, a total of 126 leaders have taken part.

We also offer other development opportunities in growth markets. In 2017, for instance, eight employees successfully completed "Afrika kommt!", a one-year scholarship offered by the German Society for International Cooperation (GIZ). This program offers training opportunities for young qualified experts and leaders from Sub-Saharan Africa. In supporting this initiative, we aim to build a pool of regional partners to encourage economic cooperation between Germany and Africa. Twelve former scholarship recipients are now working for us in various specialist and leadership positions, five of them in their home countries of Ethiopia, Ghana, Kenya, and Nigeria, and seven still in Darmstadt. In 2017, six new candidates were chosen for the sixth round of "Afrika kommt!"

# Environment



- **87** Environmental stewardship
- 90 Climate protection
- **94** Resource management

- 100 Plant and process safety
- **102** Biodiversity

# Environmental stewardship



Part of the non-financial report

As a science and technology company with manufacturing operations, we have an impact on the environment. Take for instance the emissions, wastewater and waste generated by our activities, or the materials we utilize that could adversely affect the environment if not handled properly. To mitigate this impact, all our sites meet a strict set of environmental regulations. Intelligent environmental stewardship reduces resource use and lowers costs, which makes it highly important to adapt our processes to new regulatory requirements.

# Our approach to environmental stewardship

A holistic approach is needed to minimize negative environmental impacts and preserve the environment. Our goal is to diligently monitor detrimental emissions into the air, water and soil resulting from our operations and do everything possible to prevent them.

## How we structure our environmental stewardship practices

Executive Board member Walter Galinat is responsible for overall environmental governance, which also covers climate impact mitigation, water management, waste & recycling, and plant & process safety. Our Group function Environment, Health, Safety, Security, Quality (EQ) is in charge of steering all environmental measures Group-wide. At our individual sites, each site director is responsible for environmental stewardship as well as occupational health and safety at the operational level. At larger facilities, the site directors receive day-to-day support and advice from Environment, Health and Safety (EHS) managers, with EHS coordinators

performing this role at smaller facilities. These local EHS organizations report to and work hand in hand with EQ.

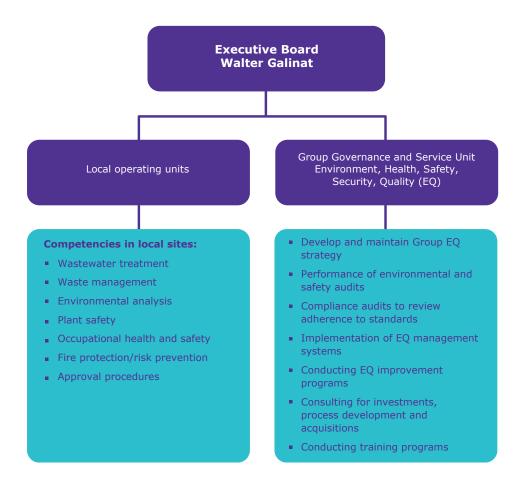
In 2017, our EHS organization comprised more than 200 EHS managers along with other EHS personnel. At the local level, these employees receive support from other units. Our Group function EQ conducts annual EHS seminars at our various sites.

In 2017, environmental stewardship efforts accounted for 26% of our EHS spending, which consisted of both ongoing expenses as well as investment costs. This includes items such as air pollution control, noise reduction and environmental remediation.

The EQ leadership meets with Walter Galinat on a regular basis, usually once a month, to report on their environmental stewardship efforts. Every six months, EQ provides the Executive Board with a report on environment, health and safety issues that also covers climate impact mitigation, water management, waste & recycling, and plant & process safety. This report focuses on our current progress, documenting and assessing the work EHS has accomplished. The Executive Board utilizes this brief as a source of information and as documentation for ISO 14001 and BS OHSAS 18001 certification.

Moreover, the Executive Board is responsible for approving internal guidelines such as our Environmental, Health and Safety (EHS) Policy. Internal standards are approved by the head of EQ. While standards provide a concrete framework, guidelines create an overarching outline of our company's position on a specific issue.

#### Our EQ Group function ("Environment, Health, Safety, Security, Quality")



### Clearly defined incident reporting procedures

We have established a variety of reporting procedures to handle incidents as quickly as possible and take corrective action. In introducing our EHS Incident Rate (EHS IR (p. 100)) and EHS Leading Indicator Rate (EHS LR (p. 100)), two of our key performance indicators, we have created a reporting process that tracks the respective environmental incident, its degree of severity and all risk mitigation efforts. All incidents are logged Group-wide and reported every six months to the Executive Board.

In the event of major incidents, our Rapid Incident Report System (RIRS) promptly notifies the Executive Board, our EHS Group function and Group Communications. These could include fatalities, accidents with multiple casualties, or injuries and damage that occur beyond our premises, along with environmental disasters such as earthquakes and floods. Through the RIRS, we can coordinate the responses of all those involved and inform other potentially impacted sites immediately.

# Our commitment: Standards and standard operating procedures

Our approach to environmental stewardship is built on our **Group-wide EHS Policy** (Corporate Environment, Health and Safety Policy), which has been endorsed by Stefan Oschmann, Chairman of the Executive Board. This policy is now aligned more closely with the stipulations of the chemical industry's Responsible Care<sup>®</sup> Global Charter, as well as with environmental management standard ISO 14001, and it emphasizes our leadership's responsibility toward environmental stewardship, health and safety (p. 80). Moreover, it addresses our suppliers (p. 104), encouraging them to adopt similarly enhanced standards for environmental sustainability and safety. In doing so, our Corporate EHS Policy complements the Responsible Sourcing Principles of our Group Procurement function.

The principles of our EHS policy are implemented through internal guidelines, standards and operating manuals. For instance, our Group EHS, Security and Quality Manual describes how environmental stewardship and occupational safety are organized across the company. This manual was

revised in 2017 to reflect the updated ISO 9001:2015 and 14001:2015 standards. Our environmental management system was also updated in 2017 to bring it in line with the requirements of ISO 14001:2015.

Potential EHS risks posed by acquisitions, divestments or site closures are assessed through due diligence, a process defined in our EHS Due Diligence and Post Merger Transaction Standard. During audits, new sites are given priority.

We regularly review our internal guidelines, standards and operating manuals. In 2017, we updated and introduced multiple standards and processes. For instance, we revised safe chemical handling standards to reflect the latest findings and state-of-the-art safety concepts. Furthermore, we updated our requirements for external warehouses to align them with our Transport Safety and Warehouse Safety standards.

# Sizable investments in environmental impact mitigation

Preventing and monitoring air, water and soil emissions involves large expenditures on our company's part, as does proper waste disposal. At our Gernsheim site in Germany, for instance, we have set aside provisions for the remediation of contamination. Moreover, we allocate **an annual budget for groundwater and soil remediation** to ensure our ability to execute all measures required throughout the year.

Our spending on environmental protection, health and safety efforts totaled  $\in$  200 million in 2017, which also includes investments made during the year. In this period, our provisions for environmental protection totaled  $\in$  137, 94% of which were attributable to Merck KGaA, Darmstadt, Germany.

### Parking lot remediation continued

In 2017, we continued our efforts to decontaminate a parking lot at our Gernsheim site. The scope of the **environmental remediation** required has turned out to be significantly greater than originally anticipated. Since 2008, we've been working to remove hexachlorocyclohexane (HCH) residue from the soil under the parking lot and have been properly disposing of it in external incinerators. In the course of the ten-year decontamination process, we have increased the relevant provisions from € 27 million to approximately € 50 million.

# Assessing environmental impacts and reporting violations

In general, we conduct risk-based assessments along with **internal and external audits** on all our production facilities every three years. Our goal is to analyze and minimize our environmental footprint as well as to ensure that our requirements are being met. Our Group function EQ is respon-

sible for these tasks. As needed, we use the results of such evaluations to define suitable measures. In addition, we have established grievance mechanisms to identify potential violations of our requirements. In 2017, our corporate EHS audits rated more than 86% of the 43 sites audited as "good" or "satisfactory". We assess performance on a fivelevel scale: "excellent", "good", "satisfactory", "poor", and "critical", which in turn determines how frequently an audit is conducted. If its findings are deemed to be good, a facility will undergo audits less often, while significant violations can increase the frequency.

Aside from using audits to identify issues, we also encourage our employees to report potential violations of our standards to our Compliance unit. All of these violations are reported to the Executive Board. In the 2017 period, no significant violations of environmental laws or regulations were recorded Group-wide.

## ISO 14001 Group certificate

We have revamped our management systems to align them with the requirements of the updated version of ISO 14001:2015. In 2017, our environmental management system was successfully certified to ISO 14001:2015.

Since 2009, our company has held a Group ISO 14001 certificate, which means that all production sites with more than 50 employees must implement the requirements of the certificate. Other sites are not obligated to implement an ISO-certified environmental management system. New sites must gradually establish a corresponding **environmental management system with predefined indicators** for factors such as greenhouse gas emissions and water use, and furthermore obtain ISO 14001 certification.



sites worldwide are currently covered by the ISO 14001 certificate.  $\,$ 

Beyond this ISO standard, we have a variety of other internal standards in place that govern environmental stewardship, such as our Air Emissions Standard, Waste Management Standard (p. 95), and Energy Management Standard (p. 90).

Every year, we contract a third party to perform a certification audit. In 2017, we passed 13 ISO 14001 audits, which also included facilities newly incorporated into the Group certificate. All sites pertinent to the Group certificate have thus been transitioned to the new version of ISO 14001:2015. Furthermore, we conduct internal audits to ensure compliance with our requirements.

### Stakeholder engagement and dialogue

By participating in a variety of industry associations, we exchange information and ideas on environmental issues. In 2017, for instance, we took part in discussions between the German Chemical Industry Association e.V. (VCI) and German legislators (p. 100) on eliminating the thermal value criteria. The head of our Group function EQ chairs the VCI plant safety working group. Additionally, we contribute to the dialogue on plant and process safety (p. 100) in our capacity

as members of the European Process Safety Center and the Commission on Process Safety of the German Federal Ministry for the Environment, Nature Conservation, Building, and Nuclear Safety.

Furthermore, we engage residents in the vicinity of our sites in discussions on issues of local relevance.

# climate protection

Climate change is one of the most pressing challenges of the 21st century. Thus far, it has only directly affected us to a minor extent. Nevertheless, because our operations generate greenhouse gas emissions, we intend to do our part for climate impact mitigation, an approach that our customers and stakeholders expect of us. Shifting regulatory requirements can lead to planning and investment uncertainty. In view of burgeoning regulations and rising energy costs, however, climate impact mitigation is also becoming an increasingly smart investment.

#### **Doing our part**

We are taking action to mitigate our impact on the climate. Our **goal** for 2020 is to reduce our direct greenhouse gas emissions (Scope 1) and indirect emissions (Scope 2) by 20% relative to the 2006 baseline, an objective set by the Executive Board in 2009. Scope 1 covers emissions that we produce ourselves, for instance by burning fossil fuels to generate power, while Scope 2 pertains to emissions from the consumption of purchased energy, such as electricity or district heating.

Across the globe, 38 of our sites account for roughly 80% of our greenhouse gas emissions, which is why we are focusing our efforts here.

**Energy conservation** represents an important component of our climate impact mitigation activities. By adapting and updating our technology, we are improving the energy efficiency of our R&D operations, our production processes and our buildings. Just as important is the **reduction of process-related emissions**. Furthermore, we are working to lower the emissions resulting from energy generation. Where financially viable, we additionally utilize renewable energies to generate our own power.

# How we structure our climate impact mitigation efforts

Our Group function Environment, Health, Safety, Security, Quality (EQ) is responsible for globally overseeing all climate impact mitigation measures (see also Environmental stewardship (p. 87)). At our individual sites, Facility Management is primarily in charge of implementing the specified measures.

Climate impact mitigation accounted for approximately 5% of our 2017 EHS costs, **which do not include** the spend on individual climate impact mitigation projects (Edison program (p. 91)).

# Our commitment: Standards and legal frameworks

Our Corporate Environment, Health and Safety (EHS) standards on energy management and emissions from coolant ensure that energy and process-related emissions are managed consistently across the Group. We conduct audits at random to verify compliance with all EHS standards.

We know that **efficient energy management** plays a major role in climate impact mitigation and is also becoming increasingly important to our customers. With this in mind, 12 of our sites decided to obtain ISO 50001 certification, the international standard for energy management.

Our company is subject to a wide array of **national and international energy and emissions regulations** such as the German Energy Conservation Act and the German Renewable Energy Sources Act. Our activities are also governed by EU Directive 2012/27/EU, which stipulates that relevant companies must establish energy management systems and regularly audit their energy consumption. The sites subject to these requirements are responsible for implementing them and furthermore undergo audits conducted by internal or external experts.

The 2015 Paris Agreement on climate change is expected to lead to even more ambitious climate targets within the EU.

With phase four (2021-2030) of the EU emissions trading program due to start soon, we expect to see a tightening of greenhouse gas emission regulations. Going forward in phase four, we foresee having to purchase the emissions allowances that we're still largely obtaining for free during phase three (2013-2020). A global set of climate change regulations could, however, reduce existing competitive disadvantages.

### Slight reduction in energy consumption

We used 2,270 gigawatt hours of energy in 2017, versus 2,241 gigawatt hours in 2016. Our energy intensity relative to sales totaled  $0.15~kWh/\varepsilon$  in 2017.

## **Emissions lowered despite growth**

Despite growth in our operating business, we managed to reduce our greenhouse gas emissions by 8% relative to the 2006 baseline. In 2017, we emitted 731,000 metric tons of  $CO_2$  equivalents, with 711,000 metric tons in 2016.

Between 2006 and 2017, we **more than doubled our sales,** which means that, relative to sales, our emissions dropped significantly.

### Greenhouse gas emissions (metric kilotons)<sup>1</sup>

(Scope 1 and 2 of the Greenhouse Gas Protocol)



<sup>&</sup>lt;sup>1</sup> In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline) the greenhouse gas emissions have been calculated based on the current corporate structure of the reporting year and retroactively adjusted for acquisitions (e.g. Sigma-Aldrich in 2015) or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

### Strategic climate program

In 2009, we launched our strategic EDISON program to consolidate all our initiatives for improving energy efficiency and reducing process-related greenhouse gas emissions. Under this program, our Group function EQ collaborates with a working group comprising representatives from all our business sectors. Any site can propose a project, with the working group subsequently assessing the proposals according to three criteria: 1.) the total absolute  $\text{CO}_2$  savings, 2.) the potential cost savings, and 3.) the ratio of  $\text{CO}_2$  savings to required spend.

Through more than 300 Edison projects initiated since 2012, we aim to save an annual amount of around 98,000 metric tons of  $CO_2$  in the medium term. Since the program's launch, these efforts

have conserved around 75,000 MWh of energy in total, primarily from electricity.

By the end of the year, we had implemented or launched 40 of the 81 Edison projects approved for 2017. These initiatives are expected to achieve savings of around 4,100 metric tons of  $CO_2$  in the medium term. We thus failed to achieve our goal of cutting up to 34,000 metric tons of  $CO_2$ . One reason is that technical issues forced us to postpone an initiative for reducing process-related emissions to 2018. As in previous years, we accepted project proposals for 2018. Through 30 new projects, we hope to realize potential savings of approximately 4,600 metric tons of  $CO_2$ .

In May 2017, the Executive Board approved a roadmap for achieving the remaining savings needed to meet our climate target.

#### Modern energy and cooling systems

In 2017, we invested approximately € 700,000 in a state-of-the-art energy station for our site in Modugno, Italy. As part of this project, we installed a new refrigeration unit and cooling tower. The facility went live in October 2017. These efforts are expected to cut energy use by roughly 950,000 kWh per year.

In Milwaukee, WI (USA), we optimized our HVAC system and thereby lowered our carbon dioxide emissions by 721 metric tons. At our Sheboygan, WI (USA) site, similar updates also led to an emissions reduction of 372 metric tons of CO<sub>2</sub>. The systems were cleaned and new coatings applied, thus enhancing the efficiency of both plants.

#### Investing in renewable energies

At our Life Science facilities in Jigani and Peenya (Bangalore, India), we spent € 775,000 on solar power units. We installed **solar collectors** with a 920 kilowatt power rating. The plants produce 1,265,000 kWh per year and lower our emissions by approximately 1,200 metric tons per year, covering roughly 30% of the energy required by each site.

In August 2017, the Indian Green Building Council (IGBC) gave our facility in Peenya, (India) a gold rating (the second highest ranking) in its Leadership in Energy and Environmental Design (LEED) index. The site's energy and water reduction efforts garnered particular praise. LEED is the world's most commonly used evaluation system for sustainable buildings.

We also installed solar collectors in Burlington, MA (USA). With a power rating of 182 kilowatt, this system is expected to generate 218,000 kWh of electricity per year and thus reduce our emissions by roughly 60 metric tons.

# **Educating employees about climate impact mitigation**

We encourage our employees to do their part to preserve the climate and regularly report on our Group-wide climate impact mitigation activities in our EHS newsletters while also providing helpful information and tips on our Intranet. Moreover, we support employees who prefer greener modes of transportation. For instance, we are constantly updating our pool of leased vehicles with more efficient models to reduce the average  $\text{CO}_2$  emissions of our business car fleet by 30% by 2020, relative to 2013.

#### Subsidies for our employees

In January 2017, we lowered the  $CO_2$  emission rate for newly registered company cars from 150 g/km to a maximum of 135 g/km. Starting in 2019, we plan to further cut this rate to 120 g/km. At most of our German subsidiaries, we offer a subsidy of  $\in$  100 towards monthly lease payments to

employees who voluntarily choose a greener car model. We intend to expand this incentive to include all subsidiaries in Germany.

The current average emission rate of our company vehicles is 131 g/km, with 10% of the fleet in Darmstadt and Gernsheim being electric.

In the United States, we provide our people with financial incentives **to live greener**. For instance, they receive up to US\$ 1,000 in subsidies towards the construction of a private solar power unit and up to US\$ 100 towards an energy audit for their home. They are also eligible for as much as US\$ 3,500 towards the purchase of a hybrid or electric car. To date, we've helped 55 of our employees install solar panels and motivated 361 employees to switch to a hybrid or electric car.

#### Recharging infrastructure at our sites

In addition to promoting electric vehicles within our motor pool, we also want to encourage our workforce to use electric cars in their private lives. To this end, our Darmstadt site offers eight **charging stations** in the employee parking lot, where our employees can recharge their vehicles for free.

Furthermore, we are working on an overall concept to expand the charging infrastructure at our German sites. In doing so, we are investigating other potential locations for charging stations along with alternative options Germany-wide for public charging and charging at home.

We have 42 charging stations across 12 Life Science sites in the United States, Ireland and France at which our employees can charge their electric vehicles for free. These facilities are currently utilized at an average rate of 50%.

#### Jobtickets and carpooling

We offer our workforce in Darmstadt a "Jobticket", an annual subscription to use local public transportation whose cost we partially cover. In 2017, more than 4,300 employees made use of this option. Our people also have access to an online tool that helps them organize carpools.

## Leased bikes in Germany

We also encourage our people to employ eco-friendly forms of transport through "bike4me", a program enabling them to lease a bike at special rates with payments coming out of their pre-tax income. In 2017, we expanded the program from employees in Darmstadt and Gernsheim to include all employees at German sites.

Furthermore, our employees can also use the DB Call a Bike service throughout Germany and borrow a bike for up to half an hour free of charge. Deutsche Bahn, the German national rail company, has set up further rental stations all around our

locations in Darmstadt, and in 2017 we doubled the number of bikes we're sponsoring in the city from 50 to 100.

### Switching to sea freight

In an effort to reduce greenhouse gas emissions resulting from the transport of our products, we utilize sea rather than air freight whenever possible. However, this is only an option for products that survive protracted transport times undamaged. At the same time, we cannot allow the quality of customer service to suffer due to extended transport times. The raw material mica, for instance, is transported primarily by ship. Furthermore, we have switched to using sea freight for shipping our Life Science products between France and Japan or the United States. These changes are cutting our annual  $CO_2$  emissions by 3,000 metric tons in total.

Besides transitioning from air to sea transport, in 2017 our Performance Materials business sector also tested using rail to ship goods to Asia.

# Transparency of CO<sub>2</sub> emissions and energy consumption

The CDP (formerly the Carbon Disclosure Project) assesses the ways in which companies are working to minimize the risks and consequences of climate change, along with their success and strategy for doing so. The rating scale ranges from A to D-, with A being the top score. We received a B in 2017 (A- in 2016), putting us among the top 37% of companies in the healthcare industry.

Since 2008, we've been reporting in detail on our climate impact mitigation efforts as stipulated by the CDP. We track our greenhouse gas emissions in line with the Greenhouse Gas (GHG) Protocol, an internationally recognized standard, reporting on Scopes 1 and 2 as well as parts of Scope 3. In terms of Scope 3 emissions, we only track emissions from business trips and employee commuting, from waste management, and from the manufacture and transport of fuel. Besides these emissions, we also measure energy consumption at our sites. However, this does not include energy use outside our field of activity such as the production of raw materials, as we do not have sufficient data available to perform these complex calculations.

# Resource efficiency

Natural resources are growing ever scarcer, which makes it imperative for us to use raw materials as efficiently as possible and help reduce waste. By conserving energy, water and materials, we are not only mitigating our impact on the environment, but are also lowering our costs.

We are constantly working to reduce the environmental footprint of our products and even help our customers lower their own resource use, thus boosting our competitive advantage.

# Our approach to resource efficiency

Our approach to resource efficiency helps us minimize our consumption of energy, water and materials while also maximizing resource reuse. Underpinned by our climate target (p. 90), we are driving energy efficiency across our company and conserving energy. Furthermore, since 2015 we've been implementing a sustainable water management system (p. 97) in a bid to reduce our water use. When it comes to waste and recycling, we are working to cut down the waste we produce by means of our Waste Scoring System (p. 95). Because we utilize a large chunk of resources for the manufacture of our products (p. 32), resource efficiency is a critical factor in developing our products and production processes.

#### How we structure resource efficiency

The measures we employ to utilize and conserve resources more efficiently are an integral component of our environmental practices and are overseen by our Group function Environment, Health, Safety, Security, Quality (EQ) (see also Environmental stewardship (p. 87)).

#### **Our commitment: Guidelines and standards**

Our key guidelines and standards for resource efficiency are detailed under Waste and recycling (p. 95) and Water management (p. 97). Overarching standards can be found under Environmental stewardship (p. 87).

### Reducing resource use

Our manufacturing operations consume a great deal of energy, but our buildings likewise require energy in the form of electricity and heat. In a bid to lower energy use, we are investing in measures to boost energy efficiency through our Edison program. These efforts are a mainstay of our commitment to climate preservation (p. 90).

We use water primarily for cooling, for exhaust air purification and as process water. Our water management (p. 97) approach combines water use reduction with wastewater treatment.

Our waste and recycling management approach (p. 95) helps us lower waste and maximize reuse, objectives we achieve by separating waste and enhancing production processes.

We primarily use chemical and pharmaceutical raw materials for our manufacturing operations. Additionally, we also employ operating supplies and packaging materials such as folding boxes, glass bottles and ampules.

We utilized 400.2 metric kilotons of material in 2017. We only record the weight of the materials that are directly used in our pharmaceuticals and chemicals.

# waste and recycling

Waste contains valuable raw materials that can be reused in the production stream, which is why we consider it highly important to both prevent and recycle as much of our waste as possible.

### Our approach to waste and recycling

We work to minimize the environmental impacts of our waste disposal activities and limit the loss of raw materials. To this end, we have set the goal of reducing the ecological impact of our waste by 5% by 2025 (relative to the 2016 baseline). This objective was adopted by the Executive Board in 2017.

We generally try to prevent waste, for instance by developing new production processes and optimizing existing ones. Since this is not always feasible, whenever possible we endeavor to reuse the accrued waste to produce materials or generate energy. Through measures such as waste separation, we ensure that **raw materials are recycled** and that unrecyclable waste is discarded in an environmentally sustainable manner in line with the strictest waste disposal standards. In doing so, we comply with local legal requirements, taking into account the available disposal options.

#### Responsibility for waste disposal process

As a generator of waste, we are responsible for the ultimate disposal of our waste products and therefore choose our service providers with the utmost care, contractually stipulating disposal requirements. Each of our vendors must prove that they properly discard our waste. Through random internal audits (and external audits in the United States), we ensure the **appropriate disposal of our waste**, especially when it comes to hazardous substances.

Failure to comply with disposal regulations could result in a fine or damage to our reputation. In terms of our service providers, such a violation may lead us to terminate the business relationship.

# How we organize our waste management and recycling activities

Our Group function Environment, Health, Safety, Security, Quality (EQ) bears overall responsibility for our waste

management and recycling activities, while our EHS managers are in charge of implementing our guidelines and requirements at our individual sites (see Environmental stewardship (p. 87)). In 2017, waste management accounted for around 25% of our EHS spending. This includes the personnel expenses of the units concerned as well as the costs for waste disposal via external service providers.

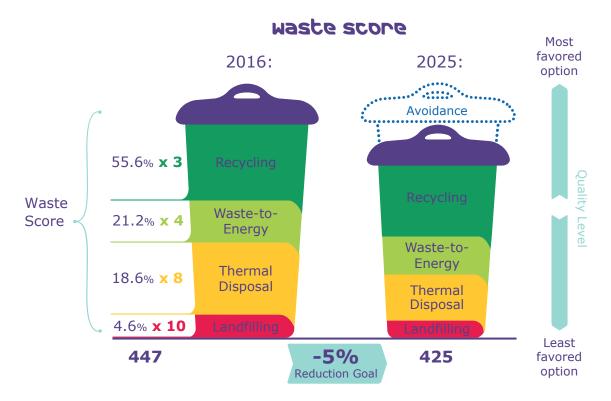
Waste management is part of our Group-wide ISO 14001-certified environmental management system. As well as undergoing external certification, we also conduct internal Corporate Environment, Health and Safety (EHS) audits to review our waste management practices. Moreover, we regularly inform and educate our local EHS managers and site directors on various waste disposal issues, for instance through EHS forums or conferences, in an effort to ensure Group-wide compliance with our environmental standards.

# Our commitment: Group-wide EHS standard

Our Group-wide EHS Waste Management standard provides a **consistent framework for waste management across all our sites**, defining organizational structures and minimum requirements. In line with this standard, all facilities document their waste by type and quantity, reporting this data to EQ.

#### **Our Waste Scoring System**

At our company, we use a variety of methods for recycling and disposing of waste, each of which have a different impact on the environment. To take these impacts into account in our waste reduction efforts, in 2016 we created the Waste Scoring System, which allows us to compare the amount of waste our individual sites are producing and monitor our various waste streams. Under this system, the volume of waste is assigned to one of five categories according to how it is disposed of (see diagram), and then multiplied by a factor that increases based on the disposal method's environmental impact. The sum of the scores of each category provides the total Waste Score of our company.



# Reducing the environmental impacts of waste by 2025

In 2017, we calculated our Group-wide Waste Score for 2016. Based on this score, in 2017 the Executive Board adopted the goal of reducing the environmental impact of our waste by 5% by 2025. To achieve this objective, in 2016 we started examining our production processes and disposal methods to identify potential areas for improvement, continuing these efforts into 2017. All sites are expected to do their part to **reduce waste**. The Waste Score excludes construction and demolition waste, along with waste resulting from the treatment of wastewater.

Relative to 2016, the amount of waste we produced in 2017 remained unchanged at 252 metric kilotons. Construction and demolition waste continue to account for the majority of our total waste – 37% in 2017 and 31% in 2016. In particular, the remodeling of our global headquarters in Darmstadt, to be completed in 2018, has generated large quantities of such waste material.

# Establishing eco-friendlier disposal methods

At our site in Molsheim (France), we are already working towards achieving our new waste disposal target. In April 2017, we switched from incinerating all solid media waste from production activities to composting it. This new method involves filling biodegradable bags with the solid media waste and shipping them to a local composting facility, where the waste is mixed with vegetable and green waste. Once turned

into compost, it can be used by municipalities or individuals for planting. This method is set to reduce the amount of incinerated waste by 80 metric tons annually.

### Reducing filter waste

In 2015, we switched our multi-step filter process for photoresists to a single-step process. Instead of requiring several filters we now use only one, thus decreasing filter waste by around 50%-70%. Already an established practice at our facilities in Hsinchu (Taiwan), Shizuoka (Japan), and Suzhou (China), in 2017 we also introduced the process to our Anseong site in Korea.

### Optimizing and modernizing our Darmstadt site

At our site in Darmstadt, we have initiated various processes to prevent waste and recycle materials. In 2016 and 2017, for instance, a solvent recycling process enabled us to recycle 500 metric tons of methanol, which is generated in the manufacture of excipients for cosmetic products and the amino acid glycine.

In addition to these efforts, in 2016 we replaced our old exhaust air purification system that used an oil scrubber with one that employs a catalytic burner. In 2017, we thus reduced waste generation by 340 metric tons, which translated to savings of around  $\in$  150,000.

# water management

More and more regions across the globe are facing potable water supply issues, and the number of areas suffering from water scarcity is also on the rise. Both the United Nations and the International Council of Chemical Associations (ICCA) consider water conservation a major objective for future efforts. At our sites, we too are dependent on a reliable supply of water that meets certain quality standards. We use water in our manufacturing activities as process water as well as for functions such as cooling and air exhaust purification, which makes sustainable water management a key focus of our environmental stewardship. In doing so, our wastewater may contain traces of heavy metals or pharmaceutical active ingredients. With heightened public awareness of water pollution and increasingly stringent legislation governing water conservation, protecting water as a resource is one of our top concerns.

# Our approach to sustainable water management

We seek to lower our water use and have therefore set ourselves the goal of **implementing a sustainable water management system** at sites with high consumption levels **by 2020.** Along these lines, we are focusing our efforts particularly on regions where water is growing scarcer and therefore intend to cut water use by 10% by 2020 at sites in such water-stressed areas, i.e. those regions where the demand for water exceeds the amount available. At the same time, it is our responsibility to minimize the impact of our wastewater across all our sites, which is why we oblige each individual site to develop and implement a water pollution response plan.

# How we organize our water management activities

Our Group function Environment, Health, Safety, Security, Quality (EQ) (see also Environmental stewardship (p. 87)) bears overall responsibility for water management. At our

individual sites, our Environment, Health and Safety (EHS) managers work closely with engineers to implement water conservation and wastewater treatment measures. In 2017, our water management spending, including the costs associated with purification of wastewater and sewage charges, accounted for approximately 9% of our EHS costs.

### Our commitment: Standards and guidelines

Our processes and responsibility for clean wastewater are defined in our EHS Water Protection standard, which focuses on trace residues that impact the environment. Through internal audits, we verify compliance with our EHS Water Protection standard, which is based on the commitments we've made under Responsible Care<sup>®</sup>. In line with this global initiative, all our sites are required to measure and assess the risks and impacts of the hazardous substances in their wastewater.

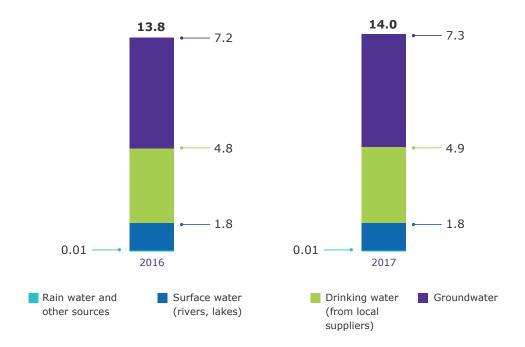
We are optimizing our production and purification processes to minimize the amount of pharmaceutical active ingredient residue in our wastewater. All our pharmaceutical manufacturing facilities also have **wastewater treatment plants** and regularly assess the composition of their wastewater.

Our Group-wide ISO 14001-certified environmental management system (p. 87) also covers aspects of water management. This system places a greater focus on manufacturing sites than administrative facilities since they have the highest potential impact on water.

#### Water from our own sources

For the most part, we draw our process water from our own wells and drinking water from local suppliers. We never do anything to compromise sensitive water sources. However, within the scope of our **sustainable water management activities**, we keep an eye on trends that could potentially lead to sources being classified as sensitive.

### Water use (millions m<sup>3</sup>)



The cooling water used for production processes generally runs in a circular system. Depending on regulatory standards, we sometimes use fresh water in a once-through cooling system if it improves our energy footprint. For certain applications, we treat production wastewater and reuse it. In 2017, we reused a total of 22.4 million cubic meters of water.

### Sustainable water management

For us, sustainable water management means not negatively impacting the bodies of water from which we obtain fresh water, or into which we discharge purified wastewater.

In a bid to mitigate our impact on the water supply, we've set the goal of implementing a **sustainable water management system** at all sites with high consumption levels **by 2020**.

To lay the ground for this undertaking, we are systematically analyzing our water data utilizing tools such as the Water Risk Filter of the World Wide Fund For Nature (WWF) and the Aqueduct Water Risk Atlas of the World Resources Institute (WRI). These tools help us determine, for instance, whether a site is located in a water-stressed area.

For our sustainable water management efforts, we use an assessment tool of the European Chemical Industry Council (CEFIC) to evaluate water management practices and progress at our facilities. Based on this assessment, our sites draft a list of steps that need to be taken and implement them gradually. This often results in the establishment of

best practices such as methods to identify water-saving measures at our various sites.

In 2016 and 2017, we conducted water risk assessments on our sites to investigate where they obtain their water from, what it is used for and where the purified wastewater is discharged. To make their internal water consumption more transparent, several sites installed additional water meters.

However, we also encourage efficient water management at facilities in areas of low or moderate water stress, which is why we are expanding our best practice sharing platform for sustainable water management. Through this medium, our EHS officers can share ideas and lessons learned.

#### Reducing water use

We seek to minimize our impact on the water situation at our sites, which is why we require facilities in areas of high water stress to **transparently report their water use** and identify the process steps that require a particularly high amount. In response to this information, we execute measures to help our individual sites lower their water use. We aim to cut water use at sites in water-scarce regions by 10% by 2020.

Our production sites in Mexico City (Mexico), Mollet del Vallès (Spain), Kankakee, IL (USA), and Norwood, OH (USA) are located in water-scarce regions and consume more than 30,000 cubic meters of water per year. Furthermore, our facilities in Savannah, GA (USA), Hsinchu (Taiwan) and Taoyuan (Taiwan) are at increased risk due to local ground-

water conditions and/or seasonal water scarcity. At each of these sites, we aim to reduce water use by 10% by 2020 relative to 2014. By the end of 2017, we had achieved savings of approximately 9%.

#### High marks for our water management practices

In addition to our climate impact mitigation measures (p. 90), since 2016 we've also been reporting water-related data to the CDP (formerly the Carbon Disclosure Project). This initiative collects environmental data from companies once a year, evaluating their processes and performance on a scale from A to D-. In 2017, we were awarded a B for our water management, thus moving up two places over 2016. This positive score was particularly attributable to three factors, namely our Water Protection standard, the strategic water use goals we set in 2016, and the concrete steps we took to conserve water.

#### Water stewardship

We also implement measures to minimize our negative impacts at sites not located in water-scarce regions. Our manufacturing facilities in India, for instance, abide by a zero discharge policy that requires used water to first be treated before being drained back into the soil. Furthermore, our Goa site collects rain water and lets it seep back into the soil as well, a process that has enabled us to prevent the water level there from sinking further.

### Our wastewater

In 2017 we generated a total of 12.3 million cubic meters of wastewater, with around 50% of our total wastewater being discharged by four sites. Our Gernsheim site in Germany discharges its purified wastewater into the Rhine, our

Savannah, GA (USA) facility into the Savannah River and our Onahama site in Japan into the Pacific Ocean. The wastewater generated at our Darmstadt site is purified in our treatment plants before being fed into Schwarzbach-Ried Creek, a tributary of the Rhine River. In 2017, we discharged a volume of water representing approximately 5% of the average annual discharge of Schwarzbach-Ried Creek. We constantly work to meet the increasingly stringent quality regulations set forth by law, coordinating our efforts with the respective authorities.

#### Wastewater continuously monitored

In 2017 our wastewater management practices were monitored and reviewed in line with our Water Protection standard. As such, 43 internal EHS audits were conducted along with 12 ISO 14001 audits performed by an external certifier. Improvements for self-monitoring were pitched at several of our sites.

#### Antibiotic residues in wastewater

We manufacture antibiotic active ingredients on a small scale. The wastewater generated from these activities is subject to an additional purification process before being discharged into the environment, as is the case, for instance, in Darmstadt. At this site, analyses showed that the amount of active ingredients contained in the wastewater was roughly comparable with that contained in household sewage.

#### Stakeholder dialogue

Starting in 2018, as part of our sustainable water management efforts we intend to engage other local water users in an exchange aimed at further reducing water use.

# plant and process safety



Part of the non-financial report

The safety of our plants and processes is a key element of our environmental sustainability efforts. This approach allows us to ensure the safety of our workforce as well as the people in the vicinity of our sites. Furthermore, functional safety systems help minimize production errors, which in turn lowers the risk of financial losses.

### Our approach to plant and process safety

We seek to eliminate as many manufacturing hazards as possible in an effort to prevent workplace accidents, production outages and chemical leaks. We also attempt to detect technical defects before they have a chance to cause damage. By training our employees, we prevent human errors as far as possible.

# How we organize our plant and process safety

Our Group function Environment, Health, Safety, Security, Quality (EQ) oversees plant and process safety at our company. At the operational level, responsibility for plant and process safety falls to our individual sites and their EHS managers. Crucial to the safety of our plants and processes is above all **fire protection**, which makes up approximately 22% of our EHS spending and primarily encompasses the costs for the fire departments at our sites.

We conduct internal EHS audits to review the safety of our plants and processes. During this process, we also evaluate relevant suppliers, using criteria such as purchasing volumes, criticality of the incoming raw materials and geographic location to decide which ones to audit. Our suppliers are obliged to address any deficiencies identified. Auditors use a follow-up system to monitor the implementation of any corrective measures required.

# Our commitment: Standards and legislation

All our sites are subject to the same requirements for plant and process safety as set forth by our Group-wide EHS Plant and Process Safety standard, which describes the safety rules for all production plants and warehouses. This document encompasses the entire life cycle of a plant from cradle to grave. Before commissioning a plant, we draft a **safety concept** that is subject to constant review and, when necessary, updated until the facility is decommissioned. This concept contains an overview of potential risks and the corresponding protective measures.

Our Group-wide EHS Spillage Control standard governs the handling of hazardous materials and stipulates organizational measures to prevent toxic substances from spilling or leaking during storage and transport. In addition to this standard, our Risk Management Process guides all our sites in identifying and assessing risks. As needed, this process can be used to develop and implement measures to minimize such risks. In 2016, we conducted our Group Procedure Hazard and Operability Study, which clearly defined the individuals responsible for identifying potential hazards during a project as well as the manner in which hazards should be identified and documented.

The 2012 EU directive on the control of major accident hazards involving dangerous substances (aka Seveso III) was transposed into German law at the end of 2016 and entered into force on January 14, 2017. Numerous amendments to this directive affect, for instance, the German Hazardous Incident Ordinance (aka 12th BImSchV). In 2017, we updated the existing processes and documents on the assessment and communication of potential hazards presented by our production plants and warehouses.

In 2017 we also made the necessary **amendments to all our safety reports** in accordance with the new Hazardous Incident Ordinance. On request, members of the public may access these safety reports at any time. We furthermore fulfilled our obligation to provide the public with information, including general information such as the potential hazards caused by an industrial accident, common accident scenarios, and the measures needed to prevent or mitigate their consequences. We update our Hazardous Incident Brochure on a regular basis and, in the case of our Darmstadt site, send the publication to approximately 17,000 households in the site's vicinity. The brochure is also available on our website.

### Making safety measurable

Our **EHS performance indicators** make it possible to measure safety and identify opportunities for improvement. We track EHS performance indicators at all our production and warehouse facilities, as well as at major research sites such as Billerica, MA (USA) and Chilworth (UK). In doing so, we record both accidents and near-accidents. We investigate each individual incident before devising appropriate countermeasures in an effort to prevent such accidents from repeating themselves in the future.

Of particular relevance are the EHS Incident Rate (EHS IR) for recording and evaluating all minor and major incidents, as well as the associated Loss of Primary Containment (LoPC) indicator. Also important is the EHS Leading Rate (EHS LR), which is calculated based on an analysis of near-accidents and critical situations.

In collaboration with our individual business sectors, we have defined specific targets for our EHS performance indicators. The Executive Board receives semi-annual reports detailing the progress of these indicators.

#### **EHS Incident Rate**

Since 2013 we have been tracking the EHS Incident Rate, an indicator that synthesizes the following four categories of data:

- the number of workplace accidents involving our employees and contractors who work at our sites
- environmentally relevant incidents as defined by the European Chemical Industry Council (CEFIC) and the German Chemical Industry Association (VCI), for instance product spills
- the activation of operational safety precautions with no adverse impact on people or the environment, such as a preemptive systems shutdown
- deviations identified during external reviews and audits

The calculation of the EHS Incident Rate includes the number of incidents and the severity of the accident relative to the number of man-hours worked. The lower the EHS Incident Rate, the safer the site is.



was our EHS IR in 2017. It has thus remained at the same stable level as in 2016.

In 2017, we recorded no significant incident-related spills across all production, research and storage sites.

### **Risk Management Process**

Our Risk Management Process guides all our sites in identifying and assessing risks. In 2017, various measures were implemented as part of this process:

Following its acquisition in 2014, we conducted a comprehensive audit of our Suzhou site in China in which we identified shortcomings and subsequently took steps to address them. Continuing with these efforts, in 2017 we improved the plant and process safety of the site's distillation facility.

## **Training and sharing lessons learned**

The safety of our plants and processes is predicated on the successful **interaction between man and machine**, which is why it's crucial for us to educate our employees and provide them with regular training. Our internal continuing education programs for site, production, engineering, and EHS officers also cover plant and process safety. Likewise, newly hired EHS managers are trained in plant and process safety during their onboarding. In 2017, 19 new employees completed the onboarding process.

In the interest of improving safety, it is extremely important to **share best practices and lessons learned**, an approach that enables all our production sites to learn from incidents at other facilities and thereby implement preventive measures. Once a month, for instance, site directors and EHS managers participate in safety leadership calls to share new lessons learned. Additionally, discussion rounds are held by the EHS managers at our sites.

# Biodiversity

The increasing loss of biodiversity is a global challenge that impacts our company as well. After all, we depend on ecosystems for natural resources such as raw materials. Prime examples include red algae (polysiphonia elongata), whose cytoplasm is used in our cosmetic active RonaCare® RenouMer, and comfrey root extract, which is used in our Kytta® pain relief cream. We therefore have a vested interest in preserving and promoting biodiversity.

# Our holistic approach to conserving biodiversity

Across all our sites, we consider the unique features of the ecosystems in our immediate vicinity with the goal of minimizing our direct impacts. Our wide array of **environmental sustainability efforts**, such as water management (p. 97) and climate impact mitigation (p. 90), directly contribute to the conservation of biodiversity.

Our own production sites are located in established industrial and commercial zones. Before acquiring a company – and thus its sites – we first conduct an ecological risk assessment, taking into consideration information from public sources such as neighbors and non-governmental organizations (NGOs). The results of the assessment influence whether we decide in favor of the acquisition.

#### How we conserve biodiversity at our sites

Our measures to protect biodiversity are overseen by our Group function Environment, Health, Safety, Security, Quality (EQ) (see also Environmental stewardship). In designing new sites and plants, we always include our Environment Health and Safety (EHS) unit to ensure that the ecological aspects of a project are also taken into consideration. EHS is on hand to assist all sites with support and advice, and furthermore carries out evaluations in the case of large-scale projects.

# Our commitment: Standards and agreements

Substances that compromise biodiversity should not be discharged into the environment, which is why we design and operate our plants in accordance with our Group-wide safety and environmental requirements. For instance, our Corpo-

rate Environment, Health and Safety (EHS) standards define the way we manage waste (p. 95) and wastewater (p. 97) treatment as well as how we improve plant safety (p. 100). To minimize our impact on the environment, we furthermore adhere to internal standards governing air emissions and energy management.

The Nagoya Protocol is an international supplementary agreement to the UN Convention on **Biological Diversity** (CBD), which was transposed into German law in 2015. The aims of the CBD include the conservation of biodiversity and the sustainable use of its components. An important instrument in achieving these aims is access and benefit sharing. We are currently developing processes that will create a consistent framework for systematically handling resources that fall under access and benefit sharing. We hope to conclude these processes in the course of 2018. In developing products, for instance, we always apply the requirements of the Nagoya Protocol when using genetic resources originating in countries covered by the protocol.

#### **Biodiversity conservation at our sites**

Unsealed surfaces represent an important habitat for plants and animals. At our facilities, however, we are required to seal certain surfaces to minimize the risk of chemicals ending up in the ecosystem. Our goal is to increase the **percentage of unsealed surfaces** insofar as safety requirements permit.

Our Darmstadt site is a prime example of our commitment to preserving biodiversity. Since 2016, we've been conducting an assessment of our facilities there to **evaluate the site's nature conservation efforts**. Based on the results, we have developed an action plan for improving the surrounding ecosystem for plants and animals and have implemented measures to create places of refuge for insects and reptiles. In addition to these efforts, we also assess the flora and fauna of new project sites before commencing activities there. Around 30% of the premises (0.4 square kilometers) have already been greened. In 1995, we developed a green open space concept for our Darmstadt site, while a 2008 agreement with the City of Darmstadt stipulates the ecological, economic and design optimization of our site's green areas.





Supply chain standards

Mica supply chain

# supply chain standards

Our company procures many raw materials, packaging materials, technical products, components, and services worldwide. Our overarching goal is to protect the stability of these supply chains and always provide our customers with the best possible products and services at optimal quality. In our fast-paced world, we believe that secure supply chains are the key to our success.

# Our approach to making our supply chains more sustainable

One of the goals of our supplier management is **compliance** with fundamental environmental and social standards, alongside high quality, delivery reliability, and competitive prices. To achieve this, we've introduced relevant strategies, processes and guidelines that we are continuously improving to prevent violations of supply chain standards.

We assign our vendors a risk category, taking into account their country risk, product category and the share of their sales that come from our company. In doing so, we pay particular attention to suppliers from non-OECD countries, as we consider vendors in these countries to be at higher risk of disregarding environmental and social standards.

To further intensify our activities in this area and identify potential sourcing risks early on, our Procurement unit has developed a concept for a comprehensive risk management system that will enable us to consider a wide variety of risk factors that also include sustainability aspects. Such processes will help us avoid errors and respond promptly to new challenges. This risk management process is defined in collaboration with all businesses involved.

# How we implement CR standards in the supply chain

Group Procurement is responsible for integrating corporate responsibility (CR) requirements into the relevant stages of our sourcing and supplier management processes. It is a global organization with direct accountability and resources in procurement-relevant local subsidiaries. Our Center of Excellence for Supplier Sustainability coordinates all relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives. Our Procurement employees in all countries are kept up to date on these guidelines and processes

through internal communication channels such as our company intranet. All new Sourcing staff are trained on sustainability aspects important for procurement. Sourcing employees are responsible for the supplier selection process.

#### **Our commitment: Guidelines and standards**

We expect all our suppliers and service providers to comply with environmental and social standards, which are primarily derived from the core labor standards of the International Labour Organization (ILO) and the UN Global Compact.

Moreover, we support the Compliance Initiative of the German Association for Supply Chain Management, Procurement and Logistics (BME) and have endorsed the BME Code of Conduct. In particular, this code sets out rules for combating corruption, antitrust violations and child labor, as well as for upholding human rights, protecting the environment and public health, and promoting fair working conditions.

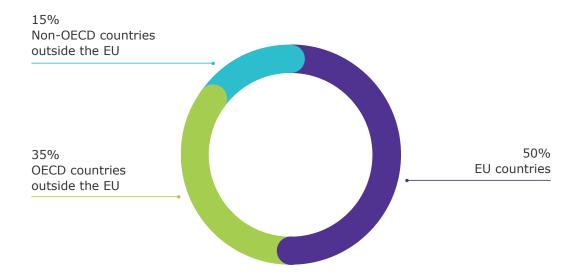
Our Group Procurement Policy stipulates our **expectations of our suppliers** and specifies how we monitor compliance with our standards. This policy further reflects both internal and external guidelines, such as our Code of Conduct, our Human Rights Charter, our EHS Policy (Environment, Health and Safety Policy), ISO 14001, and the BME Code of Conduct. In our Responsible Sourcing Principles we set out our expectations for our suppliers in terms of corporate responsibility, and formally oblige them to apply these standards to their own vendors.

Whenever legal frameworks are modified, we incorporate these changes and initiate the appropriate measures where necessary.

## **Global procurement**

In total, the goods and services we purchased from more than 64,000 suppliers in over 145 countries in 2017 amounted to around € 7.0 billion. Of these goods and services (including R&D services), we purchased 50% from suppliers based in EU countries and 35% from vendors based in OECD countries outside the EU. The share of goods and services sourced from suppliers based in non-OECD countries outside the EU increased from 14% in 2016 to 15% in 2017.

#### Share of overall goods and services purchased



# Strategy workshop on sustainability within the supply chain

In August 2017 we held a workshop in Darmstadt focusing on sustainability within the supply chain. At this event we worked with external experts to analyze which aspects of supply chain sustainability will become increasingly important to us. The aim was to uncover risks and opportunities within our supply chain and devise appropriate actions.

## How we monitor our supply chain

We pursue various approaches to keep track of our suppliers and ensure adherence to our standards and values. These approaches are generally based on the risk they pose, combining the factors of country risk, product category and sales.

- Under the Together for Sustainability (TfS) initiative launched by companies in the chemical industry, we encourage our suppliers to be assessed either on selfreported information or via audits.
- In selected cases we conduct our own CR audits on suppliers.
- Regarding our mica supply chain (p. 106), we engage the global consultancy Environmental Resources Management (ERM) to conduct audits and the Indian organization IGEP to conduct inspections.

#### TfS supplier assessments and audits

Under TfS, suppliers are assessed either on information obtained during audits, or on the basis of self-reported and publicly accessible information provided by EcoVadis, an independent rating agency. EcoVadis assesses suppliers from 110 countries and 150 sectors across the four categories of Environment, Labor Practices, Fair Business Practices, and Sustainable Procurement. The results of these supplier assessments are shared among TfS member companies in compliance with all restrictions stipulated by competition law. In 2017, the TfS initiative realigned its strategic focus to concentrate more strongly on the initiative's demonstrable improvements of supplier sustainability standards. We've been a member of TfS since 2014.

We now have access to the sustainability checks of more than 730 of our suppliers – 463 of which we initiated in 2017. Based on all the audits and assessments conducted since joining the TfS initiative, in 2017 we focused on risk reduction and risk management. Our priority was the mitigation activities for TfS audit results, with more than five major findings and assessment scores below 30 (on a scale of 1 to 100). In 37 cases, the issues related to environmental impacts, in 100 cases to labor practices and human rights, and in 65 cases to impacts on local communities and society as a whole, while some suppliers were found to have multiple issues.

#### Conducting our own audits

In 2017 we conducted five of our own risk-based CR audits, assessing vendors according to both environmental and social criteria. The non-conformances identified for two suppliers as having a potential environmental impact were related to air emissions and waste management/ground contamination. In terms of social aspects, the audits found no deficiencies. To correct the ecological shortcomings, we jointly agreed on a corrective action plan and are monitoring our vendors' progress to ensure that the improvements are being made. The defects identified did not lead us to terminate business ties with any of the suppliers.

Neither our audits nor those of TfS revealed indications of violations of the right of association, the right to collective bargaining, cases of child labor, forced labor or compulsory labor.

#### Impact on our vendors

In 2017, one of the goals we set was to make a greater impact on our suppliers' sustainability. To achieve this, we

teamed up with vendors relevant to future procurement activities whose audits revealed critical sustainability defects. Together, we identified ways to boost sustainability and then monitored their implementation.

### Favoring local suppliers for certain products

We have no internal guidelines stipulating that preference be given to local vendors in allocating contracts, and generally procure our goods and services globally. However, in some cases local vendors do have an advantage: Products bought locally may be less expensive, as proximity eliminates additional transport costs. Country-specific regulations such as import duties and licenses also help us decide whether to source our goods locally or globally. Furthermore, in some countries local laws require contracts to be awarded to regional suppliers.

# mica supply chain

Mica is the primary raw material of our effect pigments, which are used in applications such as automotive and industrial coatings, as well as in the cosmetics and food industries. Although it naturally occurs in many locations around the world, we mainly procure mica from India, where it is mined in the northern states of Jharkhand and Bihar. This region suffers from political instability and poverty with widespread child labor, so we've taken special measures to ensure compliance with our social and environmental standards.

# Our approach to responsibility in the mica supply chain

Following a study conducted in 2008, we found that the people in Jharkhand and Bihar were gathering mica from the tailings of abandoned mines or off the ground– sometimes together with their children. This constitutes a clear violation of our company values and our Human Rights Charter. We do not tolerate child labor and contractually prohibit our suppliers from employing children.

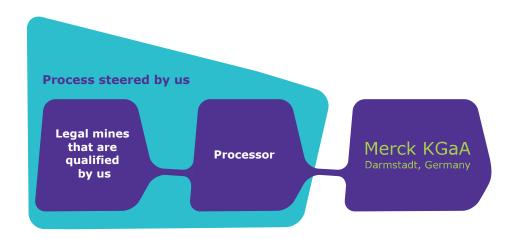
We have made a conscious decision to maintain our business relationships in the north of India and are taking on responsibility for this region by safeguarding jobs there. To ensure that we procure mica without the use of child labor, we have completely reorganized our supply chain and now source the raw material exclusively from qualified mines. This formal working environment is the only way to ensure compliance with our standards, since child labor cannot be ruled out if mica is gathered in publicly accessible areas.

### How we organize our mica supply chain

We maintain direct, regular contact with mine lease holders, mine operators and mica processing plant owners. We have informed our business partners about our social and environmental standards, and they support our efforts to keep the mica supply chain free of child labor. Our Procurement staff in Kolkata, India are in direct contact with these partners; they are present at the mines or processor sites during

audits and customer visits and are available to answer any questions or address complaints. Whenever non-compliance with our standards is identified, we work with suppliers to ensure the appropriate and swift implementation of corrective measures. This year we therefore suspended two supplier relationships. A corrective action plan was put forward, and the suppliers are now implementing the rectification measures we required.

### The mica supply chain



## Our commitment: Compliance with guidelines and standards

As a signatory to the United Nations Global Compact, we are actively involved in working to abolish child labor. Going above and beyond the legal requirements, we are committed to ensuring that our mica supply chain adheres to the same internal and external standards and guidelines that apply to our other supply chains (p. 104).

## **Auditing our mica supply chain**

To ensure that all mines and processing companies adhere to our standards, we monitor our business partners for **compliance** with our environmental stewardship requirements as well as occupational health and safety regulations. We carry out comprehensive pre-announced audits, as well as unannounced inspections.

#### Annual audits

Environmental Resources Management (ERM), a global provider of consulting services, conducts annual audits that review the working conditions along with **environmental**,

**health and safety standards**. Audit reports are compiled to document any identified shortcomings and define corrective actions. Our employees in Kolkata and Darmstadt subsequently make sure that these issues have been resolved.

In March 2017 ERM conducted nine audits. The majority of the corrective measures identified in previous audits had already been implemented at this point, or were underway. Identified defects primarily involved occupational safety precautions and gaps in the implementation of management systems. When violations are discovered, we work together with the suppliers to ensure that these are corrected in a satisfactory manner. When breaches are not rectified through the appropriate corrective action, we freeze relations with the respective company, or even terminate the business relationship altogether.

Following an amendment to Indian legislation, the responsibility for the licensing of mines was transferred from the Central Government of India to the individual states. To support the mine operators in complying with this new legislation, ERM analyzed the relevant processes in the mines between August and October 2017. At a joint workshop we explained the new approval process to the mine operators and mica processing companies.

#### Monthly inspections

Since 2013, the Indian organization IGEP has been carrying out unannounced monthly inspections of working standards in mines. In 2017 four mica mines and five processing plants were checked by IGEP. During these inspections, IGEP monitors **occupational safety and compliance with the ban on child labor**, for instance, as well as consistent process documentation. They also check whether our suppliers have held the mandatory training sessions for their employees.

#### Tracking system for mica sources

We use a tracking system to ensure that the supplied mica comes exclusively from legal mines qualified by our company. All mine owners record the daily extraction volume of their mines in a logbook. The license fees that the mine owners must pay to the government are based on these documented amounts of mica. On a monthly basis, we review the volumes of mica reported in the logbook and supplied to the processing companies. Furthermore, we carry out a cross-check by verifying the relevant transport documentation, known as "challans".

In November 2017 our employees surveyed the mining activities of our suppliers to document the actual daily output of the mica mines and cross-check the actual output against the documentation provided.

# Community outreach in the mica supply chain

The states of Jharkhand and Bihar are among the most impoverished regions in India. Together with IGEP, we are working to improve the **living conditions of the families** in the mica mining areas. The literacy rate and the number of children who attend school are far below the Indian national average, according to a 2016 study by the organization Terre des Hommes and the Centre for Research on Multinational Corporations. Among our efforts, we are financing three schools run by our partner IGEP in Jharkhand, where more than 500 children and adolescents are enrolled. Moreover, tailoring and carpentry courses are also offered. At a fourth

school opened by one of our mica suppliers in 2014, we achieved our goal of providing scholarships for 200 children in 2017.

In addition to our education efforts, we are committed to improving **local access to healthcare**. To this end, in 2010 we established a health center operated by IGEP to serve the region's 20,000 residents. Two medical professionals work at the center and also provide regular health services to schools. Previously there was no healthcare of any kind in this region.

# Stakeholder dialogue on the mica supply chain

We keep interested customers and other stakeholders regularly informed on our mica sourcing activities. Our employees in Kolkata and Darmstadt also maintain contact with our project partners and other advocacy groups, as well as with local and state authorities.

In November 2017, we attended the kick-off conference for the Responsible Mica Initiative in Delhi. We are a founding member of this initiative, which was established following the Mica Summit 2016. The program is committed to improving the traceability of mica in the supply chain and building sustainable **living conditions in local communities**. At the summit, a five-year implementation plan was announced to achieve a fully traceable and responsible mica supply chain in India, mainly focused on eliminating child labor and improving occupational safety in India's mica industry.

### New sources of mica

We have found additional sources of mica outside India that meet our stringent quality, social and environmental standards. Part of our mica, for example, is now supplied by Brazilian companies. In this way, we are securing the supply of this raw material over the long term and avoiding potential supply bottlenecks. Furthermore, as an alternative to pigments based on natural mica, we also manufacture effect pigments based on synthetic substrates.





**110** Community Involvement

**111** Health

114 Education and culture

# community involvement

We take on responsibility for the community in those areas where we can leverage our expertise. In particular, we support health, culture and education projects in the vicinity of our sites and in the countries where we operate. Moreover, we provide disaster relief in emergency situations.

### Our approach to community involvement

Across all our facilities worldwide, we are deeply committed to supporting our communities. In selecting social projects, we choose initiatives that align with our strategic focus areas, namely health, environment, and education & culture.

We are particularly determined to facilitate access to health for people across the globe. To do so, we take a multipronged approach that includes **numerous health projects** (p. 111) aimed at supporting communities. In doing so, we apply our competencies, knowledge and experience in the health industry, joining forces with dependable partners to provide people the help they need.

We view education as a key component of culture – and vice-versa. Education can help us understand culture, but culture can also build a bridge to education; it can stimulate curiosity, nurture creativity and inspire scientific discovery. We therefore sponsor **cultural initiatives** (p. 115) and support a number of **educational projects** (p. 114) to **spark a passion for science** in the next generation. As part of these efforts, we deploy our expertise to encourage and inspire curious young people who share our passion for science and technology.

Our activities are intended to have a positive, long-lasting effect on the community, which is why we promote many long-term initiatives, an approach that strengthens our relationship with stakeholders and helps reinforce our social license to operate.

#### How we structure community support

Our Group function Corporate Affairs monitors our Groupwide community outreach and oversees a portion of our activities, including our Praziquantel Donation Program (p. 111), the Global Pharma Health Fund (GPHF) (p. 111) and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany (p. 114). In addition to Group-wide efforts, our business sectors pursue their own projects such as our educational initiative SPARK (p. 114). Moreover, since 2017 several of our health initiatives in low- and middle-income countries have been operating under the auspices of the Foundation sponsored by Merck KGaA, Darmstadt, Germany (p. 111), a non-profit limited liability company. Furthermore,

our regionally focused activities are planned and executed by our local subsidiaries, who choose for themselves the focus areas within our CR strategy (p. 9) that they would like to support.

The Merck family, too, has long been committed to philanthropic work. Since 2016, their activities have fallen under the umbrella of their Family Foundation, which takes on social responsibility by supporting projects that bring benefits to the people in the vicinity of our sites. This organization focuses on healthcare and education, promoting citizens' initiatives, development cooperation, intercultural understanding, and non-profit objectives. It cooperates with government and scientific institutions as well as nongovernmental organizations, and especially supports projects that our employees are privately involved in.

### Our commitment: Principles for our community support

We align our projects with our Group Policy on Contributions to Society, which defines community involvement for our company along with the objectives we pursue. This policy also sets out roles and responsibilities, emphasizing that our activities should have a long-lasting, positive effect on the community. With this in mind, we focus our efforts on long-term projects.

This guideline provides our business sectors and subsidiaries with a framework for structuring their own respective activities.

### Our community involvement in numbers

In 2017, our subsidiaries were involved in 250 projects, spending a total of around  $\in$  34 million. This figure does not include initiatives that primarily serve to market our products.

#### **Local efforts**

In 2017, more than 400 of our U.S. employees took part in the annual EMD Serono Community Service Day. Trading their working day to help out in the community, they volunteered at various **non-profit organizations** in the vicinity of Boston, MA (USA). Here they engaged in a number of activities, such as painting pictures on hospital walls, planting gardens, giving science lessons to more than 150 elementary school children, helping out at local soup kitchens, and sorting packaged goods at local food banks. In total, our people in the United States invested over 1,500 hours in the local community.

In 2017, our employees in Brazil also engaged in **volunteer work** to help Rio de Janeiro's underprivileged inhabitants. Under our Community Action program, over 120 employees from Rio de Janeiro and São Paulo donated their time to support local institutions and provide assistance for services such as free

health exams, legal advice and cultural activities. For instance, local residents had the chance to undergo vision screening, with our company providing free eyeglasses to approximately 160 people with a visual impairment.

In Darmstadt, too, we view ourselves as **part of the community** and therefore contribute to a colorful, rich environment by supporting valuable ideas along with regional clubs and initiatives. In addition, we focus on promoting science education (p. 114) and cultural institutions.

### **Partnering with the Red Cross**

We partner with the German Red Cross (DRK) in a bid to provide relief when disaster strikes. In 2017, for instance, we donated  $\in$  18,000 to provide **aid to Yemen**. This donation went towards the German Red Cross's efforts there, setting up health stations and providing clean drinking water and food. In addition to this monetary donation, we also supplied the local health stations with sterile gloves valued at more than  $\in$  21,000.

Our subsidiaries also make regular donations to local Red Cross and Red Crescent organizations. In the United States, for instance, our Life Science business sector donated more than € 80,000 in 2017 to help the victims of hurricanes in Texas, Florida and Puerto Rico. The money was used to provide **accommodation, food and medical aid**.

### **Emergency relief following earthquake in Mexico**

After the powerful earthquake in Mexico in September 2017, our subsidiary there donated 5,000 packs of Dolo Neurobion®, our painkiller for neuropathic pain, to the Fundación IMSS, an organ of the Mexican Social Security Institute. This foundation distributed the medicine among people who were injured by partially collapsed houses or falling pieces of furniture, as well as to the wealth of helpers who were suffering pain due to the great physical strain. Our company also donated various toiletries, with our employees in Mexico donating an additional half-truck load of food and toiletries. We covered the cost of transporting the items to the affected communities.



We use our expertise to support health initiatives all over the world, particularly concentrating on promoting local health-care infrastructure, providing vocational training and continuing education for medical professionals, and educating people on health issues. In particular, we are dedicated to fighting the neglected tropical disease schistosomiasis.

# Our commitment: The principles governing our community involvement

As in the other areas in which we support the community, we align our health activities with our Group Policy on Contributions to Society. (p. 110) In addition to this policy, our Access to Health Charter also governs all health initiatives, covering pharmaceutical product donations, counterfeit medicines, and research and development for neglected tropical diseases. We calculate the value of our pharmaceutical product donations according to the WHO Guidelines for Medicine Donations.

### Fighting schistosomiasis

Worldwide, more than 200 million people suffer from schistosomiasis, a tropical parasitic infection that causes over 280,000 deaths in Africa every year. In an effort to battle this disease, we developed the active ingredient praziquantel in the 1970s under a joint research partnership. This drug is the only active ingre-

dient that can treat all forms of schistosomiasis. Since 2007, we have been **partnering with the World Health Organization** (WHO) and providing them with donations of praziquantel tablets.

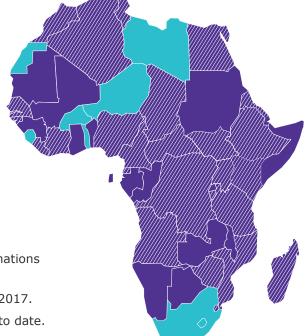
In 2017, we formed our Global Health Institute (p. 41) with the aim of creating innovative and integrated healthcare solutions for underserved populations in developing countries. Through our institute, we are also an active member of the Pediatric Praziquantel Consortium, a partnership we initiated. Within this consortium, we are working hand in hand with our partners on the development of a pediatric formulation of praziquantel for children under six (p. 38). In a bid to achieve this objective, in 2016 the Global Health Institute launched a Phase II study in Côte d'Ivoire. We expect the initial results of the study to be available in 2018.

### Schistosomiasis: 150 million children treated

We keep production capacities at a level sufficient for manufacturing 250 million praziquantel tablets a year. In response to the needs of the World Health Organization, in 2017 we donated approximately 150 million tablets for distribution in 26 African countries. This year, our donation program was expanded to include Egypt and Uganda. Since its launch, we have **supplied almost 700 million tablets free of charge**, enabling the treatment of 150 million patients, primarily school children.

#### Countries that have received donations of praziquantel tablets

Since 2007, we've donated nearly **700 million** praziquantel tablets for distribution across 43 nations in Africa.



- African countries that started receiving tablet donations from us before 2017.
- African countries to which we donated tablets in 2017.
- Countries that have received no donated tablets to date.

#### Spreading education and awareness

Since 2012, we've been donating comic booklets to African schools in a bid to help educate children on schistosomiasis. In easy-to-understand terms, these booklets explain how people can protect themselves against this tropical disease. In 2017, the materials went to 12 African countries, seven of which for the first time. In cooperation with WHO, we provided schools with approximately **200,000 booklets in five different languages**.

In addition to these efforts, we also supplied WHO with around 20,000 educational brochures and 2,000 posters on female genital schistosomiasis, the first time we have provided information on this specific manifestation of the disease. In endemic countries, this form of the infection is rarely mentioned in medical curricula or text books, meaning female genital schistosomiasis often goes undetected or is misdiagnosed. These materials aim to educate physicians on the symptoms to make it easier to diagnose the condition.

### **Our Schistosomiasis Education Project**

Since 2016, we've been financially supporting NALA, a foundation that works in concert with local communities to improve the water supply and sanitation while also educating people about neglected tropical diseases (NTDs). In 2017, the Ethiopian Federal Ministry of Health tasked the NALA Foundation with carrying out a national technical assistance project to combat NTDs. Through

improving sanitation and education, the foundation aims to make lasting behavioral change – a crucial step to eliminating schistosomiasis. This project is set to reach approximately 290 schools with over 260,000 students in Bench Maji, a region in southwestern Ethiopia. The goal is to extend this model to other regions in Africa. Under our Schistosomiasis Education Project launched in 2017, we're providing the NALA Foundation with nearly € 300,000 over a period of three years.

### Central platform in the battle against schistosomiasis

We realize that we're not going to eliminate schistosomiasis with tablets alone. That is why, at the end of 2014, we launched the Global Schistosomiasis Alliance (GSA) and **joined forces with international partners** in a bid to address the remaining gaps in the fight against this infection. Its founding members include the Bill & Melinda Gates Foundation, the Schistosomiasis Control Initiative (SCI), the United States Agency for International Development (USAID), and World Vision International.

In 2017, the GSA expanded its role as a central platform in the fight against schistosomiasis, acquiring a series of international NGOs as new members. As well as organizing several conferences, it took part in various projects aimed at driving local efforts to combat schistosomiasis. In Egypt, for instance, the GSA contributed its expertise to support the Ministry of Health in implementing its national strategy to eliminate the tropical disease.

<sup>\*</sup> Launch of our Praziquantel Donation Program.

In addition to these efforts, the GSA garnered attention at the 2017 Neglected Tropical Diseases Summit in Geneva with its #MakingSchistory campaign. Conducted to mark the the tenth anniversary of our Praziquantel Donation Program, this campaign has helped raise awareness for the disease. Moreover, the GSA also published a report entitled "The people #MakingSchistory: The global fight against schistosomiasis. This work recognizes the outstanding successes of people dedicated to combating the tropical disease and explains how it can be defeated once and for all.

### Fighting counterfeit medicines

According to a report published by the World Health Organization (WHO) in 2017, more than 10% of all medicines in developing and emerging countries are counterfeit or substandard, making them a major health risk. The Global Pharma Health Fund (GPHF), a non-profit initiative funded by our company, is fighting counterfeit medicines with its GPHF Minilab®.

The GPHF Minilab® is a **portable, compact laboratory** that fits into a tropics-resistant suitcase and can detect falsified medicines quickly, easily and inexpensively. The GPHF develops the Minilabs, supplies them at cost and provides training on how to use them. According to the aforementioned WHO report, the Minilab is one of the most important tools for detecting counterfeit, substandard and falsified medicines. As part of a study published in this report, more than 20,000 pharmaceutical samples were tested using the Minilab, with more than 1,000 of them identified as counterfeit. An international study conducted by the Difäm-EPN Minilab Survey Group in 2017 also reaffirmed how the GPHF Minilab® has helped ensure access to safe medicines in developing countries. The Minilab is currently the only product of its kind.

The majority of Minilabs are deployed in countries in Africa and Asia. These test kits are primarily utilized by national health agencies, often in partnership with the labs of governmental drug inspection centers or within multilateral health initiatives led by various UN organizations, U.S. and German aid organizations, faith-based networks, or the incoming goods inspection unit of faith-based healthcare facilities.

### Expanding Minilab use

In 2017, the GPHF developed testing methods for five additional active ingredients. As of early 2018, the Minilab **can now test 90 active ingredients**, ranging from antimalarials, antihistamines and analgesics, to antipyretics and antibiotics.

Since 1998, the GPHF has supplied a total of 836 Minilabs to nearly 100 countries, 41 of which were provided in 2017 alone. Of these 41 test kits, our company donated six to the pharmaceutical regulatory agency in Sierra Leone. The frequent reordering of materials confirms that the Minilabs are in high circulation.

### Minilab training seminars

In 2017, the GPHF and its partners held a total of ten seminars for Minilab users, mainly in Sub-Saharan Africa, which were attended by well over 100 people. During these seminars, participants learn how to correctly test medicines using the compact laboratory. While the number of Minilab seminars is increasing every year, the GPHF itself is called on for support less and less. This is a good sign: The Minilab is gaining traction, and users are taking the initiative to share their knowledge with others.

### Health projects worldwide

We are dedicated to improving medical care around the world. Every year, our Global Medical Education Department sponsors an **array of continuing education initiatives** for healthcare professionals. In doing so, we are helping build the capacities of nurses and physicians, increasing their awareness of symptoms and familiarizing them with advanced treatment methods, which ultimately benefits patients. In 2017, we supported more than 70 different continuing education programs offered by 30 independent educational institutions in the medical sector with over € 7 million. Via e-learning platforms and continuing education courses, more than 350,000 medical professionals took advantage of the offerings of these institutions.

In 2017, we launched the Broaden Your Horizon program, which encourages our Biopharma employees to spend three months working at an NGO in a developing or emerging country. During their stay, they have the opportunity to contribute to **improving the quality of local healthcare**, while also broadening their own horizons. Four of our employees took part in an initial pilot project in India, where they contributed their expertise in fields such as laboratory management and data analysis.

Established in 2017, the Foundation sponsored by Merck KGaA, Darmstadt, Germany also seeks to raise health awareness (p. 47) and improve healthcare in low- and middle-income countries. Consolidating many of our existing projects under one roof, its main aim is to bolster our access to health efforts.

We also support a wide variety of other projects, an overview of which can be found on our website.

### Education and culture

Underpinned by a longstanding tradition, the promotion of education and culture is a core element of our commitment to society. By making education and culture accessible, we nurture characteristics that are essential to us as a high-tech company, namely creativity, enthusiasm for new discoveries, curiosity, and the courage to transcend boundaries. With this in mind, we sponsor such initiatives at many of our sites, grant scholarships and facilitate learning in specific subjects.

## Our commitment: Principles for our community involvement

When it comes to our commitment to the community, we align our educational and cultural activities to our Group Policy on Contributions to Society, which is detailed under Community involvement (p. 110).

#### **Dedicated to education worldwide**

We are committed to **igniting a passion for science** especially among young people, which is why we've been supporting initiatives such as the "Jugend forscht" competition for more than 30 years. Since 1996, we've been organizing the state-level competition for the German Federal State of Hesse and have also hosted the nationals twice.

### Laboratories at TU Darmstadt expanded

We encourage young people to come to our Junior Labs and explore their **enthusiasm for conducting experiments.** This initiative links classroom lessons with trending topics and modern methods of research. Since 2008, we've been partnering with the Technical University (TU) of Darmstadt to operate a junior laboratory for chemistry. In 2017, we upped our efforts by adding experiments in new subject areas such as dyestuff synthesis and enzyme kinetics. Over the course of 2017, approximately 2,500 students conducted research here. Since 2016, we've also been running the "livfe BioLab", where students can perform biology experiments under professional guidance. In 2017, more than 1,000 students took advantage of this laboratory.

# Continuing education for teachers and expanding school partnerships

As part of our school booster program in Darmstadt and the surrounding area, in 2017 we provided approximately 70 schools with numerous science lesson materials. Around 1,500 students visited our research labs, select manufacturing plants and the classroom laboratory at our headquarters.

In Darmstadt, we support teachers through **continuing education classes** in their field of expertise and also provide educational concepts. In 2017, we once more hosted a science conference attended by more than 200 teachers from the region. In tandem to this, we offered three continuing education courses on the digitalization of classroom laboratory experiments. For our efforts, we were honored with the SchuleWirtschaft-Preis (School-Business Germany Award). In the German Federal State of Hesse, we were awarded first place in the "Business-School partnership for digital education" category.

In 2017, we initiated a pilot project to leverage the experience we've gained through long-standing school partnerships in the Darmstadt area and apply it in other countries. Having already launched one project in India in 2017, others are scheduled to follow in Chile, Kenya and Tanzania in 2018. These efforts focus on providing teachers with the tools to design exciting lessons that will spark their students' curiosity in science. We are partnering closely with education experts to develop the concepts for these lessons. Thanks to their invaluable experience and knowledge of the cultural landscapes in the respective countries, we can adapt experiments to local environments and introduce our technologies. An experiment in Tanzania, for instance, will show how food analyses are conducted using the example of local fruits. You can read more about our international education efforts in the magazine section of this report.

### SPARK: Igniting a passion for science in the next generation

As part of SPARK, our global volunteer program, employees from our Life Science business sector share their skills and experience with students in order to ignite a passion for science and inspire them to consider a STEM-related career. SPARK activities include our **Curiosity Labs<sup>TM</sup> program**, which educates students through exciting hands-on, interactive science lessons. Beyond this, we also offer them site tours and career discussions. In addition to providing all the materials pupils need for the practical lessons, we collaborate closely with education experts around the world to ensure that SPARK meets specific local requirements. In 2017, through this initiative, more than 2,500 of our employees volunteered over 13,700 hours around the world to provide exciting insights into the world of science and strengthen our communities.

#### Curiosity Cube tours the United States

As part of SPARK, in 2017 we launched the Curiosity Cube<sup>TM</sup>, a retrofitted shipping container that has been transformed into a solar-powered **mobile science lab**. The goal of this mobile lab is to bring hands-on science experiments and

state-of-the-art technology in an innovative setting to spark curiosity in the next generation of scientists. In 2017, more than 38,000 students visited the mobile lab. Each one of the nearly 23,000 experiments conducted was led by a Life Science employee.



kilometers were covered by the Curiosity Cube<sup>™</sup> throughout the United States. It stopped at schools and city centers in over 85 communities.

Most importantly, the Curiosity Cube<sup>TM</sup> had a direct impact on student achievement and cognition. Following a visit, surveyed teachers indicated that 82% of students used terms and concepts learned at the Curiosity Cube<sup>TM</sup> in classroom discussions, while 95% of students increased their understanding of life science terminology.

### Taiwan: Lab experiments in railway cars

In May 2017, we took part in Taiwan Railways of Popular Science, an event held in Taiwan in which a **science train** made a four-day journey across the country. With it, 27 of our employees traveled to 17 cities, teaching more than 3,000 students about the science behind everyday products and supervising experiments such as how to make liquid crystal display or cosmetics. The science train was developed by professors of two Taiwanese universities in 2016 and is sponsored by the Taiwan Ministry of Science and Technology.

#### Mobile research lab for environmental analysis

In 2017, we once more lent support to the "Chemistry on the go" initiative of Tamkang University in Taiwan. Under this initiative, Tamkang University has converted a truck into a **mobile research lab for environmental analysis** to give students even in remote parts of Taiwan the opportunity to perform scientific experiments. We've been supplying laboratory materials for the truck since 2014. In 2017, around 20 of our employees also taught classes to approximately 1,000 students. Beyond these efforts, in the course of 2018 we plan to donate a second, fully-equipped laboratory truck to Tamkang University in an effort to reach even more school children.

### Partnering with Seeding Labs

In 2017, we sponsored a new online platform for Seeding Labs, an organization that provides **scientists in developing and emerging countries** with lab equipment, training and opportunities to collaborate with experts in their

field. This TeleScience platform will feature 11 educational videos and training sessions led by our Life Science employees, who share techniques and tips on a wide range of topics such as sterile sampling and reducing cell culture contamination. Under the auspices of this organization, we also donated laboratory equipment to nine universities in seven countries in a bid to accelerate scientific research. More than 30 employees volunteered their time to help select, decontaminate, inventory, and pack items for donation.

### Sparking the curiosity of Chinese primary school children

At the beginning of 2017, we launched the Green Crystal project in China by donating second-hand yet still fully functional tablets to two elementary schools in Sichuan province. The aim of this project is to improve **science education** for primary school students. In September 2017, 17 of our employees in Shanghai participated in this project, traveling to the schools, teaching lessons and supervising scientific experiments. In 2017, around 400 children benefited from this initiative.

#### Music and literature as ambassadors

### Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany

What began in 1966 as a company ensemble is now a professional symphony orchestra. The Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany is an integral part of cultural life in Darmstadt and regularly goes on international concert tours. We also offer orchestra workshops where children and adolescents can experience playing in a professional orchestra for the first time. Through cushion concerts for children as young as four and youth concerts, we seek to inspire young people and ignite a passion for classical music.

In 2017, guest directors such as Joseph Bastian and Yoel Gamzou helped us celebrate the **50th anniversary of the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany**. Ben Palmer was appointed head conductor and gave his inaugural concert in the basilica of Eberbach Abbey in Eltville am Rhein (Germany). Other guest performers included the Klazz Brothers and the European Union Baroque Orchestra.



people attended performances of the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany in 2017. As part of its international tour, the symphony performed concerts in Morocco, Austria, and the Czech Republic.

#### Building social inclusion through music

In the vicinity of our site in Rio de Janeiro (Brazil), where many children and young people face social instability, we support the School of Music and Citizenship. Since 2011, around 3,700 children and adolescents have received music lessons at this school, with approximately 1,100 in 2017 alone. The dedication of this music school has produced a successful youth orchestra with approximately 40 talented young musicians.

#### Literary awards for bridge builders

Like music, literature is also an important ambassador between cultures. We therefore award **five literary prizes worldwide.** The Johann Heinrich Merck Award for Literary Criticism and Essay Writing in Germany of Merck KGaA, Darmstadt, Germany and the Premio Letterario Award of Merck KGaA, Darmstadt, Germany in Italy are presented on an annual basis, while the Kakehashi Literature Prize of Merck KGaA, Darmstadt, Germany in Japan, the Tagore Award of Merck KGaA, Darmstadt, Germany in India, and the Translation Award of Merck KGaA, Darmstadt, Germany in Russia are granted every two years. These prizes particularly recognize authors who distinguish themselves as bridgebuilders between cultures, as well as between science and literature.

Worth € 20,000 and launched in 1964, the Johann Heinrich Merck Award of Merck KGaA, Darmstadt, Germany for Literary Criticism and Essay Writing went to journalist and author Jens Bisky in 2017. According to the German Academy for Language and Poetry, he was chosen for his "brilliant style, cosmopolitan outlook and witty levelheadedness, which, given the acuity of his judgment, makes him one of the most reliable voices in current discourse".

In Italy, we've been awarding the Premio Letterario Award of Merck KGaA, Darmstadt, Germany since 2003 in recognition of authors who make science accessible to a broad audience. Worth € 10,000, the 2017 prize was presented to U.S. author Sam Kean for his essay "The Violinist's Thumb". The jury decided on an honorable mention for Paolo Zellini, an Italian mathematician, author and professor. Both have a special understanding of how to bridge the gap between literature and science.

In Italy, we also pledge resources to promoting the **next generation of literary genius**. In addition to creative writing workshops, we host a youth writing competition. The winners of La Scienza Narrata are chosen together with the winners of the Premio Letterario Award of Merck KGaA, Darmstadt, Germany.

# facts & figures



- 118 Report profile
- 120 Indicators
- **148** Goals
- **159** Recognition and rankings

- **161** Sustainable Development Goals
- **164** Non-financial report
- 173 GRI Content Index
- 190 Global Compact CoP

# Report profile



We have a long tradition of corporate responsibility reporting, with this being our ninth Corporate Responsibility (CR) Report. This started in 1993 as a series of environmental reports describing how we fulfill our responsibility to society, but then evolved in 2003 into a full CR Report that was released every two years. Since 2016, we've been publishing this report on an annual basis.

With transparency as a key goal, we aim to inform our stakeholders of our activities and successes, as well as the challenges we face. Our 2017 Corporate Responsibility Report is the first time we've met the requirements for a combined separate non-financial report as defined in the CSR Directive Implementation Act that took effect in Germany in 2017. An index on the non-financial report (p. 164) provides an overview of the relevant content. This CR Report also documents the progress we've made in implementing the principles of the United Nations Global Compact (Communication on Progress (p. 190)) and meets the criteria of the German Sustainability Code (DNK). Our Statement of Compliance with the DNK can be accessed via the DNK database.

### **Reporting framework**

This CR report covers fiscal 2017 and pertains to our entire Group including our subsidiaries across 66 countries. Any deviations from this reporting framework are indicated on a case-by-case basis.

### Data collection and consolidation systems

Since 2005, we've been using a Group-wide electronic data acquisition system to collect environmental and occupational health and safety data, which is input locally at our individual sites and approved following review. To maximize the quality of this data, we support the sites in optimizing their collection processes and their corresponding quality assurance measures. Moreover, our Group function Environment, Health, Safety, Security, Quality (EQ) conducts internal EHS audits that review both the processes and the data provided.

We compile environmental performance indicators from all our production sites across the Group, as well as those warehouse and research sites that are relevant in terms of their environmental impact and employee count. The scope of consolidation therefore covers all Group sites that have relevant impacts on the environment.

The data on employees and community outreach pertain to our entire Group. All employee master data is continually updated in an SAP database. We use community data management software to log data pertaining to our community involvement at subsidiary level.

Some employee data is only disclosed for select sites or countries, which is accordingly indicated in the respective text passages.

#### Determining report content

We align the content of our CR Report with the internationally recognized guidelines of the Global Reporting Initiative (GRI) and the principles of completeness and materiality, as well as input from our stakeholders. This report has been prepared in accordance with the GRI Standards: 'Comprehensive' option. Moreover, we have taken into consideration the requirements of the capital market for assessing companies' sustainability performance.

In 2016, we performed a comprehensive materiality assessment to determine the CR topics of relevance to our Group. In 2017, experts from the responsible business sectors reviewed these issues and validated them once again, taking into account current trends. Moreover, as stipulated by Section 289c (2) of the German Commercial Code (HGB), we checked the topics validated in 2017 for "double materiality". We have derived the content of this CR report from the results of the materiality assessment, addressing all issues identified as material. Detailed information on the materiality assessment and the materiality matrix can be found under Materiality (p. 22).

Our Executive Board has reviewed and approved this report. The content of the non-financial report has also been reviewed by the Supervisory Board in accordance with Section 111 (2) of the German Stock Corporation Act (AktG).

#### **External audit**

KPMG AG Wirtschaftsprüfungsgesellschaft has audited the annual financial statements and management report of our company for the fiscal year spanning January 1 to December 31, 2017 and issued an unqualified opinion. Furthermore, after undergoing a limited assurance audit, our company has received an independent audit certificate for the following criteria:

- Strategy & management
- Products
- Employees
- Environment
- Suppliers
- Community
- Facts & figures

The additional content provided on the company's websites and external webpages indicated in this report is not part of the non-financial report or information assured by KPMG.

#### **Contact:**

We welcome your feedback and are happy to answer any questions.

### Merck KGaA, Darmstadt, Germany

Corporate Affairs Group Corporate Responsibility

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This CR Report was published in April 2017. Our next CR Report is scheduled for publication in April 2019.

# **ECONOMICS**

Net sales, operating result (EBIT) and research and development costs, by business sector						
€ million	Healthcare	Life Science	Performance Materials	Group <sup>1</sup>		
2016						
Net sales	6,855	5,658	2,511	15,024		
Operating result (EBIT)	1,593	556	823	2,481		
R&D costs	1,496	260	213	1,976		
2017						
Net sales	6,999	5,882	2,446	15,327		
Operating result (EBIT)	1,447	834	689	2,525		
R&D costs	1,632	241	225	2,140		

<sup>1</sup> As a non-operating segment, Corporate and Other is not shown here as a separate item, but rather under Segment Reporting in our 2017 Annual Report.

### compliance



### **Internal audits on corruption and Human Rights Charter**

	2014	2015	2016 <sup>1</sup>	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany <sup>2</sup>
Number of audits relating to corruption	36	49	55	50	13
% of audits relating to corruption	68	64	68	65	17
Number of audits relating to the work- place requirements of our Human Rights Charter	32	41	47	45	12

<sup>1</sup> Includes Sigma-Aldrich as of 2016

In 2017, we audited 16% of all Group subsidiaries (status June 2017, excluding minority holdings), covering approximately 30% of all sales generated between the third quarter of 2016 and the second quarter of 2017.

In 2017, during 45 of our audits conducted in 22 countries, we additionally reviewed workplace parameters as per our Human Rights Charter. No violations were identified.

<sup>2</sup> Includes global audits which are conducted at the headquarters in Darmstadt and/or the management of the audited function is reporting into KGaA.

### **Reported compliance violations**

reported compilation riolations					
	2014	2015	2016 <sup>1</sup>	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany
Total number of reported compliance violations					
Number of reported compliance incidents	26	33	36	39	1
Number of confirmed cases	11	8	12	14	1
confirmed cases by category					
Violation of the Human Rights Charter	1	0	2	0	0
Bribery and Corruption	2	0	2	1	0
Violation of the Pharmaceutical Guidelines	2	2	4	2	0
Violation of Data Privacy and Confidentiality Guidelines	0	1	0	2	1
Manipulation of Business Documents	0	0	2	1	0
Violation of cartel laws and fair competition rules	0	1	0	0	0
Infringements in the areas of finance, accounting and banking	0	0	0	0	0
Theft and fraudulent Actions against the Group	1	2	1	1	0
Other violations of Compliance Principles for the relations with Business Partners of the Group	0	0	1	2	0
Other violations of values, internal guide- lines or legal requirements	5	2	0	5	0
				·	

<sup>1</sup> Includes Sigma-Aldrich as of 2016

In 2017 there was a total of 14 confirmed compliance cases, 2 of which were already reported in 2016, but closed in 2017.

Compliance training					
	2014 <sup>1</sup>	2015	2016 <sup>2</sup>	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany
Total number of persons trained on anti-corruption guidelines <sup>3</sup>	7,519	20,404	29,764	17,044	2,326
Total number of employees trained on anti-corruption guidelines	5,496	17,378	25,889	13,345	1,450
% of employees trained on anti-corruption	14	43	51	25	14
by employee category					
Number of Role 2+ employees trained on anti-corruption	3,071	12,747	14,379	7,080	635
% of Role 2+ employees trained on anti-corruption	17	64	84	27	13
% of employees below Role 2 trained on anti-corruption	12	22	34	24	15
by region (%) <sup>4</sup>			-		
Europe	_	-	54	18	14
North America	_	-	57	46	not applicable
Asia-Pacific (APAC)	_	_	38	25	not applicable
Latin America	_	_	52	19	not applicable

<sup>1</sup> In Q1 – Q3 2014, Group Compliance performed a thorough analysis and review of its Compliance Training Program. No courses were scheduled for these quarters.

66

29

not applicable

Middle East and Africa (MEA)

In order to address the special responsibility held by management personnel, as well as by staff with HR responsibility, these employees are increasingly receiving training on anti-corruption guidelines. This applies to all employees rated Role 2+.

Our compliance and anti-corruption principles are communicated to all our business partners, who undergo a Business Partner Risk Management (BPRM) process.

Training increased in 2016 due to the initial integration of employees of Sigma-Aldrich, a company acquired at the end of 2015.

<sup>2</sup> Includes Sigma-Aldrich as of 2016

<sup>3</sup> Includes contractors, external supervised workers (e.g. temps) and contract partners working on-site who were trained on anti-corruption guidelines (2017: 3,699).

<sup>4</sup> As of 2016, we are also reporting the training rate by region. No such data was tracked for the preceding years.

Legal actions					
	2014	2015 <sup>1</sup>	2016	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany
Total number <sup>2</sup> of legal actions pending or completed (for anticompetitive behavior, violations of anti-trust or violations of monopoly legislation)	2	2	2	3	2
pending	2	2	2	3	2
completed	0	0	0	0	0

<sup>1</sup> Includes Sigma-Aldrich as of 2015

For further information please see our annual reports:

- Annual Report 2014, pages 130-131 and pages 213-215, no. 48
- Annual Report 2015, pages 128-129 and pages 212-213, no. 27
- Annual Report 2016, pages 135-136 and pages 228-229, no. 26
- Annual Report 2017, pages 148-150 and pages 252-254, no. 27

<sup>2</sup> As published in the annual reports, the herein listed total number of legal actions refers to the significant legal risks as per the company's definition. The significance of legal risks is based on potential negative effects on projected financial objectives as well as on the probability of occurrence.

### products



Part of the non-financial report

Customer privacy <sup>1</sup>				
	2014	2015	2016	2017 <sup>2</sup>
Total number of substantiated complaints received from outside parties	0	0	0	0
Total number of complaints from regulatory bodies	1	0	0	0
Total number of identified leaks, thefts, or losses of customer data	0	0	1	0

 $<sup>\</sup>ensuremath{\mathbf{1}}$  This data only reflects incidents classified as significant.

<sup>2</sup> Includes Sigma-Aldrich as of 2017

# **Employees**



Part of the non-financial report

### Total number of employees

<sup>1</sup> Includes Sigma-Aldrich as of 2015

### Number of employees by hierarchical level<sup>1</sup>

2017 thereof Merck KGaA, 2017 Darmstadt,  $2015^{2}$ 2016<sup>2</sup> As of Dec. 31 2014 The Group<sup>2</sup> Germany **Total employees** 39,639 49,613 50,414 52,941 10,677 Senior management (Role 6+) 118 146 181 197 90 2,211 Middle management (Role 4 & 5) 1,973 2,685 2,927 1,037 Low management (Role 3) 6,109 6,622 8,139 8,904 2,451 Other employees (below Role 3) 31,439 40,634 39,409 40,913 7,099 % of women (total) 41 41 43 43 **37** thereof in senior management (Role 25 30 20 21 16 thereof in middle management (Role 4 805 & 5) 539 611 917 319 thereof in low management (Role 3) 2,385 2,636 3,361 3.714 950 thereof other employees (below Role 3) 13,422 17,348 17,375 18,197 2,613 % of men (total) **59 59 57** 57 63 thereof in senior management (Role 98 125 156 167 74 6+)thereof in middle management (Role 4 1,880 718 1,434 1,600 2,010 thereof in low management (Role 3) 3,724 3,986 4,778 5,190 1,501 thereof other employees (below Role 3) 18,017 23,286 22,034 22,716 4,486 by age group Up to 29 years old (%) 15 15 15 15 15 thereof in senior management (Role 0 0 0 0 0 6+)thereof in middle management (Role 4 7 5 3 3 & 5) 6 127 183 194 thereof in low management (Role 3) 130 100 7,229 7,479 thereof other employees (below Role 3) 5,750 7,424 1,486 30 to 49 years old (%) 64 64 62 62 55 thereof in senior management (Role 64 76 72 6+)68 33 thereof in middle management (Role 4 1,264 1,407 1,670 1,782 648 & 5) thereof in low management (Role 3) 4,424 4,770 5,784 6,308 1,670 thereof other employees (below Role 3) 24,815 23,996 24,733 19,703 3,487 50 years or older (%) 21 21 23 23 30 thereof in senior management (Role 54 78 105 125 57 6+)

<sup>1</sup> In 2017, we switched our job architecture from a Global Grading System to Roles. Figures have been retroactively adjusted for previous years.

<sup>2</sup> From 2015 on, these figures include Sigma-Aldrich, however as of Dec. 31, 2017 the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. These employees are included under "thereof other employees (Role 3 and below)".

### Number of employees by hierarchical level<sup>1</sup>

					2017
					thereof
					Merck KGaA,
		2	2	2017	Darmstadt,
As of Dec. 31	2014	2015 <sup>2</sup>	2016 <sup>2</sup>	The Group <sup>2</sup>	Germany
thereof in middle management (Role 4					
& 5)	703	799	1,008	1,142	386
thereof in low management (Role 3)	1,558	1,722	2,172	2,402	681
thereof other employees (below Role 3)	5,986	8,395	8,184	8,701	2,126

<sup>1</sup> In 2017, we switched our job architecture from a Global Grading System to Roles. Figures have been retroactively adjusted for previous years.

Average number of employees by function	onal area			
Average number of employees	2014 <sup>1</sup>	2015 <sup>2</sup>	2016 <sup>2</sup>	2017 <sup>2</sup>
Group	38,930	41,511	50,439	52,053
Thereof women	16,110	17,180	21,136	22,353
Production	10,176	11,563	14,829	15,571
Thereof women	3,202	3,642	4,698	5,059
Logistics/ Supply Chain <sup>3</sup>	2,207	2,581	3,955	3,729
Thereof women	774	913	1,459	1,442
Marketing and Sales/ Commercials <sup>3</sup>	12,113	12,871	14,887	15,115
Thereof women	4,814	5,204	6,401	6,609
Administration	6,342	6,763	8,190	9,286
Thereof women	3,557	3,757	4,421	4,798
Research and Development	4,738	5,097	6,249	6,789
Thereof women	2,534	2,674	3,274	3,591
Infrastructure and Other	3,354	2,636	2,329	1,564
Thereof women	1,230	990	883	854

<sup>1</sup> Average headcount (HC) 2014 is calculated based on the End HC of the last 5 quarters divided by 5.

<sup>2</sup> From 2015 on, these figures include Sigma-Aldrich, however as of Dec. 31, 2017 the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. These employees are included under "thereof other employees (Role 3 and below)".

<sup>2</sup> The average employee headcount for 2015 through 2017 is calculated by adding up all employees at the end of each of the last 13 months, and dividing this total by 13. Employees of Sigma-Aldrich, a company acquired in November 2015, are only included in the employee headcount calculations as of November 2015.

<sup>3</sup> In conjunction with the new job architecture implemented in 2017, some functional areas have been renamed and reorganized. Due to the new structure from 2017 on, it will only be possible to deliver a limited trend forecast in a year-on-year comparison.

Number of employees by region					
					2017 thereof Merck KGaA,
				2017	Darmstadt,
As of Dec. 31	2014	2015 <sup>1</sup>	2016	The Group	Germany
Total	39,639	49,613	50,414	52,941	10,677
Europe	20,537	23,429	24,438	25,980	10,677
women	8,893	10,316	10,884	11,627	3,898
women (%)	43	44	45	45	37
Number of employees with temporary contracts	906	1,079	1,031	1,279	513
% of employees with temporary contracts	4	5	4	5	5
North America	5,092	9,794	10,037	10,520	0
women	2,272	4,183	4,308	4,518	not applicable
women (%)	45	43	43	43	not applicable
Number of employees with temporary contracts	18	22	122	138	not applicable
% of employees with temporary contracts	0.4	0.2	1	1	not applicable
Asia-Pacific (APAC)	9,488	11,096	10,754	11,294	0
women	3,176	3,706	3,981	4,298	not applicable
women (%)	33	33	37	38	not applicable
Number of employees with temporary contracts	156	1,888	2,231	2,603	not applicable
% of employees with temporary contracts	2	17	21	23	not applicable
Latin America	3,883	4,352	4,140	4,050	0
women	1,745	1,986	1,910	1,896	not applicable
women (%)	45	46	46	47	not applicable
Number of employees with temporary contracts	28	43	40	40	not applicable
% of employees with temporary contracts	1	1	1	1	not applicable
Middle East and Africa (MEA)	639	942	1,045	1,097	0
women	280	425	483	519	not applicable
women (%)	44	45	46	47	not applicable
Number of employees with temporary contracts	111	127	153	172	not applicable
% of employees with temporary	17	13	15	16	not applicable

<sup>1</sup> Includes Sigma-Aldrich as of 2015

contracts

External contractors are currently not logged in our employee data system, nor do we currently have any plans to integrate them.

13

15

16 not applicable

17

<b>Employees by business sector</b>				
As of Dec. 31	2014	2015 <sup>1</sup>	2016	2017
Healthcare employees	17,757	18,566	18,837	19,795
Thereof women	8,130	8,522	9,090	9,656
Thereof women (%)	46	46	48	49
Life Science employees	9,796	18,611	19,178	19,607
Thereof women	4,134	7,883	7,928	8,276
Thereof women (%)	42	42	41	42
Performance Materials employees	5,995	6,228	5,469	5,529
Thereof women	1,498	1,531	1,427	1,455
Thereof women (%)	25	25	26	26

<sup>1</sup> Includes Sigma-Aldrich as of 2015

2014	2015 <sup>1</sup>	2016	2017
39,639	49,613	50,414	52,941
38,410	46,454	46,837	48,709
97	94	93	92
15,826	19,034	19,741	20,741
41	41	42	43
1,219	3,159	3,577	4,232
3	6	7	8
536	1,563	1,744	2,117
44	49	49	50
37,573	47,292	48,056	50,498
98	95	95	95
14,497	18,557	19,457	20,677
39	39	40	41
2,066	2,321	2,358	2,443
5	5	5	5
1,869	2,059	2,109	2,181
90	89	89	89
	39,639 38,410 97 15,826 41 1,219 3 536 44  37,573 98 14,497 39 2,066 5 1,869	39,639     49,613       38,410     46,454       97     94       15,826     19,034       41     41       1,219     3,159       3     6       536     1,563       44     49       37,573     47,292       98     95       14,497     18,557       39     39       2,066     2,321       5     5       1,869     2,059	39,639     49,613     50,414       38,410     46,454     46,837       97     94     93       15,826     19,034     19,741       41     41     42       1,219     3,159     3,577       3     6     7       536     1,563     1,744       44     49     49       37,573     47,292     48,056       98     95     95       14,497     18,557     19,457       39     39     40       2,066     2,321     2,358       5     5     5       1,869     2,059     2,109

<sup>1</sup> Includes Sigma-Aldrich as of 2015

New employees					
				2017	2017 thereof Merck KGaA, Darmstadt,
	2014	2015 <sup>1</sup>	2016	The Group	Germany
Total number of new employee hires	6,212	5,710	7,085	7,285	1,032
by age group					
Up to 29 years old	2,305	2,088	2,930	2,940	435
30 to 49 years old	3,361	3,252	3,736	3,848	543
50 or older	546	370	419	497	54
by gender					
Women	2,513	2,450	3,388	3,412	462
Men	3,689	3,260	3,697	3,873	570
by region					
Europe	2,312	2,119	2,689	3,058	1,032
North America	826	730	1,348	1,603	not applicable
Asia-Pacific (APAC)	2,298	1,913	2,201	1,955	not applicable
Latin America	619	780	636	497	not applicable
Middle East and Africa (MEA)	157	168	211	172	not applicable
Rate of new employee hires <sup>2</sup> (%)	16	14	14	14	10
by age group <sup>3</sup>					
Up to 29 years old	37	37	41	40	42
30 to 49 years old	54	57	53	53	53
50 or older	9	6	6	7	5
by gender <sup>3</sup>					
Women	41	43	48	47	45
Men	59	57	52	53	55
by region <sup>3</sup>					
Europe	37	37	38	42	100
North America	13	13	19	22	not applicable
Asia-Pacific (APAC)	37	33	31	27	not applicable
Latin America	10	14	9	7	not applicable
Middle East and Africa (MEA)	3	3	3	2	not applicable

<sup>1</sup> These figures exclude the 8,975 Sigma-Aldrich employees, who are not classified as new hires because they joined our company as part of the Sigma-Aldrich acquisition.

<sup>2</sup> Formula for calculating the rate of new employee hires: Total number of new employee hires divided by Number of employees at the end of the fiscal year.

<sup>3</sup> Formula for calculating the rate of new employee hires by age/gender/region: New employee hires of the focus group divided by the total number of new employee hires. In consequence of the modified calculation method and the new composition of our regions effective January 1, 2015 corresponding figures for the preceding year have been retroactively adjusted.

### Staff turnover<sup>1</sup>

	2014 <sup>2</sup>	2015 <sup>3</sup>	2016 <sup>3,4</sup>	2017 The Group <sup>3</sup>	2017 thereof Merck KGaA, Darmstadt, Germany <sup>3</sup>
Total turnover rate	11.01	10.38	12.07	9.05	2.35
Turnover rate by gender					
Men	10.75	10.13	12.87	8.75	2.18
Women	11.38	10.73	10.96	9.46	2.43
Turnover rate by age group					
Up to 29 years old	18.71	17.49	19.20	13.66	3.51
30 to 49 years old	9.72	9.69	11.37	8.38	2.08
50 or older	9.49	8.08	9.19	7.87	2.22
Turnover rate by region					
Europe	7.05	6.22	6.23	6.22	2.35
North America	12.45	12.72	11.50	11.02	not applicable
Asia-Pacific (APAC)	17.55	15.95	22.37	12.53	not applicable
Latin America	13.67	15.29	18.85	13.74	not applicable
Middle East and Africa (MEA)	13.62	12.00	10.80	11.22	not applicable
Total number of leavers	4,364	4,168	6,087	4,710	244
by gender	<u>·</u>		•	· · · · · · · · · · · · · · · · · · ·	
Men	2,502	2,386	3,771	2,596	162
Women	1,862	1,782	2,316	2,114	82
by age group					
Up to 29 years old	1,102	943	1,464	1,058	55
30 to 49 years old	2,474	2,505	3,589	2,713	120
50 or older	788	720	1,034	939	69
by region					
Europe	1,447	1,290	1,490	1,488	244
North America	634	638	1,132	1,143	not applicable
Asia-Pacific (APAC)	1,665	1,540	2,543	1,387	not applicable
Latin America	531	618	814	570	not applicable
Middle East and Africa (MEA)	87	82	108	122	not applicable

<sup>1</sup> The table contains unadjusted turnover rates. The rate excludes employees who depart due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

<sup>2</sup> Employee turnover for fiscal year 2014 is calculated as follows: Total number of leavers of the past 12 months multiplied by 100 divided by the employee headcount as of December 31.

<sup>3</sup> Employee headcount for fiscal 2015, 2016 and 2017 is calculated as follows: Total number of leavers from the past 12 months divided by the average employee headcount multiplied by 100.

<sup>4</sup> Includes Sigma-Aldrich as of 2016

Work-related accidents <sup>1</sup>					
	2014	2015 <sup>2</sup>	2016	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany
Lost Time Injury Rate (LTIR = work- place accidents resulting in missed days of work per one million man- hours)	1.8	1.4	1.3	1.5	3.1
by region					
Europe	2.9	2.6	2.2 <sup>3</sup>	2.4	3.1
North America	1.0	0.9	1.1	1.0	not applicable
Asia-Pacific (APAC)	0.5	0.3	0.4	0.3	not applicable
Latin America	1.3	0.7	0.4	1.3	not applicable
Middle East and Africa (MEA)	0.9	0.5	1.6	0.0	not applicable
Number of deaths	2	2	0	0	0
by region					
Europe	0	1	0	0	0
North America	0	1	0	0	0
Asia-Pacific (APAC)	1	0	0	0	0
Latin America	1	0	0	0	0
Middle East and Africa (MEA)	0	0	0	0	0
by gender					
Women	1	1	0	0	0
Men	1	1	0	0	0

- 1 Including supervised workers
- 2 Includes Sigma-Aldrich as of 2015
- 3 Figure retroactively adjusted.

Both our employees as well as contractors have been included in the calculation of these indicators.

Through the LTIR, we record work-related accidents that involve at least one day of missed work. A work-related accident is an injury that results from the type of work, in the course of doing said work, and that has no internal cause. Work-related accidents are considered relevant if they occur on the premises, on business trips, during goods transport, as a result of external influences (e.g. natural disasters), or due to criminal acts involving personal injury. Commuting accidents and accidents during company sporting activities are not included. First-aid incidents are generally not included in the LTIR since these usually do not result in more than one day of missed work.

By 2020, we intend to sustainably lower the LTIR to 1.5. The aim is to permanently stabilize or outperform this challenging number, which we achieved for the first time in 2015.

We have defined the LTIR as a key indicator for the Group. Therefore, we do not publish any other indicators such as work-place accidents, lost days or days of absence. The LTIR is not broken down by gender as this differentiation is not relevant to our strategic planning.

For Merck KGaA, Darmstadt, Germany (about 20% of the employees of the Group), we only report work-related illnesses if these have been diagnosed and verified by a physician. In 2017 period, no cases of work-induced illness were verified.

### Employees who regularly receive a performance and development evaluation

	2014 <sup>1</sup>	2015 <sup>2</sup>	2016 <sup>3</sup>	2017 The Group	2017 thereof Merck KGaA, Darmstadt, Germany
% of employees who receive a performance and development evaluation	79	88	97	_4	_4
by gender					
Women	84	90	97	_4	_4
Men	77	87	97	_4	_4
by employee category					
Senior management (Global Grade above 17)	97	100	100	_4	_4
Low and middle management (Global Grade 14–17)	96	100	100	_4	_4
Other employees (Global Grade below 14)	78	88	97	_4	_4
				, , , , , , , , , , , , , , , , , , ,	

- 1 The 2014 data is based on a reporting date of March 2, 2015.
- 2 The 2015 data is based on a reporting date of February 29, 2016.
- 3 From 2016 on, figures include Sigma-Aldrich, but as of Dec. 31 2017, the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany and of Allergopharma.
- 4 Figure will be available on Dec. 31, 2018.

Regular feedback and employee performance evaluations are essential to fairly ranking individual performance and to helping all employees follow their own career path. Our globally uniform Performance and Talent Management Process requires annual feedback meetings and performance assessments for all employees rated Role 2 and up in the job grading system that was used in 2017 (corresponds to Global Grade 10 or higher in the job grading system that was used until the end of 2016). Apart from evaluating employee performance, this helps us to identify individual development opportunities.

When it comes to applying this process, our individual subsidiaries can decide for themselves whether to include employees rated below Role 2 (corresponds to Global Grade 9 or lower in the job grading system that was used until the end of 2016). In Germany, all permanent employees have been participating in the Performance and Talent Management Process since 2013. In 2017, a total of 51,240 employees worldwide were involved in the process. The Performance and Talent Management Process is coordinated via our online platform HR4You.

#### **Internationality of employees**

2017 thereof Merck KGaA, 2017 Darmstadt, 2015<sup>2</sup> As of Dec. 31 2014<sup>1</sup>  $2016^{3}$ The Group<sup>3</sup> Germany Number of nationalities 122 131 97 122 129 Number of nationalities in management positions (Role 4 or above) 67 64 70 65 41 % of non-Germans in management posi-65 tions (Role 4 or above) 60 61 64

- 1 These figures do not include the employees of AZ Electronic Materials, a company that was acquired in July 2014. As of December 31, 2014, the job grading system had not yet been implemented there.
- 2 These figures do not include the employees of Sigma-Aldrich, a company that was acquired in November 2015. As of December 31, 2015, the job grading system had not yet been implemented there.
- 3 From 2016 on, figures include Sigma-Aldrich. However, as of Dec. 31 2017, the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany or for employees of Allergopharma.

### **Employee age by region**

As of Dec. 31

Number of		North	Europe (including		Asia-Pacific	Latin	Middle East and Africa
employees	Worldwide	America	Germany)	Germany <sup>1</sup>	(APAC)	America	(MEA)
2016							
Up to 29 years old	7,419	1,319	3,087	1,757	2,260	562	191
thereof women	3,331	548	1,470	695	922	312	79
30 to 49 years old	31,523	5,224	15,023	6,938	7,625	2,972	679
thereof women	13,849	2,327	6,985	2,780	2,817	1,405	315
50 or older	11,472	3,494	6,328	3,755	869	606	175
thereof women	4,386	1,433	2,429	1,333	242	193	89
Average age	41.3	44.3	42.4	42.9	36.7	39.9	39.3
Total employees	50,414	10,037	24,438	12,450	10,754	4,140	1,045
2017							
Up to 29 years old	7,676	1,438	3,272	1,589	2,257	521	188
thereof women	3,512	608	1,585	634	945	294	80
30 to 49 years old	32,895	5,465	15,680	5,838	8,099	2,913	738
thereof women	14,540	2,423	7,287	2,195	3,074	1,405	351
50 or older	12,370	3,617	7,028	3,250	938	616	171
thereof women	4,806	1,487	2,755	1,069	279	197	88
Average age	41.4	44.1	42.5	42.6	36.9	40.3	39.4
Total employees	52,941	10,520	25,980	10,677	11,294	4,050	1,097

 $<sup>1\,</sup>$  From 2017 on, the figure only includes the employees of Merck KGaA, Darmstadt, Germany.

Age of youngest employee				
As of Dec. 31	2014	2015	2016 <sup>1</sup>	2017
Age of youngest employee, excluding apprentices	17	17	17	18

<sup>1</sup> Includes Sigma-Aldrich as of 2016

### **Voluntary insurance benefits** (voluntarily introduced and (co-) financed)

2017 thereof Merck KGaA, 2017 Darmstadt, 2014<sup>1</sup> 2015<sup>1</sup> 2016 As of Dec. 31 The Group Germany  $68^{3}$ % of employees with healthcare benefits<sup>2</sup> 68 0 % of employees with Group accident 42 insurance<sup>6</sup> 39 1 % of employees with life insurance<sup>5</sup> 0 57 58 % of employees with disability insurance 0 (short-term and long-term) 32 35

- 1 Since 2016, we've been reporting voluntary insurance benefits that we offer our employees. No such data was tracked for the preceding years.
- 2 Any spend on voluntarily introduced and (co-) financed healthcare benefits for employees and possibly their dependents. Not taking into consideration any mandatory social security cover (Mostly covered by an insurance policy).
- 3 Figure retroactively adjusted.
- 4 Any spend on voluntarily introduced and (co-) financed accident insurance that pays a defined amount in case of death or disability caused by a work-related accident (not taking into consideration any mandatory social security cover, e.g. workman's compensation).
- 5 Any spend on voluntarily introduced and (co-) financed life insurance cover that pays a defined amount of money in case of natural death (not accidental).
- 6 Any spend on voluntarily introduced and (co-) financed insurance cover that disability pays for salary continuation in case of inability to work caused by an insured incident.

All our employees are covered by either statutory or voluntary accident and health insurance. Employees of Merck KGaA, Darmstadt, Germany are covered by statutory insurance as stipulated by the regulations in force in Germany.

We offer a company pension in numerous countries along with various programs for supplemental company pensions and survivor's benefits.

The global benefits listed in the table above are designed to provide additional security to our workforce and their families and to improve their quality of life. Benefits represent voluntarily employer-initiated as well as employer-financed assistance to our workforce in addition to the regular compensation package.

Our benefits offer meaningful choices, where possible, to support a diverse workforce and are sensitive to the needs and customs of the employees who use them, regardless of country, age, family status, interests, or values.

Long-term pension obligations and post-employment benefits						
€ million	2014	2015 <sup>1</sup>	2016	2017		
Present value of all defined benefit obligations as of Dec. 31	3,813	4,153	4,698	4,707		
Pension expenses	157	210	226	304		

1 Includes Sigma-Aldrich as of 2015

Depending on the legal, economic and fiscal circumstances prevailing in each country, different retirement benefit systems are provided for the employees of the Group. Generally, these systems are based on the years of service and salaries of the employees. Pension obligations of the Group include both defined benefit and defined contribution plans and comprise both obligations from current pensions and accrued benefits for pensions payable in the future. In the Group, defined benefit plans are funded and unfunded (see our Annual Report 2017, Note on Provisions for pensions and other post-employment benefits).

Flexible working hours in Germany				
As of Dec. 31	2014	2015	2016 <sup>1</sup>	2017 <sup>2</sup>
% of employees utilizing the "mywork" working model	31	35	36	40

<sup>1</sup> Includes Sigma-Aldrich as of 2016

In coordination with their teams and supervisors, employees taking advantage of the working model "mywork" can choose when and where they work.

Parental leave in Germany				
As of Dec. 31	2014 <sup>1</sup>	2015 <sup>1</sup>	2016 <sup>1</sup>	2017 <sup>2</sup>
Number of employees with a right to parental leave	331	317	359	353
thereof women (recorded via maternity leave in the respective year)	165	149	191	151
thereof men (recorded via special paternity leave in the respective year)	166	168	168	202
Number of employees who took parental leave <sup>3</sup>	507	485	480	352
thereof women	349	301	303	150
thereof men	158	184	177	202
Number of employees on parental leave who worked part time during their leave	99	102	102	49
thereof women	94	99	95	47
thereof men	5	3	7	2
Number of employees who returned from parental leave	187	183	174	312
thereof women	83	51	62	143
thereof men	104	132	112	169
Return to work rate (%)	36.9	37.7	36.3	88.6
thereof women	23.8	16.9	20.5	95.3
thereof men	65.8	71.7	63.3	83.7
Number of employees still working for the Group one year after their return from parental leave	137	184	190	_4
thereof women	35	55	73	_4
thereof men	102	129	117	_4
Retention rate (%)	90.7	96.8	95.6	_4
thereof women	58.3	98.2	93.8	_4
thereof men	112.1	96.3	96.8	_4

<sup>1</sup> Figures only pertain to the Darmstadt and Gernsheim sites in Germany (which accounted for around 20 % of the employees of the Group in 2017). Figures are calculated on the basis of the data from one entire year, which also includes those employees who took parental leave during the calendar year, but who had not returned by Dec. 31.

<sup>2</sup> Essentially reflects the figures of Merck KGaA, Darmstadt, Germany.

<sup>2</sup> Figures only pertain to Merck KGaA, Darmstadt, Germany (which accounted for around 20 % of the employees of the Group in 2017). Figures are calculated on the basis of the data from one entire year, which also includes those employees who took parental leave during the calendar year, but who had not returned by Dec. 31.

<sup>3</sup> Since parental leave can be taken for a period ranging from one month to three years, it is possible for employees to be recorded across a period of up to four calendar years. This explains why the number of employees on parental leave exceeds the number of employees who have a right to it.

<sup>4</sup> Figure will be available on Dec. 31, 2018.

Employees with disabilities <sup>1</sup> (%)				
As of Dec. 31	2014	2015	2016	2017
Employees with disabilities <sup>1</sup>	4.7	4.7	4.5	4.3

<sup>1</sup> Only pertains to Merck KGaA, Darmstadt, Germany (which accounted for around 20% of the employees of the Group in 2017, calculations based on the German Social Code IX - SGB IX).

Apprentices				
As of Dec. 31	2014 <sup>1</sup>	2015 <sup>2</sup>	2016 <sup>3</sup>	2017 <sup>3</sup>
Number of apprentices	498	506	576	588
% of apprentices	5.4	5.3	4.6	4.4

<sup>1</sup> Only pertains to Merck KGaA, Darmstadt, Germany sites in Darmstadt, Gernsheim and Grafing, Germany (which accounted for roughly 24% of the employees of the Group in 2014).

<sup>2</sup> Only pertains to Merck KGaA, Darmstadt, Germany (roughly 19% of the total employee headcount of the Group in 2015).

<sup>3</sup> Only pertains to sites in Germany (approximately 25% of the Group's total workforce in 2016 and 2017). Essentially reflects the figures of Merck KGaA, Darmstadt, Germany.

### Environment

Spending on environmental protection, safety and health						
€ million	2014	2015	2016 <sup>1</sup>	2017		
Spending	145	148	189	200		

1 Includes Sigma-Aldrich as of 2016

These figures include both investments in as well as internal and external spending on waste and wastewater management, water, occupational safety, fire protection, noise reduction, air pollution prevention, decontamination, preservation of nature and the landscape, climate impact mitigation, and energy efficiency. We do not further break down our spending on environmental protection by type.

Total greenhouse gas emissions (Scope 1 and 2 of the GHG Protocol) <sup>1</sup>					
metric kilotons	2006 <sup>2</sup>	2014	2015	2016	2017
Total CO <sub>2</sub> eq <sup>3</sup> emissions	793	731	726	711	731
Thereof					
direct CO <sub>2</sub> eq emissions	379	390	393	387	374
indirect CO <sub>2</sub> eq emissions	414	341	333	324	357
Biogenic CO <sub>2</sub> emissions	6	11	54	56	38

<sup>1</sup> In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline) the greenhouse gas emissions have been calculated based on the current corporate structure of the reporting year and retroactively adjusted for acquisitions (e.g. Sigma-Aldrich in 2015) or divestments of (parts of) companies, or for changes in emission factors (portfolioadjusted).

- 2 Baseline for our emission targets is 2006.
- 3 eq = equivalent

Our response to the Carbon Disclosure Project contains a detailed description of our calculation methods.

We have included the following gases in our calculation of direct and indirect CO2eq emissions:

- Direct CO<sub>2</sub> emissions: CO<sub>2</sub>, HFCs, PFCs; CH<sub>4</sub>/N<sub>2</sub>O negligible; SF<sub>6</sub>/NF<sub>3</sub> not available.
- Indirect CO<sub>2</sub> emissions: CO<sub>2</sub>.

In 2017, we emitted 0.048 kg of  $CO_2$ eq per euro of net sales.

Other relevant indirect greenhouse gas emissi	ions (Scope 3 o	f the GHG Pro	tocol)	
	2014 <sup>1</sup>	2015 <sup>1</sup>	2016 <sup>1,2</sup>	2017
Total gross other indirect emissions (metric kilotons CO <sub>2</sub> eq <sup>3</sup> )	319	349	426	353
Fuel- and energy-related emissions, not included in Scope 1 or 2 (category 3)	97	95	127	118
Waste generated in operations (category 5)	96	123	127	68
Business travel - air travel (category 6)	74	79	103 <sup>4</sup>	98
Business travel - rail travel (category 6)	0.02	0.02	0.02	0.02 <sup>5</sup>
Business travel - rental car travel (category 6)	1.2	1.1	0.6	0.6
Employee commuting (category 7)	51	51	68	68
Upstream leased assets (category 8)	0	06	06	0 <sup>6</sup>
Processing of sold products (category 10)	0	0 <sup>7</sup>	07	0 <sup>7</sup>
Downstream leased assets (category 13)	0	0	0	0
Franchises (category 14)	0	0	0	0

- 1 Because of the characteristics of the Scope 3 emissions data we do not correct these data subsequently.
- 2 Includes Sigma-Aldrich as of 2016
- 3 eq = equivalent
- 4 This figure covers roughly 80% 85% of the employees of the Group because the data for the employees of Sigma-Aldrich, acquired in November 2015, are only partially available.
- 5 German Railway
- 6 Already covered under Scope 1 and 2 emissions
- 7 The Group produces a huge variety of intermediate products for various purposes. Due to their many applications and our customer structure, the associated GHG emissions cannot be tracked in a reasonable fashion.

No data is available for Scope 3 categories not listed above. Their relevance to the Group is assessed in the Scope 3 document.

Biogenic emissions (Scope 3), if present, are not being recorded.

Emissions of ozone-depleting substances				
metric tons	2014	2015	2016	2017
Total emissions of ozone-depleting substances	2.0	2.5	2.2	2.1
CFC-11eq <sup>1</sup>	0.1	0.1	0.1	0.1

<sup>1</sup> CFC-11eq is a unit of measure used to compare the potential of various substances to deplete the ozone. Reference figure 1 indicates the potential of CFC-11 to cause the depletion of the ozone layer.

Substances included: R-12, R-22, R-141b, R-402a, R-409a, R-401a.

Source for the emission factors: Montreal Protocol.

Other air emissions				
metric kilotons	2014	2015	2016 <sup>1</sup>	2017
Volatile organic compounds (VOC)	0.3	0.3	0.3	0.3
Nitrogen oxide	0.2	0.3	0.2	0.2
Sulfur dioxide	0.02	0.05	0.05	0.03
Dust	0.02	0.06	0.02	0.04

<sup>1</sup> Includes Sigma-Aldrich as of 2016

The VOC, nitrogen oxide, sulfur dioxide, and dust emissions reported here are attributable to production activities as well as energy generation. These figures do not include emissions from vehicles. Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Transport of finished goods, by means of transportation					
	2014 <sup>1</sup>	2015 <sup>1</sup>	2016 <sup>2</sup>	2017	
% Truck	56	53	71	73	
% Boat	38	41	18	15	
% Airplane	6	6	11	12	

<sup>1</sup> The figures until 2015 pertain to goods shipped by our Darmstadt, Gernsheim and Hohenbrunn sites in Germany (excluding Sigma-Aldrich).

In shipping finished goods from our production sites to the local warehouses of our subsidiaries, we have been working to reduce the use of air shipping in favor of sea freight. This change aims to both reduce costs as well as lower transport-related  $CO_2$  emissions.

<sup>2</sup> From 2016 on, the figures contain the volumes of the biggest global distribution centers of our Healthcare, Life Science and Performance Materials business sectors. These figures pertain to the total weight of transported products and indicate the primary means of transport.

Energy consumption <sup>1</sup>				
In GWh	2014	2015	2016	2017
Total energy consumption	2,162	2,260	2,241	2,270
Direct energy consumption	1,354	1,452	1,445	1,386
Natural gas	1,207	1,206	1,267	1,256
Liquid fossil fuels <sup>2</sup>	120	111	37	34
Biomass and self-generated renewable energy	27	135	141	96
Indirect energy consumption	808	808	796	884
Electricity	711	712	701	740
Steam, heat, cold	97	96	95	144
Total energy sold	0.6	0.5	0.5	0.3
Electricity	0.6	0.5	0.5	0.3
Steam, heat, cold	0	0	0	0
In TJ	2014	2015	2016	2017
Total energy consumption	7,783	8,137	8,068	8,172
Direct energy consumption	4,874	5,228	5,202	4,990
Natural gas	4,345	4,342	4,561	4,522
Liquid fossil fuels <sup>2</sup>	432	400	133	122
Biomass and self-generated renewable energy	97	486	508	346
Indirect energy consumption	2,909	2,909	2,866	3,182
Electricity	2,560	2,563	2,524	2,664
Steam, heat, cold	349	346	342	518
Total energy sold	2.2	1.8	1.8	1.1
Electricity	2.2	1.8	1.8	1.1
Steam, heat, cold	0.0	0.0	0.0	0.0

<sup>1</sup> In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline) the energy consumption has been calculated based on the current corporate structure of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

At our sites in Billerica (MA, USA), Bedford (MA, USA), Molsheim (France), Tel Aviv (Israel), Rome (Italy), Guatemala City (Guatemala), Shizuoka-ken (Japan), and Shanghai (China), we use photovoltaics to produce power.

We currently only record purchased secondary energy – this is primarily electricity and, to a lesser extent, heat/steam/cold. Details on the local energy mix, including the respective percentage of primary energy, renewable energy, etc. are not available. Data on local energy efficiency in electricity or heat generation are not available either. Our production sites are located in countries with a widely varying energy mix.

Our Darmstadt and Gernsheim sites in Germany consume the most energy, representing 28% of our Group-wide total. At these sites, fossil energy (coal, gas, etc.) accounts for approx. 53.7%, nuclear energy approx. 14.3% and renewable energies approx. 32% of the energy mix. Renewable energies account for a higher share of electricity generation at production sites in Switzerland, with nuclear energy taking the lead in France. Based on an estimated global energy efficiency of 37% for the conversion and distribution of generated electricity, this results in a primary energy consumption of 2,000 GWh for 2017. Based on an estimated global energy efficiency of 85% for heat/steam/cold, this results in a primary energy consumption of 170 GWh for 2017. This yields a total primary energy consumption of 2,170 GWh for 2017. (The calculation is based on factors stated in the "Manual for energy management in practice - Systematically reducing energy costs" published by DENA, 12/2012.)

<sup>2</sup> Light and heavy fuel oil, liquefied petroleum gas (LPG), diesel and gasoline

In 2017, the Group's energy intensity relative to net sales totaled 0.150 kWh/€.

2016	2017
<b>3.8</b> <sup>2</sup>	14.0
1.8 <sup>2</sup>	1.8
7.2	7.3
4.8 <sup>2</sup>	4.9
0.01	0.01
	7.2

- 1 Includes Sigma-Aldrich as of 2015
- 2 Figure retroactively adjusted.

These figures do not include the ground water that we use for safety measures at our Gernsheim site in Germany. Here, the water is fed back directly into natural circulation.

Water reused				
millions of m <sup>3</sup>	2014	2015 <sup>1</sup>	2016	2017
Water reused	16.0	23.0	22.7	22.4

1 Includes Sigma-Aldrich as of 2015

The increase in reused water in 2015 is attributable to the recirculating cooling system that went online at our facility in Darmstadt, Germany. This system provides recirculating cooling water to both our new co-generation unit as well as our new cold and compressed air generator. The recirculating cooling system largely accounts for the amount of reused water as it allows the water to be re-utilized multiple times. The volume of reused water is thus greater than the total volume of consumed water.

Wastewater volume and quality				
	2014	2015 <sup>1</sup>	2016	2017
Total wastewater volume (millions of m <sup>3</sup> )	10.1	11.8	12.1	12.3
Chemical oxygen demand (metric tons of O <sub>3</sub> )	1,319	1,933	1,535	1,654
Phosphorous (metric tons)	10	10	12	8
Nitrogen (metric tons)	81	487 <sup>2</sup>	379 <sup>2</sup>	254
Zinc (kg)	410	491 <sup>2</sup>	448 <sup>2</sup>	351
Chromium (kg)	36	42	34	34
Copper (kg)	34	78 <sup>2</sup>	48 <sup>2</sup>	61
Nickel (kg)	128	127 <sup>2</sup>	124	138
Lead (kg)	55	54	56	63
Cadmium (kg)	10	13	11	12
Mercury (kg)	1	2	2	1
Arsenic (kg)	4	5	4	3

- 1 Includes Sigma-Aldrich as of 2015
- 2 Figure retroactively adjusted.

The wastewater volume includes indirect discharge into both public and Group-owned wastewater treatment plants, as well as direct discharge (such as rainwater and cooling water).

The wastewater treatment plant at our Gernsheim, Germany site also treats wastewater from the neighboring municipality

of Biebesheim. The communal wastewater from Biebesheim is included in the wastewater volume as well as in the emissions stated in the table.

Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Hazardous and non-hazardous waste				
metric kilotons	2014	2015 <sup>1</sup>	2016	2017
Total waste	228	320 <sup>2</sup>	252 <sup>2</sup>	252
Hazardous waste disposed <sup>3</sup>	53	55	47 <sup>2</sup>	43
Non-hazardous waste disposed <sup>3</sup>	55	35	38 <sup>2</sup>	34
Hazardous waste recycled <sup>4</sup>	49	73	78 <sup>2</sup>	69
Non-hazardous waste recycled <sup>4</sup>	71	157 <sup>2</sup>	89 <sup>2</sup>	106

- 1 Includes Sigma-Aldrich as of 2015
- 2 Figure retroactively adjusted.
- 3 Disposed = incineration (without energy recovery) and landfill
- 4 Recycled = incineration (with energy recovery) and material recycling

Exported/Imported hazardous waste				
metric kilotons	2014	2015 <sup>1</sup>	2016	2017
Exported <sup>2</sup>	9.6	5.1	4.6	4.9
Imported <sup>3</sup>	0.003	0.010	0.010	0.005

- 1 Includes Sigma-Aldrich as of 2015
- 2 Disposal within the EU and the United States.
- 3 As part of the return system for our cell tests, these kits are brought to our Gernsheim site in Germany for proper disposal.

In 2017, less than 2% of hazardous waste was shipped internationally.

Waste by disposal method				
	2014	2015 <sup>1</sup>	2016	2017
Total waste (metric kilotons)	228	320 <sup>2</sup>	252 <sup>2</sup>	252
Disposed waste (metric kilotons)	108	90	85 <sup>2</sup>	77
Landfilled waste (metric kilotons)	37	16	15 <sup>2</sup>	13
Incinerated waste (metric kilotons)	71	74	70 <sup>2</sup>	64
Recycled waste (metric kilotons)	120	230 <sup>2</sup>	167 <sup>2</sup>	175
Material recycling (metric kilotons)	93	198 <sup>2</sup>	135 <sup>2</sup>	145
Waste-to-energy (metric kilotons)	27	32	32 <sup>2</sup>	30
Recycling rate (%)	53	72	66 <sup>2</sup>	69

- 1 Includes Sigma-Aldrich as of 2015
- 2 Figure retroactively adjusted.

As in previous years, the total waste generated continues to be heavily influenced by the waste from construction and remodeling activities. Construction, excavation and demolition waste accounted for 37% of our waste in 2017. Around 74 metric kilotons of construction, excavation and demolition waste was recycled.

Significant spills				
	2014	2015 <sup>1</sup>	2016	2017
Total number of significant spills	0	0	0	0

<sup>1</sup> Includes Sigma-Aldrich as of 2015

# community

Spending on community involvement				
€ million	2014	2015	2016 <sup>1,2</sup>	2017
Total spending	50.8	100.0	43.0	33.8

<sup>1</sup> Includes Sigma-Aldrich as of 2016

We calculate the value of pharmaceutical product donations according to the WHO Guidelines for Medicine Donations; for other product donations, we apply their fair value.

Community involvement spe	ending by region <sup>1</sup>				
	Europe	North America	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
2016					
€ million	10.1	2.3	4.4	1.1	25.1
%	24	5	10	3	58
2017					
€ million	8.7	2.9	3.2	0.5	18.5
%	26	9	9	1	55

<sup>1</sup> This table presents the regions across the globe in which we support initiatives. For projects that benefit multiple regions, we have calculated the amount per region by dividing the project spending evenly per country.

Focus of our local community involvement <sup>1</sup>				
%	2014	2015	2016 <sup>2,3,4</sup>	2017
Health	33	33	35	38
Education and culture	38	33	36	43
Environment	10	7	5	4
Disaster relief	4	6	2	2
Other	15	21	22	13

<sup>1</sup> Based on number of projects

<sup>2</sup> From 2016 on, we are separating spending on patient support programs such as our Erbitux<sup>®</sup> China Patients Assistance Program from our community involvement figures.

<sup>2</sup> Includes Sigma-Aldrich as of 2016

<sup>3</sup> Since 2016, we have integrated our global projects into our community outreach figures, specifically the Global Pharma Health Fund, the Praziquantel Donation Program and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany. This change in approach was due to the increasingly international nature of our efforts. We are spearheading a rising number of global projects that account for a growing percentage of our project portfolio. To ensure maximal accuracy, we are therefore including all international initiatives in our figures as of 2016.

<sup>4</sup> From 2016 on, we are separating spending on patient support programs such as our Erbitux<sup>®</sup> China Patients Assistance Program from our charitable spending figures.

Motivations for our community involvement <sup>1</sup>						
%	2014	2015	2016 <sup>2,3,4</sup>	2017		
Charitable activities	9	3	4	9		
Community investment	59	92	87	84		
Commercial initiatives in the community	32	5	9	7		

- 1 Based on total spending on all projects
- 2 Including Sigma-Aldrich as of 2016
- 3 Since 2016, we have been integrating our global projects into our community outreach figures, specifically the Global Pharma Health Fund, the Praziquantel Donation Program and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany. This change in approach was due to the increasingly international nature of our efforts. We are spearheading a rising number of global projects that account for a growing percentage of our project portfolio. To ensure maximal accuracy, we are therefore including all international initiatives in our figures as of 2016.
- 4 As of 2016, we are separating patient support programs such as our Erbitux<sup>®</sup> China Patients Assistance Program from our charitable spending.

We categorize the motivations for our activities based on the London Benchmarking Group model as well as the guidelines of the Bertelsmann Foundation for corporate social responsibility. Projects that primarily aim to make improvements within the community are classified as community investment.

Initiatives that are predominantly aimed at company-relevant factors such as image or personnel recruitment are classified as commercial initiatives in the community. Charitable activities cover any other projects that benefit a charitable organization, but cannot be listed under either of the other two motivation categories due to missing data or their narrow scope.

# epals



# products

#### **Access to health**

We aim to improve access to health for underserved populations in low- and middle-income countries.

Goal: Monitor and assess the progress and effectiveness of our A2H programs.

Action(s):	Ву:	Progress by end of 2017:	Status:
Develop quantitative and qualitative performance indicators for the 4 As: Availability, Accessibility, Affordability, and Awareness.	2018	We developed indicators for the 2014, 2016 and 2017 CR Reports for each A of the "4As of Access" framework.	<b>⊘</b>

#### Goal: Affordability: Overcome inability to pay.

Action(s):	Ву:	Progress by end of 2017:	Status:
Participate in at least one partnership with a public-sector partner in an effort to share our intellectual property and expertise in infectious and neglected tropical diseases.	End of 2018	In 2017, we entered into a partnership with the University of California San Diego, United States to share compounds from our library under the WIPO Re:Search open innovation umbrella in order to identify potential cures for leishmaniasis, Chagas disease (American trypanosomiasis) and human African trypanosomiasis (HAT - sleeping sickness).	<b>✓</b>
Establish a partnership to share intellectual property with a non-commercial organization.	End of 2018	In April 2017, we entered into a partnership with the Drug for Neglected Diseases initiative (DNDi), under which we are participating in the Drug Discovery Booster project for neglected tropical diseases.	<b>⊘</b>

#### Goal: Awareness: Empower health workers, communities and people.

Action(s):	Ву:	Progress by end of 2017:	Status:
Create an awareness initiative run jointly by our Healthcare and Life Science business sectors.	End of 2017	In 2017, our Water for Health public-private partnership was rolled out in Ghana. Through this initiative, we are seeking to raise awareness of water quality and expand local water analysis capacities.	<b>⊘</b>
Engage in a dialogue to jointly identify the key access challenges and opportunities for our A2H strategy.	End of 2018	In 2017, we conducted an Access Dialogue on the topics of innovation and intellectual prop- erty, along with an Accessibility Platform dialogue on challenges in local supply chains.	<b>⊘</b>

We aim to improve global health for underserved populations in low- and middle-income countries, with a focus on combating infectious diseases.

# Goal: Availability: Address unmet needs through the research, development and optimization of health solutions.

Action(s):	Ву:	Progress by end of 2017:	Status:
Develop a pediatric formulation of prazi- quantel for the treatment of schistoso- miasis in children under six. Milestone: Entry into Phase III	End of 2018	In 2015, we completed both the Phase I bioavailability study (South Africa) in healthy volunteers and the swill & split taste study (Tanzania).  Since 2016, we have been conducting a Phase II study in Côte d'Ivoire aimed at assessing the efficacy and safety of two different formulations for orodispersible tablets in schistosomiasis-infected children under the age of six. We expect initial results in the second quarter of 2018.	•
Develop a new antimalarial. Milestone: Entry into Phase I	2017	In March 2015, we obtained the rights to a promising investigational antimalarial compound originating from a collaboration between the Medicines for Malaria Venture (MMV) and the University of Dundee (United Kingdom). The compound potentially offers a new mechanism of action for the treatment and prevention of malaria in young children. The project completed its preclinical phase in 2016, and the Phase I study was initiated in 2017.	•
Develop a new antimalarial. Milestone: Completion of Phase I	End of 2018	The Phase I study for the investigational antimalarial compound originating from a collaboration between MMV and the University of Dundee (United Kingdom) is expected to be completed by December 2018.	•
Develop a new diagnostic kit to detect and characterize the type of malaria parasite. Milestone: Start of clinical trial	End of 2018	In 2017 we completed the preclinical phase having achieved promising results. We will start clinical trials in 2018.	•

# Goal: Accessibility: Strengthen supply chains and provide localized health solutions

D		
By:	Progress by end of 2017:	Status
End of 2018	We have launched the Accessibility Platform as a forum for dialogue.	<b>⊘</b>
End of 2018	In 2017, one dialogue on the challenges of local supply chains was hosted under the banner of the Accessibility Platform. We also held a panel session in conjunction with the World Health Summit on "Supply Chain & Delivery Capabilities: Critical enablers to improving access to health," co-hosted with platform members Roche and Novartis.	<b>⊘</b>
End of 2019	In 2017, we identified a variety of options for developing this sort of partnership.	•
End of 2018	In 2017, a pilot was run in Kenya and showed that the system works. The decision was taken to implement the school-based deworming program in 2018.	•
	End of 2018  End of 2018  End of 2019	End of 2018  We have launched the Accessibility Platform as a forum for dialogue.  End of 2018  In 2017, one dialogue on the challenges of local supply chains was hosted under the banner of the Accessibility Platform. We also held a panel session in conjunction with the World Health Summit on "Supply Chain & Delivery Capabilities: Critical enablers to improving access to health," co-hosted with platform members Roche and Novartis.  End of 2019  In 2017, we identified a variety of options for developing this sort of partnership.  End of 2018  In 2017, a pilot was run in Kenya and showed that the system works. The decision was taken to implement the school-based deworming

# **Chemical product safety**

Goal: Use precautionary principle to establish a globally aligned hazard and risk communication system for all our relevant chemical products in the supply chain

Action(s):	Ву:	Progress by end of 2017:	Status:
Implement REACH: Register substances produced in quantities of 1-100 metric tons per year (phase 3 of REACH implementation) and register non-phase-in substances.	Mid-2018	By the end of 2017, we had registered 250 phase 3 substances for various subsidiaries of our company.	<b>©</b>
Implement the Global Product Strategy: Issue product safety summaries for all hazardous substances registered under REACH.	End of 2020	Because we were heavily focused on completing phase 3 REACH registrations on time, the product safety summaries were not a priority in 2017.	•
Projects for hazard communication: Update safety data sheets for non- hazardous materials.	End of 2020	By the end of 2017, we had updated 65% of the safety data sheets for non-hazardous materials within Performance Materials and 74% in Life Science. The integration of Sigma-Aldrich should be completed by the end of 2018, by which time we intend to have updated all safety data sheets.	•
Harmonize safety data sheets to align with a globally uniform standard.	End of 2020	Within Performance Materials, in 2017 we began drafting all safety data sheets Groupwide using a single system. Within Life Science, safety data sheets for all new product launches have been harmonized. Existing substances will be transitioned to the globally harmonized system by 2020.	•

# **Counterfeit products**

Goal: Integrate safety into relevant business processes for our Healthcare and Life Science business sectors.

Action(s):	Ву:	Progress by end of 2017:	Status:
Identify strategic and commercial data that require greater protection; minimize risks by modifying processes.	End of 2018	In 2017, we harmonized the processes for reporting incidents and conducting audits. For our Biopharma business, we are looking into ways to further harmonize security features.	<b>©</b>

Goal: Step up interdisciplinary collaboration within global security network.

Action(s):	Ву:	Progress by end of 2017:	Status:
Expand organizational structures and certify employees who deal with product crime.	Ongoing	In 2017, we expanded our MACON network to eight key countries: the United Kingdom, Poland, Russia, Indonesia, Nigeria, South Africa, Egypt, and Tunisia. Network members hold discussions twice a month.	•
Implement a Group-wide notification system for counterfeit products.	End of 2017	Our new Group-wide reporting system has been rolled out. Thanks to greater transparency and better tracking, cases can now be investigated more efficiently or prevented altogether by identifying possible ties to other incidents.	<b>⊘</b>

#### Goal: Educate employees and other target groups on the strategic relevance of counterfeit medicines.

Action(s):	Ву:	Progress by end of 2017:	Status:
Host conferences and seminars; share best practices and lessons learned through international networks.	Ongoing	In 2017, all our Product Crime Officers took part in a variety of training programs. They regularly share best practices and lessons learned.	•

Goal: Develop and implement security technology and solutions for supply chain authentication, identification, integrity, and security.

Action(s):	Ву:	Progress by end of 2017:	Status:
Support regional activities to counter product crime.	Ongoing	We supported around 128 investigations across approximately 30 countries. We also participated in workshops and seminars with law enforcement in the United Kingdom, Italy, Mexico, Brazil, Nigeria, China, and the United States, and furthermore engaged German federal authorities in dialogue.	•
Monitor the number of unreported cases of counterfeit medicines in select countries and step up internet searches to track down trademark infringement and counterfeit products.	Ongoing	We are constantly scouring the Internet for criminal offenses involving our products, tapping into partner networks in high-risk countries to do so. This enables us to raise the clearance rate for product crime incidents. Our countermeasures are increasingly covering the darknet and social media. Among other steps, we launched our "Evaluating product crime in the darknet" initiative.	<b>©</b>
Support regional activities in five highrisk countries.	End of 2017	We appointed Product Crime Officers from 20 countries to the global MACON network. An additional ten countries are slated to join in 2018 and are already undergoing preparations to do so. Half of these 30 countries are highrisk markets.	<b>⊘</b>
Monitor counterfeit pharmaceuticals in conventional distribution channels as well as online sales.	Ongoing	-	•

# **Transport and warehouse safety**

#### Goal: Ensure warehouse and transport safety for our company and our suppliers.

Action(s):	Ву:	Progress by end of 2017:	Status:
Integrate all freight forwarders into our audit process.	End of 2017	As a member of the Logistics & Distributors User Group of SQAS, a service provided by the European Chemical Industry Council, Cefic, we receive additional audit reports of our logistics providers. In 2017 we developed criteria to evaluate these findings, which we subsequently make available to all internal stakeholders.	<b>⊘</b>
Harmonize transport and warehouse safety master data through Group-wide ERP systems.	End of 2022	By the end of 2017, we had straightened out 84% of all deviations in the transport and warehouse safety master data of identical products in our Life Science portfolio.	•

#### **Animal welfare**

We work to safeguard the welfare of animals used by our company, contract research organizations, suppliers, and other partners.

#### Goal: Ensure consistently high quality across our animal facilities

Action(s):	Ву:	Progress by end of 2017:	Status:
Inspect Life Science animal facilities in preparation for potential accreditation: Conduct a feasibility study and make a decision about accreditation.	End of 2018	The feasibility study was conducted. Accreditation of additional Life Science facilities is not currently planned.	<b>⊘</b>
Re-accredit relevant animal facilities.	Ongoing	Re-accreditations are conducted every three years. In 2017, one of our animal facilities was successfully re-accredited.	<b>⊘</b>

### Goal: Promote the 3Rs (Reduce, Refine, Replace)

Action(s):	Ву:	Progress by end of 2017:	Status:
Develop a Group-wide 3R program.	End of 2019	Our award program was approved by the Group Animal Welfare Council in November 2017; the prize will be presented for the first time in 2018.	•

#### Goal: Ensure animal welfare in our supply chain

Action(s):	Ву:	Progress by end of 2017:	Status:
Identify animal welfare risks in our supply chain and develop a strategy for certifying suppliers.	End of 2017	We developed a strategy and processes to account for potential risks in our supply chain and certify suppliers. The certification process is supported by Interpharma's cross-company audit concept. We also drafted a Standard on Vendor Qualification, which describes our criteria for evaluating the quality of our suppliers' and partners' animal welfare practices. This standard took effect in March 2018.	<b>⊘</b>
Develop and implement an audit plan for suppliers.	Ongoing		0

# compliance

# **Goal: Bring Compliance closer to the business**

Status: We're working on a more integrated compliance approach, building on enhanced business accountability and ownership that are supported by a risk-based and business sector-oriented compliance framework.

Action(s):	Ву:	Progress by end of 2017:	Status:
Quantum LEAP: Develop and introduce an automated, lean process and tool landscape to support transparency reporting requirements and the streamlined processing of interactions with our partners in the Healthcare sector. Build on adapted compliance controls and enhanced business ownership and accountability.	September 2018	We have redesigned the overall system land- scape and developed processes which are now being implemented in pilot countries.	•

Business Partner Risk Management Process update: Design an updated and more automated tool with integrated risk assessment and controls.	June 2018	We developed a new tool architecture based on key user input and launched the technical implementation.	<b>©</b>
New Code of conduct of Merck KGaA, Darmstadt, Germany: The Code has a strong relation to the company's values, built on core principles to adhere to. Supported by a business specific roll-out and e-learning.	March 2018	A new Code of Conduct was rolled out in December 2017. The corresponding e-learning script will be developed and implemented by the end of March 2018.	<b>©</b>
Self-monitoring as part of the Compliance Risk Assessment process: Integrate self-assessment of compliance program implementation status in existing Compliance Risk Assessment.	September 2018	In 2017, we designed new functionalities and launched the technical implementation. Self-assessment will be driven by business, and supported by Compliance.	<b>©</b>

# **Employees**

# **Attractive employer**

#### Goal: Consistently fill at least two-thirds of leadership positions (Role 6+) with internal candidates

Action(s):	By:	Progress by end of 2017:	Status:
Use the Talent Management Process to identify suitable employees with leader-ship potential and optimize the process to systematically advance them.	Ongoing	In 2017, 84% of our vacant leadership positions (Role 6+) were filled internally.	•
Build a high-potential pool that reflects our demographic structure.	Ongoing	We are continuously developing our high- potential pool, which is a reflection of the diversity within our company.	<b>©</b>

### Goal: Position our Group as an attractive employer for university graduates

Action(s):	Ву:	Progress by end of 2017:	Status:
Participate in university fairs and organize in-house events for graduates; position our company via employer branding channels.	Ongoing	We are continuously positioning ourselves as an attractive employer for university graduates via editorial articles on careerloft, through event information on e-fellows.net and through trainee and employee films on YouTube.  By the end of 2017, all 49 planned trainee slots and direct hires were filled through our employer branding and talent sourcing efforts.	<b>©</b>

#### Goal: Increase the share of employees (Group-wide) with development plans to 70% by 2020

Action(s):	Ву:	Progress by end of 2017:	Status:
Conduct extensive internal communications and people development campaigns, and optimize existing tools.	2020	The percentage of employees with development plans increased from 26% (2016) to 61% (2017).	<b>©</b>

# **Diversity**

Goal: Our target for 2021 is to maintain a 30% representation of women in leadership roles (Role 4+)

Action(s):	Ву:	Progress by end of 2017:	Status:
Deploy teams at departmental level to develop goals and measures to move women into positions in various units and hierarchies.	End of 2021	All business sectors have performed analyses and identified focus areas for actions.	•

# **Health and safety**

Goal: Reduce the lost time injury rate Group-wide (to 1.5 or less).

Action(s):	By:	Progress by end of 2017:	Status:
Reinforce our safety culture to prevent behavior-related accidents/Roll out our BeSafe! program at all newly acquired sites and monitor ongoing implementa- tion via appropriate performance indica- tors.	End of 2020	In 2017, we achieved a Group-wide LTIR of 1.5. Through manager training, safety tours and train-the-trainer programs, we continued to sustain a high level of safety awareness in 2017 as well. We took these steps at numerous sites – including ten newly acquired ones.	<b>©</b>

# **Employee engagement**

Goal: Measure and improve employee engagement

Action(s):	Ву:	Progress by end of 2017:	Status:
Implement a regularly occurring process to measure employee engagement and take actions to improve it.	Ongoing	Action plans were implemented throughout the organization based on 2016 results. Repeat survey conducted in November 2017 to check progress.	<b>©</b>

# **Good leadership**

Goal: Ensure that people managers are enabled to motivate and develop their employees

Action(s):	Ву:	Progress by end of 2017:	Status:
Have at least 50% of people managers rated Role 3+ take part in a management program.	End of 2018	As planned, all 400 of our top executives have taken part in our Global Leadership Program. Regarding our other management programs, 765 employees completed our Advanced Management program and 2,901 our Managerial Foundation program.	•

# Environment

# **Environmental stewardship**

Goal: Incorporate all production sites into our Group ISO 14001 certificate for environmental management systems.

Action(s):	Ву:	Progress by end of 2017:	Status:
At newly acquired production sites, introduce environmental management systems in line with our Group ISO 14001 certificate and certify them accordingly.	Ongoing	In 2017, 15 sites transferred their environ- mental management system to our Group certificate. All sites pertinent to the Group certificate have thus been transitioned to the new version of ISO 14001:2015.	•

# **Climate protection**

Goal: 20% reduction in our direct and indirect greenhouse gas emissions (Scope 1 and 2) by 2020 (2006 baseline)

Status: By the end of 2017, we had lowered our greenhouse gas emissions by roughly 8% relative to 2006 – despite operational growth.

Action(s):	By:	Progress by end of 2017:	Status:
Systematically examine the energy consumption at our individual production sites	End of 2020	We continued to systematically examine potential energy savings at our production facilities. In 2017, these analyses became part of our routine processes.	<b>⊘</b>
Identify potential energy savings and implement appropriate measures	End of 2020	In 2017, we implemented $\bf 36$ Edison projects with a view to cutting $\rm CO_2$ emissions by $\bf 3,500$ metric tons in the medium term. We thus failed to achieve our goal of saving up to 34,000 metric tons of $\rm CO_2$ . Multiple projects had to be postponed until 2018. In 2018, we intend to initiate 30 new projects with potential savings of 4,600 metric tons of $\rm CO_2$ .	•
Reduce process-related emissions	End of 2020	We have successfully completed an emissions reduction project for process-related emissions (launched in 2015). Through this project, we hope to cut greenhouse gas emissions by up to 28,000 metric tons per year. In 2017, the project saved approximately 10,000 metric tons of $CO_2$ . Technical issues have forced us to postpone another project (offering savings of roughly 23,000 metric tons of $CO_2$ ) until 2018. We intend to roll out two further projects in 2018 that aim to reduce $CO_2$ emissions by 24,000 metric tons.	•

### Waste and recycling

Goal: Set a reduction target by the end of 2017 for the volume of waste generated by our company

#### Status: goal achieved

Action(s):	Ву:	Progress by end of 2017:	Status:
Implement a waste scoring model (Waste Score of Merck KGaA, Darmstadt, Germany) to quantify our waste reduction efforts and set a baseline.	End of 2017	Using the Waste Score, we established a Group-wide baseline for 2016 from which has been used to set a new reduction target.	<b>⊘</b>

Goal: Reduce the environmental impact of our waste disposal (Waste Score of Merck KGaA, Darmstadt, Germany) by 5% by 2025 (baseline 2016)

Status: The goal was adopted by the Executive Board, under the guidance of the CR Committee, in November 2017. We are now developing a course of action to achieve it.

### Water management

Goal: Introduce a sustainable water management system at seven appropriate sites in water-stressed areas and reduce their water consumption by 10% by the end of 2020 (2014 baseline)

Status: By the end of 2017, we had reduced our water use at relevant sites by around 9% relative to 2014. Going forward, we want to ensure a sustainable 10% reduction in water use.

Action(s):	Ву:	Progress by end of 2017:	Status:
Create a water balance to make water use transparent.	April 2017	In 2017, the relevant sites developed their own water balances, thus creating transparency regarding their water use. To help in their efforts, water meters were installed at individual sites and consumption was measured at various points within the facilities.	<b>⊘</b>

Goal: Introduce a sustainable water management system at 24 production sites with high water use by 2020.

Status: Using the CEFIC Water Matters flagship initiative self-assessment tool, our sites are implementing a water management system in three stages. While stage 1 (basic) has already been achieved, we expect to achieve stage 2 (progressed) by May 2018 and stage 3 (advanced) by May 2020. Based on water use in 2016, a further site (Sheboygan, WI, USA) was included in the target group in 2017.

Action(s):	Ву:	Progress by end of 2017:	Status:
Meet the basic requirements set out in the CEFIC flagship self-assessment tool (stage 1). These include water quantity and quality evaluations at the sites, as well as an environment analysis.  One of the measures to be taken during stage 1, for instance, is the creation of water balances to make water use transparent.	April 2017	Stage 1 of the self-assessment was largely concluded in 2017.	<b>Ø</b>

Meet the "progressed" requirements set out in the CEFIC flagship self-assessment tool (stage 2). This involves creating transparency regarding the situation in the vicinity of the respective sites and beginning the evaluation of the sites' influence on their environment.	May 2018	During stage 2 of the self-assessment, we will essentially create transparency regarding the water situation in the vicinity of our individual sites. We will also start work on evaluating the influence our sites have on their surroundings.	<b>©</b>
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# suppliers

Goal: Ensure that suppliers adhere to ethical, social, environmental, and compliance standards.

Action(s):	By:	Progress by end of 2017:	Status:
Perform a qualitative analysis of the available assessment and audit findings, and define potential courses of action.		After analyzing 670 audit and assessment results, it became clear that 45 suppliers fell short of the score we specified for a working relationship and for procurement activities, and/or returned more than five critical defects.	<b>⊘</b>
		Joint meetings were held to discuss risk minimization options based on the evaluation results from Procurement and Quality Assurance. Following implementation of the corrective actions, suppliers are either re-assessed or reaudited.	
Create a holistic approach to managing sustainability within global supply chains.	2017	During the first half of 2017, Group Procurement conducted a management workshop and drafted a position statement on sustainability. As a result, four focus areas were defined and were further elaborated by the individuals responsible for sourcing within each business sector.	<b>⊘</b>

# community

#### Health

Hand in hand with our partners, we aim to eliminate the tropical worm disease schistosomiasis worldwide.

#### Goal: Eliminate schistosomiasis in African school children

Status: Since the start of our donation program, more than 150 million patients have been treated, primarily school-aged children.

Action(s):	Ву:	Progress by end of 2017:	Status:
Donate up to 250 million praziquantel tablets annually to WHO for African school children.	Ongoing	We keep production capacities at a level sufficient for manufacturing 250 million praziquantel tablets a year. In response to the needs of WHO, in 2017 we donated approximately 150 million tablets for distribution in 26 African countries.	•
Optimize the praziquantel formulation.	End of 2019	In 2017, we coordinated with WHO to draft the design for the bio-equivalence study. It is currently under consideration by the Mexican Food and Drug Administration. The study is to be carried out in 2018.	•

Develop a pediatric formulation of prazi- quantel for children under the age of six.	End of 2019	Since 2016, we've been conducting a Phase II study in Côte d'Ivoire to test the efficacy and safety of two different formulations for orodispersible tablets in schistosomiasis-infected children under six. We expect to have initial results by the second quarter of 2018. At the same time, we are preparing the Phase III study.	<b>©</b>
Initiate new partnerships to promote behavioral change in African school children.	Ongoing	Since 2017, we have been partnering with the NALA Foundation to raise awareness. Together, we are supporting a national health project sponsored by the Ethiopian Federal Ministry of Health.	•
Provide WHO with educational booklets to teach children about schistosomiasis and ways to prevent it.	Ongoing	In 2017, we donated 200,000 educational booklets to WHO for distribution across 12 African countries.	•
Position the Global Schistosomiasis Alliance (GSA) as a partner platform for advocacy, implementation, research, communication, and strategy develop- ment.	Ongoing	In 2017, the GSA expanded its global collaboration with schistosomiasis stakeholders. Furthermore, several NGOs became members of the organization.  The GSA hosted multiple schistosomiasis research conferences with experts from across the globe and continued to work towards the elimination of the disease in Ethiopia, Cameroon, Uganda, and Egypt.	<b>©</b>

# Minilab

# Goal: Provide and further develop the GPHF $\mbox{Minilab}^{\mbox{\scriptsize B}}$

Through the GPHF  $Minilab^{\otimes}$ , we seek to fight counterfeit medicines in developing and emerging economies.

End of 2017	In 2017, the GPHF developed test methods for five new active ingredients, meaning that a total of 90 test protocols are now available. The manuals have been updated accordingly.	<b>⊘</b>
End of 2017	In 2017, the GPHF conducted three Minilab training seminars with a total of around 50 participants. Seven additional seminars with well over 100 participants were conducted by GPHF partner organizations.  The GPHF sold a total of 41 Minilabs at cost and supplied 49 additional material deliveries for Minilabs currently in use.	<b>⊘</b>
End of 2018		•
End of 2018		0
End of 2020		0
	End of 2017  End of 2018  End of 2018	five new active ingredients, meaning that a total of 90 test protocols are now available. The manuals have been updated accordingly.  End of 2017  In 2017, the GPHF conducted three Minilab training seminars with a total of around 50 participants. Seven additional seminars with well over 100 participants were conducted by GPHF partner organizations. The GPHF sold a total of 41 Minilabs at cost and supplied 49 additional material deliveries for Minilabs currently in use.  End of 2018  End of 2018

# Recognition and rankings

The following overview presents a selection of major ratings and rankings. Information on additional ratings and accolades received by individual businesses or sites can be found in the respective chapter of our 2017 Corporate Responsibility Report, or on our company's website.

#### **CR** performance

#### Access to Medicine Index

In 2016, our company moved up to fourth place in the Access to Medicine Index (2014: sixth place). This index assesses 20 pharmaceutical companies with respect to their efforts to improve access to medicine in developing countries. It is published every two years by the Access to Medicine Foundation, an international non-profit organization.

www.accesstomedicineindex.org

#### CDP climate and water

Since 2008, we've been reporting our climate impact mitigation activities to the CDP (formerly the Carbon Disclosure Project). In 2017, we scored a B in the CDP and are thus among the top 37% of healthcare companies. The CDP assesses the strategy used and the success achieved by companies in reducing their greenhouse gas emissions, as well as how they address the risks and consequences of climate change.

In addition to these efforts, since 2016 we have also been reporting our water-related performance and processes to the CDP. In 2017, we received a B for our water management, thus moving up two places over the previous year. This good score was particularly attributable to our Water Protection standard, our strategic goals and the concrete steps we took to conserve water. The CDP evaluates performance in the areas of climate and water on a scale from A to D-, with A being the top score.

www.cdp.net

#### EcoVadis rating

The independent rating agency EcoVadis assesses suppliers from 120 countries across the categories of Environment, Labor Practices, Fair Business Practices, and Sustainable Procurement. As a member of the Together for Sustainability initiative, we also undergo this assessment. In 2017 we were awarded the Gold recognition level and were thus among the top 1% of all participating companies.

www.ecovadis.com

#### Good Company Ranking

In 2016 Kirchhoff Consult, a management consultancy, published its fifth Good Company Ranking. Among the 30 companies included in the DAX, we took tenth place. The ranking is published every two years.

www.kirchhoff-consult.com

#### oekom research Sustainability Rating

In 2017, the sustainability ratings agency oekom research AG gave our company a B- on a scale of A+ (top grade) to D-. As in the previous year, we thus once more achieved oekem Prime Status ("good" to "very good").

www.oekom-research.com

#### Vigeo Eiris Human Rights Study

In 2016 Vigeo Eiris, a sustainability rating and research agency, analyzed the extent to which over 3,000 companies meet their social responsibility to respect human rights. Our company ranks among the top 30 companies and achieved 69 out of 100 points, a score which corresponds to the highest of the four levels.

www.vigeo-eiris.com

#### Sustainability indices

#### Ethibel Sustainability Index (ESI) Excellence Europe and Ethibel EXCELLENCE Investment Register

In 2015 we were added to the ESI Excellence Europe, which includes the 200 top-rated European companies based on their corporate responsibility performance. We are also included in the Ethibel EXCELLENCE Investment Register.

www.forumethibel.org

#### Euronext Vigeo Eurozone 120 Index

Since 2015, we have been included in the Euronext-Vigeo Eurozone 120, which comprises the 120 highest-ranking European companies in terms of their environmental, social and governance efforts.

www.vigeo-eiris.com

#### FTSE4GOOD Global Index

Since 2008, we have been included in the FTSE4GOOD Global Index, a leading international sustainability index that annually measures the performance of companies in demonstrating strong environmental, social and ethical practices.

www.ftse.com

# STOXX® Global ESG Leaders Index

In 2017, our company was once again included in the STOXX Global ESG Leaders sustainability index, which assesses companies based on key environmental, social and governance criteria.

www.stoxx.com

### **CR** awards

#### Annual Report Competition (ARC) awards

In October 2017, our 2016 CR Report was awarded eight international ARC accolades across various categories, in particular in Interactive Annual Report, Interior Design, and Design/Graphics. Established by MerComm, Inc. in 1987, the ARC awards were created to honor particularly harmonious concepts in the fields of design, picture composition and written text.

www.mercommawards.com

#### Econ Awards

Presented by the German publisher Econ, the Econ Awards recognize outstanding concepts and practices in corporate communications. In November 2017, we won a Gold Econ Award for the digital version of our 2016 CR Report, with special mention made of its user-friendliness, information content and attractive presentation. We also received a Gold Econ Award for our curiosity campaign entitled #catchcurious, which was especially praised by the jury for linking scientific curiosity with our company values.

www.econforum.de (German only)

# sustainable pevelopment goals

In 2015, the United Nations adopted the Sustainable Development Goals (SDGs), which are aimed at all countries and organizations across the globe. We too are doing our bit to achieve these targets.

#### **Our efforts**

Under our Corporate Responsibility (CR) strategy (p. 9), we're already working to solve key challenges through efforts in the spheres of health, environment, and culture & education. We especially support Good Health & Well-Being (SDG 3), Quality Education (SDG 4) and Affordable & Clean Energy (SDG 7). To achieve these goals, we build strategic partnerships (SDG 17) that allow us to work hand in hand with other companies, non-governmental organizations and governments.



#### SDG 3: Good Health & Well-Being

"Ensure healthy lives and promote well-being for all at all ages."

Across the globe, two billion people have no access to medicines. According to estimates, approximately 400 million people lack access to effective and affordable medical care, a situation we intend to rectify through our Access to Health strategy (p. 38). Recognizing that we can't solve these challenges alone, we have joined forces with strong partners to work towards a solution.

# **Examples of our activities:**

- Eliminating schistosomiasis
- Efficient supply chains for better access to health (p. 44)
- Battle against neglected tropical diseases (p. 41)
- SDG 17: Partnerships for the goals (p. 19)

### **SDG 4: Quality education**

"Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all."

The sciences in particular play a key role in the development of pioneering solutions. A well-educated and well-trained work-force is also essential to our future as a science and technology company, which is why we are working to spark students' passion for science. To this end, we conduct a number of education projects (p. 114) across our sites worldwide, going to great lengths to provide underprivileged students with access to education.

#### **Examples of our activities:**

- School sponsorship project in India
- Supporting education at our Darmstadt site and our facilities worldwide (p. 114)
- School funding and scholarships across our supply chain (p. 108)
- SDG 17: Partner in the GIZ capacity building program "Afrika kommt!" (p. 85)

#### **SDG 5: Gender equality**

"Achieve gender equality and empower all women and girls."

- Promoting diversity and equal opportunity (p. 77)
- Promoting women's health and economic participation in developing countries (p. 50)

#### SDG 6: Clean water and sanitation

"Ensure availability and sustainable management of water and sanitation for all."

Protecting water as a resource (p. 97)

#### SDG 7: Affordable and clean energy

"Ensure access to affordable, reliable, sustainable and modern energy for all."

Our materials create ultra-efficient solar cells that can be used in innovative applications. Moreover, our products help customers save energy. For instance, state-of-the-art liquid crystals and OLED technology from our Performance Materials business sector make displays more energy-efficient. You can find more information under Sustainable product design (p. 32).

#### Examples of our activities:

- Integrating solar cells into architecture
- Energy-efficient products (p. 33)
- Investing in renewable energy (p. 92)

#### SDG 8: Decent work and economic growth

"Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all."

- Respecting human rights (p. 17)
- Creating a safe work environment (p. 80)

#### SDG 12: Responsible consumption and production

"Ensure sustainable consumption and production patterns."

- Design for Sustainability (p. 34)
- Preventing and recycling waste (p. 95)

#### SDG 13: Climate action

"Take urgent action to combat climate change and its impacts."

- Edison, our climate impact mitigation program (p. 91)
- Educating employees about climate impact mitigation (p. 92)

#### SDG 17: Partnerships for the goals

"Strengthen the means of implementation and revitalize the global partnership for sustainable development."

- Partnerships for quality healthcare (p. 19)
- Partnerships for discovering new compounds (p. 38)
- Active participation in the Alliance for Integrity (p. 16)
- Partner in the GIZ capacity building program "Afrika kommt!" (p. 85)

# Non-financial report



#### Index for the combined separate integrated non-financial report

Through our combined separate integrated non-financial report (hereinafter referred to as "non-financial report"), we fulfill the requirements arising from the CSR Directive Implementation Act. The separate non-financial report of the Group has been combined with the separate non-financial report of the parent undertaking, Merck KGaA, Darmstadt, Germany, in accordance with Section 289b (3) sentence 2 in conjunction with Section 298 (2) of the German Commercial Code, and integrated into our Corporate Responsibility Report. The following index provides an overview of the contents of the non-financial report and contains links to the relevant passages in the CR report. External references within our CR Report are not part of the non-financial report.

To provide the type of framework stipulated in Section 289b in conjunction with Section 315c (3) of the German Commercial Code, we have applied the standards of the Global Reporting Initiative (Option: Comprehensive) for this report.

#### Description of business model

We describe our business model, corporate structure, governance, and Group strategy under Company profile (p. 6).

#### Strategic and organizational approach to sustainability

Under Governance (p. 8), we present external guidelines and initiatives to which we've committed ourselves, along with Group-wide guidelines that are the cornerstone of our responsible governance. Our CR strategy (p. 9) sets out how we practice corporate responsibility, both in terms of strategy and at the organizational level.

#### Material aspects and issues

To determine the aspects and issues of relevance to the non-financial report, we conducted a materiality assessment (p. 22) that identified several issues that could not be assigned to any of the five aspects defined as minimum contents under Section 289c (2) of the German Commercial Code. Along with these five aspects, we have therefore decided to report on the following additional relevant issues:

Aspect	Issue
Environmental matters	<ul> <li>Environmental stewardship</li> <li>Pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste)</li> <li>Plant &amp; process safety</li> </ul>
Employee-related matters	<ul><li>Attracting, recruiting and retaining employees</li></ul>
Social matters	<ul><li>Patient safety</li><li>Counterfeit products</li><li>Responsible marketing</li><li>Data protection</li></ul>

Aspect	Issue
Respect for human rights	<ul><li>Bioethics (incl. genome editing)</li></ul>
	<ul><li>Clinical studies</li></ul>
Anti-corruption and anti-bribery	Compliance
,	Interactions with health systems
	<ul><li>Chemical product safety</li></ul>
	Labeling of chemicals and other products
	<ul><li>Transport and warehouse safety</li></ul>
	Prices of medicines
	<ul><li>Innovation and R&amp;D</li></ul>
	<ul><li>Digitalization</li></ul>

Within our approach to comprehensive risk and opportunity management, we also identify current and potential risks and opportunities in the areas of environment, community and governance. This includes information on the gross risks in terms of potential damage and probability, as well as the residual net risks remaining after mitigation measures have been effected. We did not identify any net risks that fulfill the materiality criteria as set forth by Section 289c (3) no. 3 and 4 of the German Commercial Code. Additional risks are described in the Report on Risks and Opportunities in the combined management report.

#### **Aspect: Environmental matters**

Within our Group, environmental matters fall under environmental stewardship. In the following section, we report on the measures implemented to further environmental stewardship, enhance plant & process safety, and address pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste).

Issue	Specification	n Reference
Environmental	Concepts incl.	<ul><li>Organizational structure of the Group function EQ (p. 87)</li></ul>
stewardship	due diligence processes	<ul> <li>Standards and standard operating procedures for environmental stewardship (p. 87)</li> </ul>
		Assessing environmental impacts (p. 89)
		ISO 14001 Group certificate (p. 89)
		<ul><li>Stakeholder engagement and dialogue (p. 197)</li></ul>
		Goals: Environment (p. 155)
	Outcome of	<ul> <li>Updating standards and standard operating procedures in line with amended</li> </ul>
	activities	version of ISO 14001:2015 (p. 87)
		Sizable investments in environmental impact mitigation (p. 89)
		<ul><li>Auditing our sites and reporting violations (p. 89)</li></ul>
		Sites obtain ISO 14001 certification (p. 89)
		Goal progress: Environment (p. 155)
Pharmaceutical and chemical residues in the	Concepts incl. due diligence processes	<ul><li>Provisions for environmental impact mitigation (p. 89)</li></ul>

Issue	Specification	Reference
environment (incl. aban- doned hazardous waste)	Outcome of activities	<ul> <li>Amount of provisions for environmental impact mitigation (p. 89)</li> <li>Remediation of contamination at Gernsheim site (p. 89)</li> </ul>
Plant & process safety	Concepts incl. due diligence processes	<ul> <li>Organizational structure: Plant &amp; process safety within EQ (p. 100)</li> <li>EHS standards and processes (p. 100)</li> <li>Tracking EHS performance indicators (p. 100)</li> <li>"Risk Management Process" (p. 101)</li> <li>Employee training and sharing lessons learned (p. 101)</li> </ul>
-	Outcome of activities	<ul> <li>EHS Incident Rate (p. 100)</li> <li>Substance spills and environmental impacts (p. 101)</li> <li>Employee training (p. 101)</li> </ul>

#### **Aspect: Employee-related matters**

Within our Group, employee-related matters fall under the purview of Human Resources (HR). Under this aspect, we report on concepts pertaining to attracting, recruiting and retaining employees.

Issue	Specification	Reference
		■ BeSafe! safety culture initiative (p. 81)
		<ul><li>Workplace health management (p. 81)</li></ul>
		<ul><li>Structural organization for engagement and inclusion (p. 82)</li></ul>
		■ Employee engagement surveys (p. 82)
		Rewarding innovative ideas (p. 82)
		Innovation Center (p. 82)
		<ul><li>Keeping employees informed and encouraging dialogue (p. 83)</li></ul>
		■ Deepening employee engagement (p. 83)
		- Competency model (n. 94)
		Competency model (p. 84)  Management program for leaders (p. 85)
		Management program for leaders (p. 85)
		University of Merck KGaA, Darmstadt, Germany (p. 85)
		Programs in growth markets (p. 85)
	Outcome of activities	<ul> <li>Participation in Performance and Potential Management Process and advanced training courses (p. 74)</li> </ul>
		Gender pay equity (p. 74)
		<ul><li>Number of trainees at Merck KGaA, Darmstadt, Germany (p. 74)</li></ul>
		<ul><li>Number of apprentices and hiring rate (p. 75)</li></ul>
		<ul><li>Leveraging digitalization (p. 75)</li></ul>
		■ Good standing in employer rankings (p. 76)
		<ul><li>Flexible working models, part-time work and parental leave (p. 76)</li></ul>
		Goal progress: Employees (p. 153)
		Indicators: Employees (p. 126)
		<ul><li>Increasing diversity awareness through "Different Perspectives" Diversity mont (p. 78)</li></ul>
		<ul><li>Activities within networks to bolster diversity (p. 79)</li></ul>
		<ul><li>No suspected cases of discrimination (p. 79)</li></ul>
		<ul><li>Key figures on international employees (p. 79)</li></ul>
		<ul><li>Demographic change campaign (p. 79)</li></ul>
		<ul><li>Sites obtain OHSAS 18001 certification (p. 80)</li></ul>
		<ul><li>Reducing our accident rate (p. 80)</li></ul>
		Initiatives and awareness campaigns as part of BeSafe! 2017 (p. 81)
		Projects to promote the health of our workforce (p. 81)
		<ul><li>Improving working environment (p. 82)</li></ul>
		Participation in innovation initiatives (p. 82)
		■ Teams at the Innovation Center (p. 82)
		Biopharma Innovation Cup 2017 (p. 83)
		<ul><li>Availability of pro and EVA (p. 83)</li></ul>
		Participation in management program (p. 85)
		Participation in University courses of Merck KGaA, Darmstadt, Germany (p. 85)
		Participation in Growth Markets Management Program (p. 85)

# **Aspect: Social matters**

"Social matters" encompasses our relationship with consumers. Under this heading, we report on concepts relating to patient safety, counterfeits, responsible marketing, and data security.

Issue	Specification	Reference
Patient safety	Concepts incl.	<ul><li>Approach to patient safety (p. 53)</li></ul>
	due diligence	Pharmacovigilance (p. 53)
	processes	■ Infrastructure for patient safety (p. 53)
		<ul><li>Patient safety guidelines (p. 53)</li></ul>
		Pharmacovigilance monitoring (p. 54)
		Product labeling (p. 54)
		■ Internal and external training (p. 54)
	Outcome of	<ul> <li>Inspecting and auditing our pharmacovigilance system (p. 54)</li> </ul>
	activities	Changing product labels (p. 54)
		■ Pharmacovigilance campaigns (p. 54)
Counterfeit	Concepts incl.	<ul><li>Approach to anti-counterfeiting (p. 55)</li></ul>
products	due diligence	<ul><li>Anti-counterfeiting organization (p. 55)</li></ul>
	processes	<ul><li>Anti-counterfeiting guidelines and standards (p. 55)</li></ul>
		<ul> <li>Monitoring and reporting systems (p. 56)</li> </ul>
		Supporting customers and patients (p. 56)
		■ Industry-wide exchange (p. 57)
		<ul><li>Educating our employees and business partners (p. 57)</li></ul>
		<ul> <li>Safety audits for contract manufacturers and distributors (p. 57)</li> </ul>
		Goals: Products (p. 148)
		Goals. Froducts (p. 146)
	Outcome of	<ul><li>Our own approach to supporting customers and patients (p. 56)</li></ul>
	activities	■ Employee training (p. 57)
		Findings from safety audits (p. 57)
		Goal progress: Products (p. 148)
Pasnansihla	Concepts incl	<ul><li>Infrastructure for responsible marketing (p. 59)</li></ul>
Responsible marketing	due diligence	Code of conduct and industry-wide rules (p. 59)
	processses	Reviewing marketing material (p. 60)
		Employee training (p. 60)
		Direct marketing only in certain countries (p. 60)
		Marketing chemicals (p. 60)
	Outcome of	<ul> <li>Addressing violations of standards and regulations (p. 60)</li> </ul>
	activities	■ Employee training participants (p. 60)
		Preventing chemical misuse (p. 60)

Issue	Specification	n Reference
Data Privacy	Concepts incl. due diligence processes	<ul> <li>Organization: Integrated into Compliance (p. 11)</li> <li>Policy for Data Protection and Personal Data Privacy (p. 11)</li> <li>Data privacy management system (p. 15)</li> </ul>
	Outcome of activities	■ Indicators: Protecting customer data (p. 125)

# **Aspect: Respect for human rights**

Under "Respect for human rights", we report on concepts related to bioethics (including genome editing) and clinical studies.

Issue	Specification	Reference
Bioethics (including genome editing)	Concepts incl. due diligence processes	<ul> <li>Organizational structure for addressing bioethical issues (p. 61)</li> </ul>
	Outcome of activities	<ul> <li>Discussions within the Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP) (p. 61)</li> </ul>
		■ Genome Editing Technology Principle (p. 62)
		■ Stem Cells Principle (p. 62)
		Fertility Principle (p. 62)
		<ul> <li>Guidelines and standard operation procedures for biosampling and biobanking (p</li> <li>62)</li> </ul>
		■ Guidelines on off-label use (p. 62)
Clinical studies	Concepts incl.	■ Fundamental requirements for clinical studies (p. 63)
	due diligence processes	<ul><li>Organizational structure for clinical studies (p. 63)</li></ul>
		<ul><li>Clinical study guidelines and agreements (p. 63)</li></ul>
		<ul><li>Supervision of clinical studies (p. 64)</li></ul>
		■ Teaming up to get results (p. 65)
		<ul><li>Close dialogue with patients and advocacy groups (p. 65)</li></ul>
		<ul><li>Responsible data sharing and data publication (p. 65)</li></ul>
_		■ Early Access Program (p. 66)
	Outcome of	■ Findings from audits on contract research organizations (p. 65)
	activities	■ EUPATI (p. 65)
		<ul><li>Marketing approval for Avelumab (p. 66)</li></ul>
		Position paper on the Early Access Program (p. 66)

# **Aspect: Anti-corruption and anti-bribery matters**

Within our corporate structure, anti-corruption efforts fall under Compliance Management, so we report here on compliance and interactions with health systems.

Issue	Specification	Reference
Compliance	Concepts incl. due diligence processes	<ul> <li>Structural organization: Group Compliance (p. 11)</li> <li>Compliance guidelines and standards (p. 11)</li> <li>Compliance audits (p. 14)</li> <li>Compliance training (p. 14)</li> <li>Compliance. Because We Care initiative (p. 14)</li> <li>SpeakUp Line (p. 14)</li> <li>Businss Partner Risk Management (p. 15)</li> <li>Alliance for Integrity (p. 15)</li> <li>Goals: Compliance (p. 152)</li> </ul>
	Outcome of activities	<ul> <li>Compliance training participants (p. 14)</li> <li>SpeakUp Line for reported and confirmed cases of non-compliance (p. 14)</li> <li>Risk analysis and training of business partners (p. 15)</li> <li>Goal progress: Compliance (p. 152)</li> <li>Indicators: Compliance (p. 121)</li> </ul>
Interactions with health systems	Concepts incl. due diligence processes	<ul> <li>Organizational structure for interactions with health systems (p. 70)</li> <li>Group-wide guidelines and industry-wide standards (p. 70)</li> <li>Transparent reporting (p. 70)</li> <li>Collaboration with patient advocacy groups (p. 71)</li> <li>Transparent promotion of research and education (p. 71)</li> </ul>
	Outcome of activities	<ul> <li>Publication of an EFPIA transparency report (p. 70)</li> <li>Publication of a position paper on continuing medical education (p. 71)</li> </ul>

#### Other matters

In the following section, we report on significant issues that are not covered in any of the five minimum aspects stipulated in section 289c (2) of the German Commercial Code:

Specification	Reference
Concents incl	<ul><li>Organizational structure for product safety (p. 50)</li></ul>
due diligence	Group-wide and industry-wide guidelines (p. 50)
processes	REACH registration (p. 50)
	Supporting our Global Product Strategy (p. 50)
	<ul> <li>Assessing safety during product development (p. 51)</li> </ul>
	Safe nanotechnology (p. 51)
	Standardized product safety information (p. 52)
	Goals: Products (p. 148)
	Goals. Floudets (p. 140)
Outcome of	<ul><li>Number and languages of safety data sheets (p. 52)</li></ul>
activities	ScIDeEx (p. 52)
	Goal progress: Products (p. 148)
•	• Organizational structure for product safety (p. 50)
processes	Statutory regulations and Group-wide guidelines (p. 50)
	Standardized product safety information (p. 52)
	Goals: Products (p. 148)
Outcome of	<ul><li>Number and languages of safety data sheets (p. 52)</li></ul>
activities	ScIDeEx (p. 52)
	Goal progress: Products (p. 148)
Concents incl	Structural organization: EQ and dangerous goods manager (p. 57)
1 1919	Globally applicable standards (p. 57)
processes	Transport & warehouse safety audits (p. 58)
	<ul> <li>Strengths and weaknesses profile (p. 58)</li> </ul>
	<ul> <li>Employee training and regular discussions (p. 59)</li> </ul>
	Proper transport (p. 59)
	Transport vehicles (p. 59)
	Goals: Products (p. 148)
Outcome of	Number and results of audits (p. 58)
activities	No incidents or violations (p. 58)
	<ul><li>Employee training and internal best practice sharing events (p. 59)</li></ul>
	Employee training and internal nest practice sparing events in 500
	Concepts incl. due diligence processes  Outcome of activities  Concepts incl. due diligence processes  Outcome of activities  Concepts incl. due diligence processes

Issue	Specification	Reference
Prices of medi-	due diligence	Structural pricing organization (p. 46)
cines		<ul><li>Medicine price guidelines and principles (p. 46)</li></ul>
	processes	<ul><li>Data-based pricing (p. 46)</li></ul>
		■ Innovative contracting models (p. 46)
		Government tenders (p. 46)
		<ul><li>Second lower-price brands (p. 47)</li></ul>
		■ Patient Access Programs (p. 47)
	Outcome of	<ul><li>Examples of innovative contracting models (p. 46)</li></ul>
	activities	<ul><li>Examples of government tenders (p. 46)</li></ul>
		<ul><li>Examples of second lower-price brands (p. 47)</li></ul>
		Examples of Patient Access Programs (p. 47)
Innovation and	Concepts incl.	<ul><li>Continuous innovation process (p. 29)</li></ul>
R&D	due diligence	<ul><li>Structural organization of research and development (p. 29)</li></ul>
	processes	■ Innovation Center (p. 30)
		■ Displaying Futures Award (p. 31)
		■ Fostering young talent: An investment in the future (p. 31)
	Outcome of	Research & development spending (p. 29)
	activities	<ul><li>Strategic partnerships (p. 29)</li></ul>
		■ Venture Fund of Merck KGaA, Darmstadt, Germany (p. 29)
		<ul><li>Projects in the Innovation Center (p. 30)</li></ul>
		<ul><li>2017 Displaying Futures Award (p. 31)</li></ul>
		Examples of fostering talent (p. 31)
Digitalization	Concepts incl.	Structural organization of research and development (p. 29)
	due diligence processes	■ Four strategic focus areas (p. 29)
	Outcome of activities	■ Examples from the strategic focus areas (p. 32)

# general disclosures

The CR Report 2017 has been prepared in accordance with the GRI Standards: 'Comprehensive' option. The following GRI content index provides an overview of general disclosures, the GRI standards (Topic-specific Standards) and management approaches identified as relevant, as well as where the corresponding contents are described.

#### **GRI Content Index: General disclosures**

GRI St	andards and Disclosure Number	Comment	Reference
Organi	izational profile		
102-1	Name of the organization		Company profile (p. 6)
102-2	Activities, brands, products, and services		Company profile (p. 6) Products & Industries
102-3	Location of headquarters		Company profile (p. 6)
102-4	Location of operations		Company profile (p. 6) List of shareholdings
102-5	Ownership and legal form		Company profile (p. 6)
102-6	Markets served		Company profile (p. 6) Macroeconomic and Sector-Specific Environment
102-7	Scale of the organization		Company profile (p. 6) Indicators: employees (p. 126) Indicators: environment (p. 139) Net sales Capitalization Consolidated Balance Sheet
102-8	Information on employees and other workers	Supervised workers such as temps are not logged in our employee data system.	Indicators: employees (p. 126) Attractive employer (p. 73)
102-9	Supply chain		Supply chain standards (p. 104) Mica supply chain (p. 106) Resource efficiency (p. 94)
102-10	Significant changes to the organization and its supply chain		Company profile (p. 6) Supply chain standards (p. 104) Resource efficiency (p. 94) Fundamental Information about the Group
102-11	Precautionary Principle or approach		Transport and warehouse safety (p. 57) Health and safety (p. 80) Environmental stewardship (p. 87) Climate protection (p. 90) Plant and process safety (p. 100) Chemical product safety (p. 50)
102-12	External initiatives		Governance (p. 8) Compliance (p. 11) Human rights (p. 17)
102-13	Membership of associations		Stakeholder dialogue (p. 19) Environmental stewardship (p. 87)

#### Strategy

102-14 Statement from senior decision-maker	Letter from the CEO (p. 3)
102-15 Key impacts, risks, and opportunities	CR strategy (p. 9) Materiality analysis (p. 22) Goals (p. 148) Report on Risks and Opportunities
Ethics and integrity	
102-16 Values, principles, standards, and norms of behavior	Diversity (p. 77) Good leadership (p. 84) Governance (p. 8) Human rights (p. 17) Compliance (p. 11) Bioethics (p. 61) Clinical studies (p. 63) Animal welfare (p. 67)
102-17 Mechanisms for advice and concerns about ethics	Compliance (p. 11) Diversity (p. 77) Mica supply chain (p. 106) Bioethics (p. 61) Clinical studies (p. 63) Animal welfare (p. 67)
Governance	
102-18 Governance structure	CR strategy (p. 9) Management Statement on Corporate Governance
102-19 Delegating authority	CR strategy (p. 9) Procedures of the corporate bodies
102-20 Executive-level responsibility for economic, environmental, and social topics	CR strategy (p. 9)
102-21 Consulting stakeholders on economic, environmental, and social topics	CR strategy (p. 9) Stakeholder dialogue (p. 19) Employee engagement (p. 82) Materiality analysis (p. 22)
102-22 Composition of the highest governance body and its committees	Management Statement on Corporate Governance The Executive Board The Supervisory Board Objectives of the Supervisory Board with respect to its composition
102-23 Chair of the highest governance body	Management Statement on Corporate Governance
102-24 Nominating and selecting the highest governance body	Diversity (p. 77) The Executive Board Statement on Corporate Governance Diversity policy Objectives of the Supervisory Board with respect to its composition
102-25 Conflicts of interest	Compliance (p. 11) Information on corporate governance practices
102-26 Role of highest governance body in setting purpose, values, and strategy	CR strategy (p. 9) Values and compliance Report of the Supervisory Board

CR strategy (p. 9) The Executive Board Statement on Corporate Governance
Company profile (p. 6) Board of Partners The Supervisory Board Statement on Corporate Governance
CR strategy (p. 9) Compliance (p. 11) Materiality analysis (p. 22) Report profile (p. 118) Report on Risks and Opportunities Statement on Corporate Governance
CR strategy (p. 9) Report profile (p. 118) Report on Risks and Opportunities Report of the Supervisory Board
CR strategy (p. 9) Report profile (p. 118) Report on Risks and Opportunities Report of the Supervisory Board
Report profile (p. 118)
Compliance (p. 11) Values and compliance
Compliance (p. 11) Values and compliance
Compensation report
Compensation report
Attractive employer (p. 73) Compensation report

102-38 Annual total compensation ratio

Competitive salaries and additional benefits not only increase our attractiveness as an employer; they also motivate our people and build loyalty to the company. The compensation we offer is based on market analyses in the relevant field and the value of the respective position, as well as the employee's skill set and performance. Our Global Rewards Policy defines the framework for compensation and benefits across the entire Group. As far as possible, we strive to offer all our employees comparable compensation structures. Furthermore, we monitor compliance with minimum standards. We do not consider the information required under GRI 102-38 and GRI 102-39 to be relevant to assessing the fairness of our compensation structures.

# 102-39 Percentage increase in annual total compensation ratio

Competitive salaries and additional benefits not only increase our attractiveness as an employer; they also motivate our people and build loyalty to the company. The compensation we offer is based on market analyses in the relevant field and the value of the respective position, as well as the employee's skill set and performance. Our Global Rewards Policy defines the framework for compensation and benefits across the entire Group. As far as possible, we strive to offer all our employees comparable compensation structures. Furthermore, we monitor compliance with minimum standards. We do not consider the information required under GRI 102-38 and GRI 102-39 to be relevant to assessing the fairness of our compensation structures.

#### Stakeholder engagement

102-40 List of stakeholder groups	Stakeholder dialogue (p. 19) Materiality analysis (p. 22)
102-41 Collective bargaining agreements	Employee engagement (p. 82)
102-42 Identifying and selecting stakeholders	Stakeholder dialogue (p. 19) Materiality analysis (p. 22)

102-43 Approach to stakeholder engagement	Stakeholder dialogue (p. 19) Materiality analysis (p. 22)
102-44 Key topics and concerns raised	Stakeholder dialogue (p. 19) Materiality analysis (p. 22)
Reporting practice	
102-45 Entities included in the consolidated financial statements	Report profile (p. 118) Company profile (p. 6)
102-46 Defining report content and topic Boundaries	Report profile (p. 118) Materiality analysis (p. 22)
102-47 List of material topics	Materiality analysis (p. 22)
102-48 Restatements of information	Report profile (p. 118)
102-49 Changes in reporting	Report profile (p. 118) Materiality analysis (p. 22)
102-50 Reporting period	Report profile (p. 118)
102-51 Date of most recent report	Report profile (p. 118)
102-52 Reporting cycle	Report profile (p. 118)
102-53 Contact point for questions regarding the report	Report profile (p. 118)
102-54 Claims of reporting in accordance with the GRI Standards	GRI content index (p. 173)
102-55 GRI content index	GRI content index (p. 173)
102-56 External assurance	GRI content index (p. 173) Report profile (p. 118)

# Economic standards

# **GRI Content Index: Economic Standards**

GRI S	tandards and Disclosure Number	Comment	Reference
GRI 2	01: ECONOMIC PERFORMANCE 2016		
103-1	Explanation of the material topic and its Boundary		Employee engagement (p. 82) Materiality analysis (p. 22)
103-2	The management approach and its components		Statement on Corporate Governance Economic performance Pension schemes
103-3	Evaluation of the management approach		Report on Risks and Opportunities
201-1	Direct economic value generated and distributed		Indicators: community (p. 146) Consolidated Income Statement Consolidated Cash Flow Statement Information by business sector /country and region Personnel expenses
201-2	Financial implications and other risks and opportunities due to climate change	We report in detail on various aspects of climate change as part of our participation in the CDP (formerly known as the Carbon Disclosure Project).	Climate protection (p. 90) Water management (p. 97) Global Compact CoP (p. 190) Report on Risks and Opportunities
201-3	Defined benefit plan obligations and other retirement plans		Indicators: employees (p. 126) Pension schemes
201-4	Financial assistance received from government		Accounting: Property, plant and equipment Property, plant and equipment Research and development costs
GRI 2	02: MARKET PRESENCE 2016		
103-1	Explanation of the material topic and its Boundary		Good leadership (p. 84) Diversity (p. 77)
103-2	The management approach and its components		Employee engagement (p. 82) Materiality analysis (p. 22)
103-3	Evaluation of the management approach		

202-1 Ratios of standard entry level wage gender compared to local minimum wage	This indicator is not relevant to us, which is why we do not collect data on the ratio of the standard entry level wage compared to local minimum wage. Our Global Rewards Policy applies to all our subsidiaries worldwide and guarantees a systematic compensation structure. Both base pay and short-term variable compensation are oriented to the median base pay of the relevant reference market. Our pay brackets are reviewed on an annual basis and reflect market conditions It goes without saying that walways adhere to local minimum wage levels.	
202-2 Proportion of senior management hi from the local community		
GRI 204: PROCUREMENT PRACTICES 2	016	
103-1 Explanation of the material topic and its Boundary	1	Supply chain standards (p. 104) Mica supply chain (p. 106) Materiality analysis (p. 22)
103-2 The management approach and its components		ridectionery unarysis (p. 22)
103-3 Evaluation of the management approach		
204-1 Proportion of spending on local suppliers		Supply chain standards (p. 104)
GRI 205: ANTI-CORRUPTION 2016		
103-1 Explanation of the material topic and its Boundary	1	Compliance (p. 11) Interactions with health systems (p. 70)
103-2 The management approach and its components		Materiality analysis (p. 22)
103-3 Evaluation of the management approach		
205-1 Operations assessed for risks related corruption	I to	Compliance (p. 11) Indicators: compliance (p. 121) Values and compliance Report on Risks and Opportunities
205-2 Communication and training about anti-corruption policies and procedu	res	Governance (p. 8) Compliance (p. 11) Indicators: compliance (p. 121)
205-3 Confirmed incidents of corruption ar actions taken	d As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Compliance (p. 11) Indicators: compliance (p. 121) Report on Risks and Opportunities

GRI 206: ANTI-COMPETITIVE BEHAVIOR 2016	
103-1 Explanation of the material topic and its Boundary	Compliance (p. 11) Materiality analysis (p. 22)
103-2 The management approach and its components	
103-3 Evaluation of the management approach	
206-1 Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Indicators: compliance (p. 121)
Additional material topics	
TECHNOLOGY (Innovation and R&D, Digitalization)	
103-1 Explanation of the material topic and its Boundary	Innovation and digitalization (p. 29) Materiality analysis (p. 22)
103-2 The management approach and its components	
103-3 Evaluation of the management approach	
DATA SECURITY	
103-1 Explanation of the material topic and its Boundary	Compliance (p. 11) Materiality analysis (p. 22)
103-2 The management approach and its components	
103-3 Evaluation of the management approach	

# Environmental standards

# **GRI Content Index: Environmental Standards**

<b>GRI Standards and Disclosure Number</b>	Comment	Reference
<b>GRI 301: MATERIALS 2016</b>		
<ul><li>103-1 Explanation of the material topic and its Boundary</li><li>103-2 The management approach and its components</li></ul>	In all our endeavors, we attempt to efficiently utilize materials and recycle as much as possible. Where feasible, we use recycled materials (in	Resource efficiency (p. 94) Packaging (p. 36) Reuse and recycling (p. 37) Materiality analysis (p. 22)
103-3 Evaluation of the management approach	packaging, for instance). Overall, material consumption is not a major concern for us. There are few opportunities to use recycled material in our production processes because our business model puts us at the start of the value chain. We therefore do not collect such data at the Group-level. Individual data and measures are reported under the respective chapters.	
301-1 Materials used by weight or volume	See GRI 103: 301	Resource efficiency (p. 94) Sustainable product design (p. 32) Packaging (p. 36)
301-2 Recycled input materials used	See GRI 103: 301	Packaging (p. 36) Reuse and recycling (p. 37) Resource efficiency (p. 94) Sustainable product design (p. 32) Waste and recycling (p. 95)
301-3 Reclaimed products and their packaging materials	Owing to the multitude of products we supply and the minimal comparability of our various initiatives, we do not collect quantitative data at the Group level. The individual measures taken by our various businesses are reported in the respective chapters.	Packaging (p. 36) Reuse and recycling (p. 37)
GRI 302: ENERGY 2016		
103-1 Explanation of the material topic and its Boundary		Climate protection (p. 90) Sustainable product design (p. 32) Materiality analysis (p. 22)
103-2 The management approach and its components		riaceriality alialysis (p. 22)
103-3 Evaluation of the management approach		
302-1 Energy consumption within the organization		Climate protection (p. 90) Indicators: environment (p. 139)
302-2 Energy consumption outside of the organization		Climate protection (p. 90)
302-3 Energy intensity		Climate protection (p. 90) Indicators: environment (p. 139)
302-4 Reduction of energy consumption		Climate protection (p. 90) Indicators: environment (p. 139)

302-5 Reductions in energy requirements of products and services		Sustainable product design (p. 32) Resource efficiency (p. 94)
GRI 303: WATER 2016		
103-1 Explanation of the material topic and its Boundary		Water management (p. 97) Materiality analysis (p. 22)
103-2 The management approach and its components		
103-3 Evaluation of the management approach		
303-1 Water withdrawal by source		Water management (p. 97) Indicators: environment (p. 139)
303-2 Water sources significantly affected by withdrawal of water		Water management (p. 97)
303-3 Water recycled and reused		Water management (p. 97) Indicators: environment (p. 139)
GRI 305: EMISSIONS 2016		
103-1 Explanation of the material topic and its Boundary		Climate protection (p. 90) Materiality analysis (p. 22)
103-2 The management approach and its components		
103-3 Evaluation of the management approach		
305-1 Direct (Scope 1) GHG emissions		Climate protection (p. 90) Indicators: environment (p. 139)
305-2 Energy indirect (Scope 2) GHG emissions		Climate protection (p. 90) Indicators: environment (p. 139)
305-3 Other indirect (Scope 3) GHG emissions		Climate protection (p. 90) Indicators: environment (p. 139)
305-4 GHG emissions intensity		Indicators: environment (p. 139)
305-5 Reduction of GHG emissions		Climate protection (p. 90) Indicators: environment (p. 139) Sustainable product design (p. 32) Packaging (p. 36)
305-6 Emissions of ozone-depleting substances (ODS)	This disclosure is not material to Merck KGaA, Darmstadt, Germany.	Indicators: environment (p. 139)
305-7 Nitrogen oxides (NOX), sulfur oxides (SOX), and other significant air emissions	This disclosure is not material to Merck KGaA, Darmstadt, Germany.	Indicators: environment (p. 139)
GRI 306: EFFLUENTS AND WASTE 2016		
103-1 Explanation of the material topic and its Boundary		Water management (p. 97) Waste and recycling (p. 95)
103-2 The management approach and its components		Materiality analysis (p. 22)
103-3 Evaluation of the management approach		
306-1 Water discharge by quality and destination		Water management (p. 97) Indicators: environment (p. 139)
306-2 Waste by type and disposal method		Waste and recycling (p. 95) Reuse and recycling (p. 37) Indicators: environment (p. 139)
306-3 Significant spills		Plant and process safety (p. 100) Indicators: environment (p. 139)
306-4 Transport of hazardous waste		Indicators: environment (p. 139)

306-5 Water bodies affected by water discharges and/or runoff	Water management (p. 97)
GRI 307: ENVIRONMENTAL COMPLIANCE 2016	
103-1 Explanation of the material topic and its Boundary	Environmental stewardship (p. 87) Materiality analysis (p. 22)
103-2 The management approach and its components	
103-3 Evaluation of the management approach	
307-1 Non-compliance with environmental laws and regulations	Environmental stewardship (p. 87)
GRI 308: SUPPLIER ENVIRONMENTAL ASSESSMENT 2016	
103-1 Explanation of the material topic and its Boundary	Supply chain standards (p. 104) Materiality analysis (p. 22)
103-2 The management approach and its components	Mica supply chain (p. 106)
103-3 Evaluation of the management approach	
308-1 New suppliers that were screened using environmental criteria	Supply chain standards (p. 104) Mica supply chain (p. 106)
308-2 Negative environmental impacts in the supply chain and actions taken	Supply chain standards (p. 104) Mica supply chain (p. 106)

# social standards

# **GRI Content Index: Social Standards**

GRI S	tandards and Disclosure Number	Comment	Reference
GRI 4	01: EMPLOYMENT 2016		
103-1	Explanation of the material topic and its Boundary		Attractive employer (p. 73) Diversity (p. 77)
103-2	The management approach and its components		Health and safety (p. 80) Materiality analysis (p. 22)
103-3	Evaluation of the management approach		
401-1	New employee hires and employee turnover		Indicators: employees (p. 126)
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	At Merck KGaA, Darmstadt, Germany (20% of the company's total workforce), part-time employees receive the same job benefits as full-time workers. Employees with temporary contracts, however, are not entitled to all company benefits, such as a company pension.	Indicators: employees (p. 126) Attractive employer (p. 73)
401-3	Parental leave		Attractive employer (p. 73) Indicators: employees (p. 126)
GRI 4	02: LABOR/MANAGEMENT RELATIONS	S 2016	
103-1	Explanation of the material topic and its Boundary		Attractive employer (p. 73) Health and safety (p. 80)
103-2	The management approach and its components		Employee engagement (p. 82) Materiality analysis (p. 22)
103- 3	Evaluation of the management approach		
402-1	Minimum notice periods regarding operational changes	The regulations on periods of notice vary worldwide. We apply the rules that are in force locally. There is no need for us to track periods of notice at Group level.	
GRI 4	03: OCCUPATIONAL HEALTH AND SAF	ETY 2016	
103-1	Explanation of the material topic and its Boundary		Health and safety (p. 80) Materiality analysis (p. 22)
103-2	The management approach and its components		
103-3	Evaluation of the management approach		

### Workers representation in formal joint management—worker health and safety committees are required by lew in Germany. All employees of Merck KGaA, Darmstadt, Germany are therefore represented by such committees, which operate at the state level. These expresented by such committees, which operate at the state level. These overselves on the state level, or facilities outside Germany also have health and safety committees to represent their employees. Each individual site is responsible for arranging and maintaining such committees to represent their employees. Each individual site is responsible for arranging and maintaining such committees.  #### Workers with high incidence or high risk of diseases related to their occupation.  #### Workers with high incidence or high risk of diseases related to their occupation.  #### Workers with high incidence or high risk of diseases related to their occupation.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety topics covered in formal agreements with trade unions.  #### Health and safety (p. 80)  #### Health an				
occupational diseases, lost days, and absenteeism, and number of work-related fatalities  403-3 Workers with high incidence or high risk of diseases related to their occupation  403-4 Health and safety topics covered in formal agreements with trade unions  403-6 Health and safety topics covered in formal agreements with trade unions  403-7 Health and safety topics covered in formal agreements with trade unions  403-8 Health and safety topics covered in formal agreements with trade unions  403-9 Health and safety issues are governed Group-wide by our EHS Policy. The organizational implementation of the policy is the responsibility of our individual sites and is subject to local laws and regulations. Merck KGaA, Darmstadt, Germany, which accounts for approximately 20% of our total workforce, has bylaws on occupational health and safety in place.  404-1 Explanation of the material topic and its components  404-1 Average hours of training per year per employee employee  404-1 Average hours of training per year per employee  404-2 Programs for upgrading employee skills and transition assistance programs  404-2 Programs for upgrading employee skills and transition assistance programs regular performance and career devel-	403-1	management–worker health and safety	safety committees are required by law in Germany. All employees of Merck KGaA, Darmstadt, Germany are therefore represented by such committees, which operate at the site level. These employees account for around 20% of our total workforce. The majority of facilities outside Germany also have health and safety committees to represent their employees. Each individual site is responsible for arranging and main-	Health and safety (p. 80)
risk of diseases related to their occupa- tion  403-4 Health and safety topics covered in formal agreements with trade unions  Els Policy. The organizational implementation of the policy is the responsibility of our individual sites and is subject to local laws and regulations. Merck KGaA, Darmstadt, Germany, which accounts for approximately 20% of our total workforce, has bylaws on occupational the Boundary  6RI 404: TRAINING AND EDUCATION 2016  Explanation of the material topic and its Boundary  The management approach and its components  Possible and the management approach and its components  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  Possible for the management approach and warehouses affety (p. 50)  Counterfit products (p. 55)  Attractive employer (p. 73)  Diversity (p. 77)  Health and safety (p. 50)  Counterfit products affety (p. 50)  Attractive employer (p. 73)  Diversity (p. 77)  Health and safety (p. 50)  Counterfit products (p. 55)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Plant and process safety (p. 100)  Transport and warehouse safety (p. 57)  Responsible marketing (p. 59)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Plant and process safety (p. 100)  Transport and warehouse safety (p.	403-2	occupational diseases, lost days, and absenteeism, and number of work-	time injury rate (LTIR) as a key performance indicator for	
formal agreements with trade unions  governed Group-wide by our EHS Policy. The organizational implementation of the policy is the responsibility of our individual sites and is subject to local laws and regulations. Merck KGaA, Darmstadt, Germany, which accounts for approximately 20% of our total workforce, has bylaws on occupational health and safety in place.  GRI 404: TRAINING AND EDUCATION 2016  103-1 Explanation of the material topic and its Boundary  103-2 The management approach and its components  Evaluation of the management approach and its components  Evaluation of the management approach and its open and its employee employee employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  Compliance (p. 11) Patient safety (p. 50) Chemical products (p. 55) Animal welfare (p. 67) Altimative employee (p. 73) Diversity (p. 77) Health and safety (p. 80) Good leadership (p. 84) Plant and process safety (p. 100) Transport and warehouse safety (p. 57) Responsible marketing (p. 59)  404-2 Programs for upgrading employee skills and transition assistance programs  Attractive employee (p. 73) Diversity (p. 77) Good leadership (p. 84) Patrictive employee (p. 73) Diversity (p. 77) Good leadership (p. 84) Attractive employee (p. 73) Indicators: employees (p. 126)	403-3	risk of diseases related to their occupa-		
103-1 Explanation of the material topic and its Boundary  103-2 The management approach and its components  103-3 Evaluation of the management approach  404-1 Average hours of training per year per employee  404-1 Average hours of training per year per employee  404-1 Average hours of training per year per employee  405-3 Evaluation of the management approach  406-3 Programs for upgrading employee skills and transition assistance programs  406-3 Percentage of employees receiving regular performance and career devel-	403-4		governed Group-wide by our EHS Policy. The organizational implementation of the policy is the responsibility of our individual sites and is subject to local laws and regulations. Merck KGaA, Darmstadt, Germany, which accounts for approximately 20% of our total workforce, has bylaws on occupational health and safety	
its Boundary  The management approach and its components  Evaluation of the management approach  Average hours of training per year per employee  Average hours of training per year per employee  Spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  Compliance (p. 11)  Patient safety (p. 53)  Chemical product safety (p. 50)  Counterfeit products (p. 55)  Animal welfare (p. 67)  Attractive employer (p. 73)  Diversity (p. 77)  Health and safety (p. 80)  Good leadership (p. 84)  Plant and process safety (p. 100)  Transport and warehouse safety (p. 57)  Responsible marketing (p. 59)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Attractive employer (p. 73)  Indicators: employees (p. 126)	GRI 4	04: TRAINING AND EDUCATION 2016		
103-3 Evaluation of the management approach  404-1 Average hours of training per year per employee  404-1 Average hours of training per year per employee  404-1 Average hours of training per year per employee  404-2 Programs for upgrading employee skills and transition assistance programs  404-3 Percentage of employees receiving regular performance and career devel-  404-3 Percentage of employees receiving regular performance and career devel-  404-1 Average hours of training per year per everage hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  404-1 Average hours of training per year per everage hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  404-1 Average hours of training per year per everage hours our employees safety (p. 50)  404-2 Compliance (p. 11)  Patient safety (p. 50)  Counterfeit products (p. 55)  Attractive employer (p. 73)  Diversity (p. 77)  Responsible marketing (p. 59)  404-2 Programs for upgrading employee skills and transition assistance programs  404-3 Percentage of employees receiving regular performance and career devel-		its Boundary		Diversity (p. 77)
approach  404-1 Average hours of training per year per employee  Employee We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  Compliance (p. 11)  Patient safety (p. 53)  Chemical product safety (p. 50)  Counterfeit products (p. 55)  Animal welfare (p. 67)  Attractive employer (p. 73)  Diversity (p. 77)  Health and safety (p. 80)  Good leadership (p. 84)  Plant and process safety (p. 57)  Responsible marketing (p. 59)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Attractive employer (p. 73)  Diversity (p. 77)  Good leadership (p. 84)  Attractive employer (p. 73)  Indicators: employees (p. 126)		components		
employee average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.  Patient safety (p. 53) Chemical product safety (p. 50) Counterfeit products (p. 55) Animal welfare (p. 67) Attractive employer (p. 73) Diversity (p. 77) Health and safety (p. 80) Good leadership (p. 84) Plant and process safety (p. 100) Transport and warehouse safety (p. 57) Responsible marketing (p. 59)  404-2 Programs for upgrading employee skills and transition assistance programs  Attractive employer (p. 73) Diversity (p. 77) Good leadership (p. 84)  Attractive employer (p. 73) Indicators: employees (p. 126)	103-3			
and transition assistance programs  Diversity (p. 77) Good leadership (p. 84)  404-3 Percentage of employees receiving regular performance and career devel-  Indicators: employees (p. 126)	404-1		average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our	Patient safety (p. 53) Chemical product safety (p. 50) Counterfeit products (p. 55) Animal welfare (p. 67) Attractive employer (p. 73) Diversity (p. 77) Health and safety (p. 80) Good leadership (p. 84) Plant and process safety (p. 100) Transport and warehouse safety (p. 57) Responsible marketing (p. 59)
regular performance and career devel-  Indicators: employees (p. 126)	404-2			Diversity (p. 77)
	404-3	regular performance and career devel-		

# **GRI 405: DIVERSITY AND EQUAL OPPORTUNITY 2016**

	US. DIVERSITT AND EQUAL OF TORTO		
103-1	Explanation of the material topic and its Boundary		Diversity (p. 77) Attractive employer (p. 73)
103-2	The management approach and its components		Materiality analysis (p. 22) Objectives of the Supervisory Board with respect to its composition
103-3	Evaluation of the management approach		
405-1	Diversity of governance bodies and employees	Since there is no globally uniform definition of the term "minority", we do not record this sort of data. Moreover, many countries in which we operate have strict data privacy regulations governing the recording of personal employee data.	Diversity (p. 77) Indicators: employees (p. 126) The Executive Board The Supervisory Board Objectives of the Supervisory Board with respect to its composition
405-2	Ratio of basic salary and remuneration of women to men	The salaries we offer are predicated on the respective job description and are based on our Global Job Catalog, which has fixed salary bands that are identical for men and women. Variable salary components that fall under performance-based compensation are paid on the basis of whether mutually agreed targets have been achieved. A performance management system governs this process.	Attractive employer (p. 73)
GRI 4	06: NON-DISCRIMINATION 2016		
103-1	Explanation of the material topic and its Boundary		Diversity (p. 77) Materiality analysis (p. 22)
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
406-1	Incidents of discrimination and corrective actions taken		Diversity (p. 77)
GRI 4	07: FREEDOM OF ASSOCIATION AND C	COLLECTIVE BARGAINING 201	6
103-1	Explanation of the material topic and its Boundary		Supply chain standards (p. 104) Mica supply chain (p. 106)
103-2	The management approach and its components		Attractive employer (p. 73) Human rights (p. 17) Compliance (p. 11)
103-3	Evaluation of the management approach		Materiality analysis (p. 22)
407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk		Supply chain standards (p. 104) Mica supply chain (p. 106) Attractive employer (p. 73)

103-1	Explanation of the material topic and	Supply chain standards (p. 104)
	its Boundary	Mica supply chain (p. 106)
103-2	The management approach and its	Attractive employer (p. 73) Human rights (p. 17)
02.2	components	Compliance (p. 11)
.03-3	Evaluation of the management approach	Materiality analysis (p. 22)
08-1	Operations and suppliers at significant	Supply chain standards (p. 104)
	risk for incidents of child labor	Mica supply chain (p. 106) Attractive employer (p. 73)
		Indicators: employees (p. 126)
RI 4	09: FORCED OR COMPULSORY LABOR 2016	
03-1	Explanation of the material topic and	Supply chain standards (p. 104)
	its Boundary	Mica supply chain (p. 106) Attractive employer (p. 73)
03-2	The management approach and its	Human rights (p. 17)
	components	Compliance (p. 11)
03-3	Evaluation of the management approach	Materiality analysis (p. 22)
09-1	Operations and suppliers at significant	Supply chain standards (p. 104)
	risk for incidents of forced or compul-	Mica supply chain (p. 106)
	sory labor	Attractive employer (p. 73) Human rights (p. 17)
RI 4	12: HUMAN RIGHTS ASSESSMENT 2016	
.03-1	Explanation of the material topic and	Human rights (p. 17)
	its Boundary	Compliance (p. 11)
03-2	The management approach and its components	Materiality analysis (p. 22)
103-3	Evaluation of the management approach	
412-1	Operations that have been subject to human rights reviews or impact assessments	Human rights (p. 17)
412-2	Employee training on human rights policies or procedures	Human rights (p. 17)
412-3	Significant investment agreements and contracts that include human rights clauses or that underwent human	Human rights (p. 17)
	rights screening	
RI 4	14: SUPPLIER SOCIAL ASSESSMENT 2016	
103-1	Explanation of the material topic and its Boundary	Supply chain standards (p. 104) Mica supply chain (p. 106)
103-2	The management approach and its components	Materiality analysis (p. 22)
103-3	Evaluation of the management approach	
114-1	New suppliers that were screened using social criteria	Supply chain standards (p. 104) Mica supply chain (p. 106)
414-2	Negative social impacts in the supply chain and actions taken	Supply chain standards (p. 104) Mica supply chain (p. 106)
GRI 4	15: PUBLIC POLICY 2016	
102 1	Explanation of the material topic and	Stakeholder dialogue (p. 19)
103-1	its Boundary	Materiality analysis (p. 22)

103-3	Evaluation of the management approach		
415-1	Political contributions		Stakeholder dialogue (p. 19)
GRI 4	16: CUSTOMER HEALTH AND SAFETY 20	)16	
	Explanation of the material topic and its Boundary		Patient safety (p. 53) Chemical product safety (p. 50) Sustainable product design (p. 32)
	The management approach and its components		Plant and process safety (p. 100) Materiality analysis (p. 22)
	Evaluation of the management approach		Report on Risks and Opportunities
416-1	Assessment of the health and safety impacts of product and service categories		Patient safety (p. 53) Chemical product safety (p. 50) Sustainable product design (p. 32) Plant and process safety (p. 100)
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Report on Risks and Opportunities
GRI 4	17: MARKETING AND LABELING 2016		
	Explanation of the material topic and its Boundary		Patient safety (p. 53) Chemical product safety (p. 50) Responsible marketing (p. 59)
	The management approach and its components		Interactions with health systems (p. 70) Materiality analysis (p. 22)
	Evaluation of the management approach		
417-1	Requirements for product and service information and labeling	Within our businesses, product labels are both important and mandatory. All pharmaceuticals and chemicals are subject to reporting and notification requirements that we fulfill. The individual requirements are reported in the respective chapters.	Patient safety (p. 53) Chemical product safety (p. 50)
417-2	Incidents of non-compliance concerning product and service information and labeling		Patient safety (p. 53) Chemical product safety (p. 50) Report on Risks and Opportunities
417-3	Incidents of non-compliance concerning marketing communications	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Responsible marketing (p. 59) Report on Risks and Opportunities
GRI 4	18: CUSTOMER PRIVACY 2016		
103-1	Explanation of the material topic and its Boundary		Clinical studies (p. 63) Compliance (p. 11)
103-2	The management approach and its components		Materiality analysis (p. 22)
103-3	Evaluation of the management approach		
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data		Indicators: products (p. 125) Clinical studies (p. 63) Compliance (p. 11)
GRI 4	19: SOCIOECONOMIC COMPLIANCE 201	16	
	Explanation of the material topic and its Boundary		Compliance (p. 11) Materiality analysis (p. 22) Report on Risks and Opportunities
103-2	The management approach and its components		Report on Risks and Opportunities

103-3	Evaluation of the management approach		
419-1	Non-compliance with laws and regulations in the social and economic area	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Indicators: compliance (p. 121) Report on Risks and Opportunities
Additi	onal material topics		
ETHIC	AL CONDUCT (Bioethics, Clinical stud	ies, Animal welfare)	
103-1	Explanation of the material topic and its Boundary		Bioethics (p. 61) Clinical studies (p. 63)
103-2	The management approach and its components		Animal welfare (p. 67) Materiality analysis (p. 22)
103-3	Evaluation of the management approach		
	TH FOR EVERYONE (Access to health, I ses, Health awareness)	Prices of medicines, Medicals	to combat rare and neglected
103-1	Explanation of the material topic and its Boundary		Access to health (p. 38) Prices of medicines (p. 46)
103-2	The management approach and its components		Infectious diseases (p. 41) Health awareness (p. 47) Materiality analysis (p. 22)
103-3	Evaluation of the management approach		Place lainty analysis (p. 22)
COUN	TERFEIT PRODUCTS		
103-1	Explanation of the material topic and its Boundary		Counterfeit products (p. 55) Materiality analysis (p. 22)
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
сомм	UNITY INVOLVEMENT		
103-1	Explanation of the material topic and its Boundary		Community involvement (p. 110) Health (p. 111)
103-2	The management approach and its components		Education and culture (p. 114) Materiality analysis (p. 22)
103-3	Evaluation of the management approach		
03-1 03-2	Explanation of the material topic and its Boundary  The management approach and its components  Evaluation of the management		Health (p. 111) Education and culture (p. 114)

# Global compact cop

# 2017 Communication on progress in implementing the ten principles of the Global Compact

We have been a UN Global Compact participant since 2005. As a signatory of the initiative, we have committed ourselves to ten principles based on key UN conventions regarding human rights, labor standards, environmental protection, and anti-corruption. At the same time, the UN Global Compact calls on its signatories to actively engage in propagating the principles within their own sphere of influence.

The following table summarizes the key measures we took in 2017 to support and implement the principles of the Global Compact.



This is our **Communication on Progress** in implementing the Ten Principles of the **United Nations Global Compact** and supporting broader UN goals.

We welcome feedback on its contents.

Link: www.unglobalcompact.org

UNGC principles:	Key measures in 2017	Relevant GRI disclosures:	Reference:
Human rights			
Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights.	<ul> <li>Updated our Code of Conduct, entitled "What guides us"</li> <li>Analyzed the results of our human rights self-assessment</li> </ul>	410-1, 411-1, 103-2: 412, 412-2, 413-1, 413-2	Compliance (p. 11) Human rights (p. 17) Health (p. 111)
p. 00.0000	<ul> <li>Launched an electronic confirmation course on our Human Rights Charter for certain groups and leaders</li> </ul>		
	Donated 150 million praziquantel tablets to the World Health Organization to treat schistosomiasis, a donation that included Egypt and Uganda for the first time.		
Principle 2: Businesses should make sure that they are not complicit in human rights abuses.	<ul> <li>Analyzed the results of our human rights self-assessment</li> <li>Launched an electronic confirmation course on our Human Rights Charter for certain groups and leaders</li> <li>Conducted internal and external audits, assessments and inspections of suppliers with regard to corporate responsibility, and collected self-reported information.</li> </ul>	412-3, 414-1, 414-2	Human rights (p. 17) Compliance (p. 11) Supply chain stan- dards (p. 104)

#### Labor standards

# Principle 3:

Businesses should uphold the freedom of association and the effective recognition of the rights to collective bargaining.

- Analyzed the results of our human rights self-assessment
- Conducted internal audits on workplace aspects of our Human Rights Charter
- Conducted internal and external audits, assessments and inspections of suppliers with regard to corporate responsibility, and collected self-reported information.

102-41, 402-1, 407-1 Human rights (p. 17) Compliance (p. 11) Employee engagement (p. 82)Supply chain standards (p. 104)

# Principle 4:

Businesses should support the elimination of all forms of forced and compulsory labor.

- Conducted internal audits on workplace aspects of our Human Rights Charter
- Analyzed the results of our human rights self-assessment
- Published the UK Modern Slavery Statement, which was adopted by our Executive Board, on our website
- Conducted internal and external audits, assessments and inspections of suppliers with regard to corporate responsibility, and collected self-reported information.

409-1

Human rights (p. 17) Compliance (p. 11) (p. 82)Supply chain standards (p. 104)

#### Principle 5:

Businesses should support the effective abolition of child labor.

- Analyzed the results of our human rights self-assessment
- Conducted internal audits on workplace aspects of our Human Rights Charter
- Participated in the kick-off conference of the Responsible Mica Initiative in Delhi: jointly announced a five-year action plan for a responsible mica supply chain
- The Indian organization IGEP performed monthly inspections on mica mines and mica processors
- Conducted internal and external audits, assessments and inspections of suppliers with regard to corporate responsibility, and collected self-reported information.

408-1

Human rights (p. 17) Compliance (p. 11) Supply chain standards (p. 104)Mica supply chain (p. 106)

# Principle 6:

Businesses should support the elimination of discrimination in respect of employment and occupation.

- Conducted internal audits on workplace aspects of our Human Rights Charter
- Identified focus areas to achieve our 2021 target of maintaining a 30% representation of women in leadership roles (role 4+)
- Expanded internal diversity initiatives.

102-8, 202-1, 202-2, 401-1, 401-3, 404-1, 404-3, 405-1, 405-2, 406-1 Human rights (p. 17) Compliance (p. 11) Diversity (p. 77)

#### **Environmental stewardship**

# Principle 7:

Businesses should support a precautionary approach to environmental challenges.

- Recertified environmental management systems to updated version of ISO 14001 (Group certificate for 83 sites)
- Annually reduced CO<sub>2</sub> emissions (reduction target by 2020: 20% versus 2006 baseline)
- Implemented more than 300 climate impact mitigation projects since 2012
- Analyzed and assessed our water management practices with the goal of implementing a sustainable water management system at sites with high consumption levels by 2020
- Implemented measures to ensure product safety (e.g. REACH, GHS, Global Product Strategy) as well as plant and process safety (e.g. Risk Management Process)
- Had internal and external EHS audits performed
- Introduced the Waste Scoring System of our company with the goal of reducing the environmental impact of our waste by 5% by 2025.

201-2, 301-1, 302-1, 303-1, 305-1, 305-2, 305-3, 305-6, 305-7

Environmental stewardship (p. 87) Climate protection (p. 90) Resource efficiency (p. 94) Water management (p. 97) Waste and recycling (p. 95) Plant and process safety (p. 100) Sustainable product design (p. 32)Packaging (p. 36) Patient safety (p. 53) Chemical product safety (p. 50) Transport and warehouse safety (p. 57)

#### Principle 8:

Businesses should undertake initiatives to promote greater environmental responsibility.

- Systematically examined potential energy savings at our production facilities
- Reduced maximum CO<sub>2</sub> emissions for new company vehicles as of January 1, 2017
- Offered employees sustainable mobility options such as Jobtickets and rental bicycles
- Labeled products to provide information on their use and disposal.

301 - 308

Climate protection (p. 90)
Water management (p. 97)
Waste and recycling (p. 95)
Plant and process safety (p. 100)
Chemical product safety (p. 50)
Patient safety (p. 53)
Transport and warehouse safety (p. 57)

# Principle 9:

Businesses should encourage the development and diffusion of environmentally friendly technologies.

- Developed sustainable products such as liquid crystal technologies, raw materials for natural cosmetics and green alternatives to chemicals
- Developed a new, sustainable packaging strategy
- Used and took back eco-friendlier reusable packaging
- Updated a recycling program for our Life Science customers.

302-4, 302-5, 305-5 Sustainable product design (p. 32) Packaging (p. 36) Reuse and recycling (p. 37) Performance Materials

# **Anti-corruption**

# Prinzip 10:

Businesses should work against corruption in all its forms, including extortion and bribery.

- Redesigned our Business Partner Risk Management process
- Performed internal corruption audits
- Strategically reorganized our Group function Compliance
- Trained employees on anti-corruption
- Provided global SpeakUp Line for employees to report corruption anonymously
- Published annual EFPIA transparency report
- Updated our anti-corruption guideline, for instance regarding rules for gifts and invitations.

102-16, 102-17, 205-1, 205-2, 205-3, 415-1 Compliance (p. 11) Interactions with health systems (p. 70)

# Glossary

# 3R principle

The international guiding principle for all animal testing. The number of laboratory animals used as well as the stress placed on them before, during and after testing are to be kept to an absolute minimum by using methods to replace animal experiments (replacement), reduce the required number of tests and animals (reduction), and improve the test methods (refinement).

# Biodiversity

The diversity of ecosystems, habitats and landscapes on earth, the diversity of the species, and the genetic diversity within a biological species or population.

## Biosimilars

Officially approved subsequent versions of innovator biopharmaceutical products made by a different company after the original product's patent or exclusivity expires. Based on guidance from the EMA (European Medicines Agency), biosimilars must demonstrate comparability, or biosimilarity, to an existing approved product.

# Chromatography

A technique used to separate mixtures.

# CLP

The European CLP regulation (Classification, Labelling and Packaging of Substances and Mixtures) is based on the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

# CO<sub>2</sub>eq

Short for  $CO_2$  equivalents, this indicates how much a specified quantity of a specific greenhouse gas has contributed to the greenhouse effect and uses the global warming potential of carbon dioxide as a reference.

# Compliance

Adherence to laws and regulations as well as to voluntary codices that are internal to Merck KGaA, Darmstadt, Germany. Compliance is a component of diligent corporate governance.

# CRISPR/Cas

A biomolecular method for targeting, cutting and editing the DNA of an organism (genome editing). Experts think this technique has great potential for curing diseases or generating plants and animals with new traits.

# Design thinking

An approach to developing new ideas. Design thinking uses the designer's sensibility and methods to match people's needs with what is technologically feasible and what a viable business strategy can convert into customer value and market opportunity.

#### Disease burden

The impact of a health problem, often measured in terms of quality-adjusted life years or disability-adjusted life years, both of which quantify the number of years lost due to disease.

#### Dual-use products

Goods that are normally used for civilian purposes, but that may also have military applications.

# Due diligence

A risk analysis exercised with particular care that is done in preparation for a business transaction.

#### **EHS**

Environment, Health and Safety describes environmental management, health protection and occupational safety throughout the company.

# End-user declaration

A binding customer statement regarding the intended use of a product.

# **Endemic countries**

Countries in which a certain disease, in many cases an infectious disease, occurs.

# **Essential medicines**

Defined by the World Health Organization as "those drugs that satisfy the health care needs of the majority of the population".

# Exposure assessment

The U.S. Environmental Protection Agency defines exposure assessment as the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure between an agent and an organism. This analysis forms part of the chemical safety assessment process.

# **FDA**

The U.S. Food and Drug Administration is the U.S. government agency responsible for protecting and advancing public health, especially as concerns food and drugs.

#### First-line treatment

A therapy regimen that is generally accepted by the medical establishment for the initial treatment of a given disease. If the first-line treatment is not adequately successful, a second-line treatment may be administered.

#### Global Grade

Merck KGaA, Darmstadt, Germany uses a market-oriented system to rate positions within the company. Until the end of 2016, all positions within the company were assigned a Global Grade. In 2017, we replaced this system so that each position is now assigned a role.

# Global Product Strategy

An initiative of the International Council of Chemical Associations (ICCA) through which participating companies of the chemical industry make a commitment to comprehensive product responsibility.

# Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

An international standard system to classify chemicals that covers labeling as well as safety data sheets.

# Good clinical practice (GCP)

An international quality standard that enforces tight guidelines on ethical aspects of clinical studies.

# Good distribution practice (GDP)

An EU guideline that regulates the proper distribution of medicinal products for human use.

# Good manufacturing practice (GMP)

Good manufacturing practices (GMP) is a system for ensuring that products are consistently manufactured and controlled according to quality standards. These guidelines are used in the production of medicines, pharmaceutical active ingredients and cosmetics, as well as foodstuffs and feed.

# Greenhouse gases

Gases in the atmosphere that contribute to global warming. They can be either naturally occurring or caused by humans (such as  $CO_2$  emissions caused by burning fossil fuels).

## GxP

The general term for good (anything ...) practice quality guidelines and regulations that are used in many fields,

including the medical, pharmaceutical and pharmaceutical chemistry industries.

#### Hackathon

Portmanteau from the words hacking and marathon. A hackathon is an event attended by people from different professional backgrounds. Teams are given a few hours or days to develop innovative solutions and ideas for predefined issues or challenges.

#### HazCom 2012

A U.S. OSHA (Occupational Safety and Health Administration) standard pertaining to the safe handling of chemicals in the workplace, with an emphasis on occupational safety and environmental protection. This standard requires manufacturers and distributors to provide information on the hazards posed by a product as well as ways to minimize risks.

## ICH

The aim of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is to promote uniform assessment criteria for product registration in Europe, the United States and Japan. The ICH makes recommendations toward achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration.

#### In vitro

Procedures involving components of an organism that have been isolated from their usual biological surroundings (e.g. test tube experiments).

# In vivo

Latin for "within the living", this term describes processes that take place within a living organism.

# Investigational drug

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including approved as well as unapproved products when used or assembled (formulated or packaged) in a way different from the approved form, when used for an unapproved indication, or when used to gain further information about an approved use.

# ISO 14001

This international environmental management standard sets globally recognized requirements for an environmental management system.

## ISO 50001

This international standard defines globally recognized requirements for energy management systems.

# ISO 9001

This international standard defines globally recognized requirements for a quality management system.

## Least developed countries (LDC)

Countries that, according to the United Nations, exhibit the lowest indicators of socioeconomic development.

# Liquid Crystals (LC)

Liquid crystals are a hybrid of a crystalline and liquid state. In general, molecules are perfectly arranged only when in a solid crystal state, in contrast to the liquid state, when they move around chaotically. However, liquid crystals are a hybrid of the two states: Although they are liquid, they exhibit a certain crystalline arrangement. Their rod-shaped molecules align themselves like a shoal of fish. In addition, they respond to the electromagnetic waves of light like tiny antennae. Therefore, such swarms of molecules can either allow specially prepared "polarized" light to pass through, or they can block it. This takes place in the pixels of liquid crystal displays – as it does similarly in liquid crystal windows, which can provide shade against sunlight.

# Liver-stage malaria

Certain forms of the malaria parasite (P. vivax and P. ovale) can remain dormant after they have infected the liver cells. In this stage, they persist for many weeks and even years until they relapse into a new disease cycle. Currently, no treatment of this dormant form is possible.

# **LTIR**

The lost time injury rate measures the number of accidents resulting in missed days of work (one or more days) per one million man-hours.

### Mutagen

A substance that changes the DNA of an organism.

# Neglected tropical disease (NTD)

Diseases that occur primarily in developing countries. NTDs include schistosomiasis, intestinal worms, trachoma, lymphatic filariasis, and onchocerciasis. This group of diseases is called neglected because, despite the large number of people affected, they have historically received less attention and research funding than other diseases.

## **Nucleases**

Nucleases are a group of enzymes whose primary function is to partially or fully degrade nucleic acids.

# OHSAS

The Occupational Health and Safety Assessment Series (OSHAS) is an international occupational health and safety management system.

#### **OLED**

Organic light-emitting diodes are a new technology for displays and lighting.

#### Onchocerciasis

A chronic parasitic infection caused by nematodes that occurs in the tropical regions of Africa and South America. In approximately 10% of those infected, the disease leads to blindness, which is why onchocerciasis is also referred to as river blindness.

# Orodispersible tablet

A tablet that dissolves in the mouth within 30 seconds and does not have to be taken with water. The active ingredient is absorbed through the mucous membrane in the mouth and also partly through the lining of the stomach.

# Patent pool

A consortium of at least two competing companies that allows partners to share the use of patents relating to a particular technology.

#### Patient support program

Any organized system providing services, direct patient or patient-caregiver interactions that are intended and designed to educate patients about certain diseases, help patients with access to and/or the management of prescribed medication and/or disease outcomes, or provide healthcare professionals with support for their patients.

# Pharmacovigilance

The continual, systematic monitoring of a drug's safety.

# Phase I study

Phase I clinical trials test a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to evaluate safety (for instance to determine a safe dosage range and to identify side effects).

Source: http://www.who.int/ictrp/glossary/en/

# Phase II study

Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Source: http://www.who.int/ictrp/glossary/en/

# Phase III study

Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Source: http://www.who.int/ictrp/glossary/en/

#### **Prediabetes**

A condition regarded as indicative that a person is at risk of progressing to Type 2 diabetes.

# Product safety summary

Intended to provide a general overview of the chemical substance and its use. It cannot take the place of a safety data sheet.

#### PS-VA

Abbreviation for polymer-stabilized vertical alignment: A polymer layer pre-aligns the molecules inside the display in a certain direction. In the black state, the liquid crystals are not exactly vertical, but slightly tilted, allowing them to switch more quickly. The light transmittance of the display is significantly higher, thus reducing the backlighting, one of the most costly components to produce.

# Public-private partnership (PPP)

A collaboration between public sector (government) organizations, private companies and/or not-for-profit organizations.

# REACH

A European Union chemical regulation (EC No. 1907/2006) that took effect on June 1, 2007. REACH stands for Registration, Evaluation, Authorization, and Restriction of Chemicals.

# Reproductive health

This term covers various areas such as pregnancy, sexually transmitted diseases, contraception, and infertility.

# Role

Merck KGaA, Darmstadt, Germany uses a market-oriented system to rate positions within the company. To facilitate consistency across the organization, each position is assigned a specific role, with an overarching job architecture classifying each role as one of 11 levels, 15 functions and an array of career types (Core Operations, Services & Support Groups; Experts; Managers; Project Managers).

# Schistosomiasis

A parasitic disease spread in warm lakes and ponds by snails that serve as intermediate hosts.

# Scope 3

Scope 3 includes other indirect greenhouse gas emissions, such as the extraction and production of purchased materials, transport-related activities, waste disposal, and employee travel.

#### Security

This term stands for all necessary measures and governance activities to detect, analyze, handle, and mitigate security-and crime-based threats to the company. This helps to protect employees as well as the tangible and intangible assets of Merck KGaA, Darmstadt, Germany.

#### Stakeholder

People or organizations that have a legitimate interest in a company, entitling them to make justified demands. Stakeholders include people such as employees, business partners, neighbors in the vicinity of our sites, and shareholders.

# **STEM**

Science, technology, engineering, and mathematics.

#### Stem cells

Undifferentiated cells with the potential to develop into many different cell types that carry out different functions.

# Sugar cane bagasse

A fibrous waste product of sugar refining, which is left when sugarcane stalks are crushed to extract their juice.

#### Sunshine Act

The Sunshine Provisions of the U.S. Patient Protection and Affordable Care Act aim to create more transparent relationships between manufacturers of drugs, medical devices and medical aids on the one hand, and doctors and teaching hospitals on the other.

#### Traces

Substances dissolved in water that are present only in minute amounts. Also referred to as micropollutants, these are synthetic substances present in concentrations ranging from one nanogram to one microgram per liter of water.

# **TRIPS**

The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement between all the member nations of the World Trade Organization. TRIPS seeks to ensure that the measures and procedures for enforcing intellectual property rights do not become a barrier to lawful trade.

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