

Business ethics

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corporate governance

GOVERNANCE

Part of the non-financial report

Alongside Courage, Achievement, Respect, Integrity, and Transparency, Responsibility is one of our six core values and has been an integral part of our corporate identity for 350 years. 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 **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** and our Group-wide guidelines.

These 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®** Global Charter within our company. Or our **Safety Policy** for chemical products, which defines product safety processes along with 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:

- Since 2005, we have 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.
- As a signatory to the chemical industry's **Responsible Care® 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.
- 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.
- We are a member of **Chemie³**, 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**). The partners of this globally unique alliance seek 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.

compliance

Part of the non-financial report

First and foremost, responsible entrepreneurship means acting in accordance with the law, a practice commonly known as compliance. All our activities must adhere to laws, regulations and international ethical standards around the world because compliance violations don't just result in possible 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. As an international company with operations in developing and emerging countries, we have extremely stringent requirements for effective compliance management. For us, however, there is more to compliance than simply 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 highest ethical standards.

How we ensure compliance

Our Group Compliance function manages the core topics of anti-corruption, healthcare compliance, antitrust, anti-money laundering, fraud prevention, third party due diligence, data privacy, transparency reporting, and dawn raid preparedness. To cover these core compliance topics, we have **Group-wide policies**, procedures and processes in place that ensure our business activities align with the relevant laws, regulations and international ethical standards. Other compliance related issues, including respective internal regulations and guidelines, are managed by the responsible functions (such as [Pharmacovigilance](#), [Export and Import Controls](#) and [Environment, Health, Safety, Security, Quality](#)).

Supported by our Group Compliance function, 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
- Investigations and case management
- Whistleblowing hotline (SpeakUp Line for anonymous and non-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.

Our 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** for the

Executive Board 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 to highlight current developments and the status of relevant projects and initiatives.

Our Group Compliance Officer oversees 77 Compliance Officers around the world, 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 and 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.

Our global Transparency Operations team has the responsibility of incorporating 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 United States Physician Payments Sunshine Act.

We have successfully integrated our compliance framework more closely within our business sectors. For example, a new holistic concept is being developed, which combines the existing monitoring controls into a single system, providing a dashboard view of potential compliance risks across the organization. Compliance requirements specific to each business sector are also integrated into employee training material.

Designated Compliance Ambassadors support local compliance implementation and operate independently of our Compliance Organization. Located in the various regions in which we operate, these Compliance Ambassadors are global compliance representatives who support compliance initiatives across our businesses and functions, increasing accountability and ownership of business ethics.

Our Compliance Ambassadors are located in the following regions:

- **Europe:** Austria, Germany, Switzerland
- **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
- **Asia Pacific:** China, Japan, Korea
- **Latin America:** Argentina, Chile

Clear chain of command for reporting violations

Any reports of potential compliance violations that we receive via our whistleblowing hotline "SpeakUp Line" are reviewed by the Compliance Investigations and Case Management team and appropriate investigative steps are initiated. Exposed cases showing a certain risk profile are additionally presented to the Compliance Case Committee, which consists of senior representatives from Compliance, Corporate Security, Data Privacy, Human Resources, Internal Auditing, and Legal. Duties of the committee include assessing and classifying ethical issues, investigating their background and terminating these issues through appropriate measures. If during the investigation a root cause is identified that could lead to further compliance violations, it is monitored continuously, and preventive or corrective actions are applied. An associated sub-committee advises on disciplinary action if necessary.

Conflicts of interest

We take all potential conflicts of interest seriously, which is why we have dedicated a section of our Anti-Corruption Policy to this topic. It states that employees must strictly avoid situations where their professional judgment may come into conflict with their personal interests, that they disclose every potential conflict of interest to their superior and that they document the disclosure. Such issues are usually resolved directly between the employee and their manager but can also be routed to superordinate HR or employment law functions. We have therefore implemented a specific governance process that also includes the Executive Board and ensures that shareholders and related parties are regularly provided information on potential conflicts.

Beyond this, our commitment to an appropriate conflict of interest process is documented in our [Annual Report](#).

Data Privacy integrated into Group Compliance

Our Data Privacy unit is integrated into our Group Compliance organization. As required by law, this unit acts independently and submits frequent data privacy updates as well as compiling a regular comprehensive data privacy report as a part of the compliance report. Besides a central Group Data Privacy Officer, we also have Local Data Privacy Officers at various sites around the world.

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. In 2018, we completed the roll-out of an updated version called "What guides us". This version is closely linked to our Values and includes newer topics such as data protection, supplier

due diligence and bioethics. The code has been provided to all employees worldwide 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 (especially transportation and accommodation) to or from third parties (including public officials and external business partners).
- Our Pharma Code (for prescription medicines) and our Consumer Health Code (for over-the-counter medicines) as well as underlying policies and additional guideline documents, 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.

We use 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. This confirmation process was also used to roll out our Code of Conduct. With this initiated process, we are striving to draw the attention of all our managers and employees to take note of the updated Code of Conduct.

Guidelines for new business units

Where necessary, we update our policies according to external requirements. Our Medical Devices and Services unit falls under the scope of existing Biopharma Compliance policies and we have 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 have therefore revised our corresponding compliance policy. More information on our commitment to our Code of Conduct and health-care compliance regulations can be found under [Responsible marketing](#).

Requirements for our business partners

To be effective, compliance management must not be restricted to 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 via our established global Business Partner Risk Management process – usually every three years, or ad hoc when new risks are identified.

While our **supplier management processes** focus on vendor compliance with our standards, our Global Business Partner Risk Management Process governs interactions with sales partners such as sales agents, distributors and wholesalers. Our Business Partner Risk Management approach is integrated in 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. We therefore employ a global approach for responding to external Code of Conduct acknowledgment requests. To implement this framework, the Corporate Responsibility Letter of Merck KGaA, Darmstadt, Germany and a correlation clause were introduced in 2017.

Harmonizing data privacy Group-wide

Our “Policy for Data Protection and Personal Data Privacy” defines our standards for processing, saving, using and transmitting 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 legislation, which also entails the EU General Data Protection Regulation (EU GDPR) that came into effect in May 2018. We also consider local data privacy requirements, as not all requirements at all sites are covered by EU standards. When in doubt, the respective national legal obligations take precedence.

Compliance audits

As part of operational audits, our Group Internal Auditing function regularly reviews relevant matters at our sites to determine which compliance guidelines, processes and structures are in place and how effective they are. The unit 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 produces recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the prescribed corrective actions. In 2018, 54 operations were assessed for corruption-related risks.

Compliance training

We provide regular 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. Employees are requested to attend these courses based on their risk indication, and some are also extended to independent contractors and supervised workers (such as temporary staff). We regularly update our training plan and adapt it to new developments. In 2018, our training concept was reviewed thoroughly with a special focus on formats, media usage, target groups, and frequency, and a refresher concept was included to **strengthen learning measures**. Additionally, a large amount of the training material was reviewed to make sure it addresses the compliance topics in a way that allows employees to better connect to their working environment.

In 2018, we started the roll-out of our business sector-specific e-learning program that is centered on our new Code of Conduct and aims to make employees aware of the consequences of compliance violations. 10,421 people have already been trained as part of the program, which will be made available to all new employees on a regular basis.

Using global slide deck materials that can be adapted for local use according to business and country-specific regulations and situations, local Compliance Officers are now providing classroom **training sessions on the Code of Conduct**. We specifically develop some seminars on special topics with certain roles in mind. When participating in pharma-specific training, for example, employees in our Healthcare business sector also receive training on relevant compliance issues.

We continually educate our employees on new compliance requirements, guidelines and projects. One example is an online course on our Anti-Corruption Policy, which is available in 15 languages. In 2018, a total of 11,404 employees and contractors took part in **anti-corruption training**.

Also in 2018, in response to the European General Data Protection Regulation (EU GDPR), we redesigned our regular Data Privacy eLearning course, rolling it out in 17 languages.

“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, this communications campaign engages our employees in the key compliance aspects and thus heightens their sensitivity to and understanding of these issues. Launched in 2017, the initiative is being implemented gradually Group-wide. This style of communicating has also been incorporated in the Code of Conduct and was used to enhance our compliance training materials during 2018.

In addition to providing training via webinars, Skype meetings and on-site events, we inform our staff about compliance issues through a variety of media, including our Intranet, newsletters, posters and our employee magazine "pro". **Video clips** from all board members strengthen the tone from the top and have been in use since 2018 across different channels including our Compliance Learning Management Platform.

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 whistleblowing SpeakUp Line **free of charge and anonymously** to report violations in their local language by telephone or via a web-based application. Based on recommendations from the Compliance investigation team or the Compliance Case Committee, disciplinary actions may also be taken, where necessary, by the responsible superiors against employees who have committed a compliance violation. These actions may range from a simple warning to dismissal, 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 increased last year. In 2018, 72 compliance-related reports that led to investigations were received via the SpeakUp Line and other channels. In 2018, there were 19 confirmed cases of violations of the Code of Conduct.

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)**, which is maintained by Transparency International, and assess potential partners against other parameters such as the nature of the intended business and sales volume. We also tap into background information from various databases and information reported by the business partners themselves, for instance on their own compliance programs.

If we encounter compliance violations, we decide whether to reject the potential business partner, terminate the existing relationship, or impose conditions to mitigate identified risks. 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 3,500 business partners, and in 2018, we used this process to assess 335 business partners.

Ensuring data privacy and information security

We operate a data privacy management system as part of our Group Compliance function. This system has been harmonized across the whole Group. Furthermore, it is necessary to protect our information systems, their contents and our communication channels against criminal activities (eCrime, cyber-attacks) of any kind, including unauthorized access, information leakage and misuse of data or systems. Our Group Security and IT Security units implement organizational, process and technical based information security countermeasures based on recognized international standards. We have harmonized electronic and physical security measures (e.g. access control) to bolster our ability to handle sensitive data such as trade secrets. Aside from active security monitoring, our Group Internal Auditing verifies that we are implementing and complying with our data privacy policy and data security programs.

Our data privacy management system applies the **PDCA principle** (plan, do, check, act), to ensure that data privacy policies and tools (plan), data privacy training (do), inspections and assessments (check), and incident and issue management processes (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, registering data processing activities and reporting potential data privacy incidents. We had zero sanctioned complaints or incidents concerning breaches of customer privacy leaks, thefts or losses of customer data in 2018. In one case, a minor personal data breach was reported to the supervisory authority, which was not sanctioned.

EFPIA and other transparency initiatives

Members of the Transparency Initiative of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are 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 with health systems** and include them in our transparency reporting.

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 and India. The Steering Committee leads the decision-making process for developing measures in these countries, while local advisory groups oversee implementation at the country level. In 2018, our company was elected chair of the advisory group of Ghana. Our local Compliance organizations also collaborate with these groups and offer **training to small and medium-sized companies**. We furthermore support anti-corruption conferences such as the Global Conference of the Alliance for Integrity, which takes place once a year. 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 2018, we engaged stakeholders in 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](#), the German Association for Supply Chain Management, Procurement and Logistics e. V. ([BME](#)) and the International Association of Privacy Professionals ([IAPP](#)).

Responsible Marketing

Part of the non-financial report

Pharmaceutical marketing is regulated by legislation worldwide. In marketing our pharmaceuticals, the wellbeing of patients is always our primary consideration. A variety of internal guidelines shape our business conduct. Since November 2018, we mainly commercialize prescription medicines. In order to strategically focus on innovation-driven businesses, we divested our over-the-counter Consumer Health business.

Our approach to responsible marketing

We adhere strictly to all regulations concerning pharmaceutical marketing. In Germany, for instance, manufacturers are only permitted to advertise prescription drugs to medical professionals such as physicians and pharmacists. These adverts must always disclose the active ingredients, adverse effects and contraindications of the drug. Our internal guidelines governing 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**. This 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 and revise them as required, in response to any new developments.

How we conduct ethical marketing

Our Group Compliance unit is responsible for setting up internal overarching compliance policies to ensure our business activities adhere to the statutory regulations that are applicable to our sales and marketing activities. This unit is further supported by other functions that provide topic-specific expertise to offer further detailed guidance and processes for review. For instance, our Global Regulatory Affairs unit has established a dedicated policy and corresponding process document on the review and approval of our promotional materials. The necessary training and communications are carried out by the units responsible for each of the respective policies. At the operational level, the relevant business and all employees involved in our sales and marketing activities must adhere to our internal policies and procedures. Our Group Internal Auditing 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](#).

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.

In 2018, we revised ten Biopharma compliance policies to ensure we provide the required up-to-date compliance guidance to the business. We also extended the scope of this policy to our Healthcare business in the United States,

operating under the name of EMD Serono, to Allergopharma and to the Foundation sponsored by Merck KGaA, Darmstadt, Germany. This will enable them to effectively adhere to our compliance principles and guidance around the world while maintaining the necessary flexibility to implement **specific local policies or procedures** that additionally comply with local regulations.

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. All our employees involved in creating promotional materials have received training on updates made to the principles and the associated standard processes.

In addition to local laws and our own standards, we comply with the codes of conduct of various industry organizations, such as the Code of Practice published by the International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)). This code was revised in May 2018 and became effective on January 1, 2019. We simultaneously revised our internal policy "Items Provided to Healthcare Professionals" to harmonize our internal guidance with [IFPMA Code of Practice](#) requirements. We are also 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 harmonized **Group-wide review and approval system**. Approximately 2,200 Healthcare employees use 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 also helps us identify opportunities for improvement.

Addressing violations of standards and regulations

We have a number of channels for reporting wrongful marketing practices to the industry associations where we are members. 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 2018, no significant complaints of this kind were sustained against our company worldwide.

We have also established an internal SpeakUp Line that allows our employees to anonymously report potential

compliance violations. If our marketing or advertising rules of conduct are broken, we have a committee in place to take immediate countermeasures. Any violations are dealt with using **appropriate corrective action**. In 2018, we experienced no significant cases of non-compliance regarding regulations and voluntary codes.

Regular employee training

Employees who are 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.

During 2018, we asked newcomers to our company to participate in an **onboarding training** on the topic of "Review and Approval of Promotional Materials and Other External Communications". More than 1,100 employees already took part in a similar training course in 2017. Additionally, employees in charge of marketing and the promotion of pharmaceuticals can also access our respective compliance guidelines 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,

and we only pursue DTC campaigns in these areas. We use direct advertising to try and increase people's awareness of certain diseases and the therapies that are available, thus empowering patients to **make informed decisions** about their own treatment.

Marketing chemicals

We also 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 we 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 and Customs Regulations unit, as well as by trade and export control officers at our local subsidiaries. If we suspect or are informed of misuse, we terminate our business relationship with the customer. When necessary, we work with the responsible authorities to prevent illegal use. In 2018, there were eight attempts to obtain our products for illegal purposes. The business relationship with these customers was terminated.

interactions with health systems

Part of the non-financial report

It is essential that research institutes, physicians, patient advocacy groups and other key players in health systems have access to detailed and up-to-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. We also promote outstanding research projects, for example through our Global Grants for Innovation. 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, patient advocacy groups, university clinics and other hospitals. These contributions are absolutely not intended to influence decisions regarding treatment, prescriptions or purchasing. We have therefore 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, and we comply with all applicable laws and industry codes on transparency. In countries that have statutory or industry obligations regarding the transfers of values to health systems, we comply with these and are transparent in our reporting.

How we ensure 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 applicable employees. 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 local implementation of these initiatives. Before entering into a partnership or collaboration with a third party, we also apply a selection process based on a policy and standard operating procedure. This is part of our Business Partner Risk Management compliance program, which is conducted by Group Compliance. The [Compliance](#) 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. This policy was updated in April 2018 to include more **guidance for interactions with patients and patient organizations** and is directly applicable to our Biopharma business,

Allergopharma and the Foundation sponsored by Merck KGaA, Darmstadt, Germany. 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 reinforces our belief that patient well-being is always a top priority. Through this policy, the supplementary guideline and specific local policies, we provide a robust guidance structure to support our employees in being compliant during their interactions with patients, patient opinion leaders and patient organizations. We are also active in the enhancement of self-regulation within the industry, such as in the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) subgroup discussions with patient organizations and industry representatives on delivering guidelines on patient compensation.

Transparent reporting

In 2018, we continued to publish all financial and non-financial contributions that we 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 the applicable data privacy regulations.

In addition to disclosing monetary transfers of value on an individual level, we continue to publish overall [spending on our research & development activities](#), as required by the EFPIA Disclosure Code. In 2018, EFPIA issued further guidance on the **disclosure of non-interventional studies** (NIS) differentiating between retrospective NIS and prospective NIS for different reporting methods, either on an individual level or in aggregate amount. We have adopted the new requirement in our preparation of reporting from 2018 onward. When the EU General Data Protection Regulation ([GDPR](#)) became effective in May 2018, we revised our global agreement templates with healthcare professionals, healthcare organizations, patients and patient organizations, and the related disclosure consent templates, in relevant countries to ensure all clauses and processes related to transparency reporting are aligned with the requirements of the regulation.

We also adhere to all statutory transparency requirements worldwide, such as the [Transparency Code](#) of the German Association of Voluntary Self-Regulation for the

Pharmaceutical Industry (FSA), 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. We consistently adhere to the applicable data privacy legislation and endeavor to ensure the full compliance of our partners.

In 2018, we registered an increase in the number of countries adapting new transparency disclosure rules, including Canada and Saudi Arabia. The province of Ontario (Canada) has passed the Health Sector Payment Transparency Act, which came into effect on January 1, 2019. This makes it the first province in Canada to formally address the transparency of payments made by pharmaceutical and medical device companies. In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) introduced new transparency reporting rules that were implemented on October 1, 2018.

Relevant employees participate in **mandatory online training and classroom seminars**, so that they stay informed about our interactions guideline and policy, and important changes to reporting requirements for transfers of value.

Partnering with patient advocacy groups

Patient advocacy groups support patients, family members and caregivers, providing them with information on disease management. We have also made it our goal to improve patient quality of life, which is why we support the vitally important work of these organizations. We ensure **transparency on our donations** by publishing the details of contributions to European patient organizations on our [website](#). The report is updated annually and includes all donation amounts, recipients and the purpose of each donation, thus fulfilling our obligation as a member of EFPIA.

Transparently promoting medical research and education

We sponsor research and continuing medical education around the world so that we can 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](#). As of 2018, a total of 99 research proposals have been selected to receive research grants through the Global Grants for Innovation program since its inauguration in 2009.

Through our Global Medical Education and External Relations 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. As with our other collaborations, we take an entirely transparent approach to this. All direct and indirect financial support 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 2018, we continued our partnership with the International Pharmaceutical Alliance for Continuing Medical Education (iPACME). This group of 20 professionals from 17 different companies from around the world engages in continuous discussions for improving and harmonizing **quality standards for continuing medical education**.

We continue to promote research and education in and for developing countries through a series of programs, with a focus on malaria and schistosomiasis. These research programs, involving African post-doctoral fellows, include, for example, the sponsorship of three PhD fellowships in support to the governmental malaria control programs in Namibia, Botswana and Zambia.

Other examples of research programs enhancing local expertise include collaborations with the University of Cape Town and Medicine for Malaria Venture (MMV) to identify new potential anti-malarial drug candidates. We also work with the Kenya Medical Research Institute (KEMRI) to study the impact of schistosomiasis infection on the severity of malaria co-infection in children, and with the European and Developing Countries Clinical Trials Partnership (EDCTP) in a fellowship program on clinical practices and management.

Introduction of a new compliance tool

In May 2018, we introduced a new compliance tool called Quantum Connect, which replaced our previous tools for supporting the planning, review and confirmation of compliant interactions with healthcare professionals, healthcare organizations, patients, and patient organizations. Quantum Connect stands as a single global tool that is applied to all markets in which we operate. The new software encompasses elements to determine the **appropriate compensation for service engagement** and ensures agreements are compliant with applicable laws and codes, such as the EU General Data Protection Regulation (GDPR).

suppliers

supply chain standards

Our company procures many raw materials, packaging materials, technical products, components and services from across the world. The overarching goal of Group Procurement, in close collaboration with our supply chain departments of each business sector, 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 this fast-paced world, we believe that secure supply chains are the key to our success. We expect our suppliers to adhere to the same ethical, social and compliance standards as we do.

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, reliable delivery 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. Our supply chains are diverse and differ in their characteristics. While some supply chains are automated, others, especially in the service sector, are labor intensive. Our risk-based supplier selection and management approach takes this diversity into account. If the risk probability exceeds our risk appetite, we take further actions. For example, we ask the supplier to conduct a sustainability assessment or an audit. This additional step helps our sourcing employees to identify required mitigation actions with relevant suppliers and work on improvements.

We further developed our **supplier and material risk management** and launched a new program in 2018. This program covers our key suppliers and aims to identify, assess, respond, and monitor third-party risks that could have an impact in our supply continuity. It has four main elements:

- **Supplier Risk Assessments:** to capture the overarching risks at supplier legal entity level, including multiple risk domains. This system was tested and implemented in 2018.
- **Alert system:** to notify our Procurement unit when any of our suppliers face a potential disruption. The system was implemented in 2018.
- **Material Risk Assessments:** to capture the risks of relevant materials that make up our most significant finished products. The Material Risk Assessments were aligned with our business in 2018.

- **Risk Response Tracker:** to create and monitor risk mitigation activities. The Risk Response Tracker is currently under development.

A "risk factor" for the Supplier and the Material Risk Assessments is calculated by multiplying risk probability and risk impact. Risk probability considers 29 risk titles such as "Economic freedom", "Social unrest", "Unfair business practices" or "Poor labor practices" throughout the five "risk domains": financial, geo-political, compliance, operations, and sustainability. Risk impact is calculated by considering supplier spend and the number of our businesses impacted. The aspect of risk impact will be further refined to take into consideration the impact to our finished products and our customers.

How we implement Corporate Responsibility 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. Sourcing staff are responsible for the supplier selection process and collaborate closely with the stakeholders in each business sector. All new Sourcing staff are trained on those sustainability aspects that are of importance for procurement.

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 **expectations for our suppliers** and specifies how we monitor compliance with our standards. This policy 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 these expectations for our suppliers and formally oblige them to apply these standards to their own vendors.

All modifications to legal frameworks are incorporated and appropriate measures are initiated where necessary.

Global procurement

In total, the goods and services we purchased in 2018 from **more than 60,000 suppliers** in almost 150 countries amounted to around € 7.4 billion compared with € 7.0 billion in 2017, representing an increase of 4.8%. Of these (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 14.8% in 2017 to 15% in 2018.

Share of overall goods and services purchased



Material use

We primarily use **chemical and pharmaceutical raw materials** for our manufacturing operations, in addition to operating supplies and packaging materials such as folding boxes, glass bottles and ampules. We utilized 487.6 metric kilotons of material in 2018, a slight increase compared to 2017. We only record the weight of the materials that are directly used in our pharmaceuticals and chemicals.

How we monitor our supply chain

A number of different approaches are used to keep track of our suppliers and ensure adherence to our standards and values. These 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 self-reported information or via audits.
- In selected cases we conduct our own CR audits on suppliers.
- Regarding our [mica supply chain](#), we engage with a global consultancy 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 150 countries and 190 sectors across the four categories of **Environment, Social, Ethics, and Sustainable Procurement**. The results are shared among TfS member

companies in compliance with all restrictions stipulated by competition law. The strategic focus of the TfS activities concentrates strongly on the initiative's demonstrable improvements of supplier sustainability standards. We've been a member of TfS since 2014.

Via a collaborative platform, we now have access to **evaluated supplier self-assessments of more than 10,700 suppliers** and audit reports from over 1,000 suppliers, partially initiated by our company and partially by other TfS members. Based on all the audits and assessments conducted since joining the TfS initiative, in 2018 we focused on scorecard improvements of our suppliers rather than additional new assessments and audits.

Conducting our own audits

We continuously conduct our own audits in selected cases based on business requirements.

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.

Local suppliers

We have no internal guidelines stipulating that preference be given to local vendors in allocating contracts and therefore do not collect this type of data. We generally procure our **goods and services globally**. In some cases, however, local vendors do have an advantage, as products bought locally may be less expensive, due to a reduction in additional transport costs. Country-specific regulations such as import duties and licenses also help us decide whether to source our goods locally or globally. 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 automotive and industrial coatings and plastic mass coloration, as well as in the cosmetics and food industries. Although it occurs naturally in many places, we mainly procure mica from India, specifically the north-eastern states of Jharkhand and Bihar. This region suffers from political instability and poverty, with widespread child labor, so we've taken special measures to meet compliance with our social and environmental standards.

Our approach to responsibility in the mica supply chain

In procuring mica from north-east India, we are supporting this region by safeguarding local jobs and livelihood. We only source the raw material from formal working environments, such as mines qualified by our company, as this is the only way to monitor compliance with our standards including our ban of child labor.

Our mica suppliers have been informed of our standards and have confirmed that they adhere to the principles of our [Human Rights Charter](#) as well as the requirements of our [Responsible Sourcing Principles](#). **We do not tolerate child labor** and contractually prohibit our suppliers from employing children. Hence, we are driving initiatives and taking measures to improve the conditions of mica sourcing based on our high standards. We constantly review our monitoring processes and work on improving their effectiveness.

How we organize our mica supply chain

We have established direct business relationships with those suppliers who handle mica mining and processing in India. Our procurement unit is in direct contact with the suppliers to reiterate the importance we place on ethical, social and environmental standards. Whenever non-compliance with our standards is identified, we work with suppliers to ensure the appropriate implementation of corrective measures.

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. Our [Human Rights Charter](#) underscores this commitment. In our [Responsible Sourcing Principles](#), we set out our expectations for our suppliers in terms of corporate responsibility and human rights, including the ban of child labor.

Auditing our mica supply chain

We have implemented a series of **oversight mechanisms** through a system that monitors and audits compliance with our social and environmental standards. In addition to regular self-inspections, we conduct comprehensive announced audits at mica mines and processors, as well as unannounced check visits.

Annual audits

The international consultancy firm Environmental Resources Management (ERM) conducts annual audits of all mines and processing plants, investigating working conditions as well as **environmental, health and safety issues**. The

audit reports document any identified shortcomings in this respect and propose corrective actions. Our employees in Kolkata (India) and Darmstadt (Germany) then follow up to work on resolving any identified issues.

In 2018, ERM conducted six audits. 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** on corrective measures. When breaches are not rectified, we take further actions up to freezing relations with the respective company or even terminating the business relationship altogether.

Monthly inspections

Since 2013, the [IGEP Foundation](#), a local non-government organization, has been arranging monthly unannounced visits to check the working standards in the mines and at the processors. In 2018, three mica mines and three processing plants were regularly checked. During these visits, IGEP monitors productivity and occupational safety as well as **compliance with the ban on child labor**. They also check whether our suppliers have held mandatory training sessions for their employees. In October 2018, IGEP - supported by one of our EHS specialists - held a workshop on workplace health and safety for our suppliers.

Tracking system for mica sources

We use a tracking system to ensure mica that is supplied to us comes from **mines qualified by our company** and to monitor the productivity of the mines. All mine owners record the daily extraction volume of their mines in a logbook, and we review the volumes of mica reported in the logbook and supplied to the processing companies.

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 study in 2016 and a [report](#) in 2018 by the organization [Terre des Hommes](#) and the [Centre for Research on Multinational Corporations](#).

As part of our efforts, we are financing three schools run by our partner IGEP in Jharkhand, which are attended by a total of almost 500 children and adolescents. All three schools introduced a sixth grade in 2018. This change will contribute to school attendance of **children and younger students**. Tailoring and carpentry courses are also offered.

At a fourth school run by one of our mica suppliers, we provide scholarships for 200 children.

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.

In August 2018 we supported a health checkup camp that was run in collaboration with the Indian hospital chain Medanta at two different locations in the state of Jharkhand (India). The first took place in Jhumri Telaiya in the Koderma district with the second one in Tisri in Giridih district. These health camps were visited by more than 1,000 people and gave them access to up-to-date diagnostic tools and doctors without charge. Patients were then provided with initial treatment. The follow-up will be done by our health center. The camps are regarded as starting point for further health camps in the communities.

Stronger together: Joint action in the mica supply chain

We are a founding member of the Responsible Mica Initiative (RMI), which was established as a multi-stakeholder group following the Mica Summit 2016. From January 2018 to January 2020, our company holds the presidency of the organization. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply

chain by **joining forces across industries**. In 2018, we actively supported the RMI's work to improve traceability along the Indian mica supply chain: "Responsible Mica specifications" have been developed and pilot tests on the field have been conducted. To build sustainable living conditions in local communities, the RMI started a community empowerment program in the mica mining area. The goal is to address the root causes of child labor and to improve the livelihood of the local community. In 2018, 40 villages in Jharkhand and Bihar (India), were selected for the program.

We participated in **dialogues with various stakeholders** and at conferences in 2018, such as the Child Labor Platform (CLP) of the International Labour Organization (ILO) in Paris (France), the Mica Stakeholder Event in The Hague (Netherlands) organized by Terre des Hommes and the OECD Forum on Responsible Mineral Supply Chain in Paris. During these meetings, approaches on fighting child labor were critically reviewed and best practices were shared.

New sources of mica

Our processes undergo constant review and improvement. We are evaluating other sources for mica according to our quality, social and environmental standards both in India and in other regions. Part of our mica, for example, is obtained from Brazil. This helps us to secure supply over the long term and avoid potential bottlenecks. We also manufacture effect pigments based on synthetic substrates as an alternative to pigments based on natural mica.

HUMAN rights

First and foremost, all nations have a duty to establish a regulatory framework to protect human rights. As an international enterprise, 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 must better understand the potential impact of our business activities and relationships on human rights, as well as 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 support programs, strategies and processes 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 Corporate Responsibility unit 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 initiating the necessary actions.

In 2018, we formed an internal, cross-functional human rights working group that has two overarching objectives. First, it helps us meet our obligation to respect human rights through joint, cross-functional actions. And secondly, it is intended to establish an ongoing dialogue on the subject. The group meets three to four times a year, with the first meeting having been held in November.

In 2018, we also added the topic of human rights to our manual for new managing directors in an effort to heighten awareness at the executive level. The manual is primarily intended to consolidate all the legal and compliance-related responsibilities of a managing director into one document.

Our commitment: Guiding principles, 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](#). In 2018, we started the process of updating our Human Rights Charter, **partnering with external stakeholders** such as trade unions, business federations and representatives of potentially impacted groups. Additionally, we are currently drafting a Group-wide Social and Labor Standards Policy. Aligning with the core labor standards of the International Labour Organization (ILO), this policy is scheduled for publication in 2019.

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. We welcome this plan, which reflects the UN Guiding Principles and sets out the duty of states to protect human rights as well as the responsibility of companies to uphold them. It furthermore provides specific guidance on how the German federal government and German businesses can do so. Through our current efforts and initiatives, such as evaluating our existing grievance mechanisms, 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. In 2018, our company once again issued our [UK Modern Slavery Statement](#), which has been endorsed by our Executive Board and is available on our [website](#).

Creating awareness

In 2018, we started to implement measures based on the findings from the Group-wide human rights self-assessment of our subsidiaries, which included initiating steps to raise awareness of certain human rights risks. In 2018, we hosted a **workshop on modern slavery**, which was attended by representatives from the Group functions Environment, Health, Safety, Security, Quality (EQ), Procurement, Human Resources, Compliance, and Corporate Responsibility. Human rights and modern slavery were also on the agenda of our annual Global Security Network Meeting in Darmstadt and our Environment, Health, Safety (EHS) forums in Tokyo and Shizuoka (both Japan) and Corsier-sur-Vevey (Switzerland). They were also part of "EHS StartUp!", our EHS orientation program for all new EHS managers in Darmstadt.

Launched in 2017, our Group-wide online course on our Human Rights Charter was successfully completed by 194 people in 2018. This course was mandatory Group-wide for all managing directors as well as all leaders from the first managerial level below Executive Board. In addition to this, Procurement executives from the second and third managerial tiers were 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 working to promote its values.

Continually improving our management processes

We are continuing our efforts to further integrate human rights into our operational processes, reviewing our approach to human rights risks and their impacts and working to improve them. We focus on external manpower, product and service sourcing, and collaboration with contract partners. We are currently working to obtain an overview of the use of external manpower Group-wide. Building on these findings, we intend to execute risk-based measures to increase awareness of modern slavery at the local level as well. To support these efforts, in 2018, we developed an interactive database for human rights risks and issues that also covers specific risks in individual countries.

Our annual compliance risk reporting covers human rights issues. In 2018, our Compliance Group function started updating their compliance risk reporting process with human rights and modern slavery now featuring more prominently in our risk reporting and our newly created self-monitoring process.

To reinforce human rights due diligence within our company, in 2018 we reviewed our existing grievance mechanisms, focusing particularly on their scope and effectiveness. Based on the results, in 2019 we decided to open up our SpeakUp Line, previously only accessible to employees, to external stakeholders as well. Grievances can now be reported via a link on our external website.

Human rights and investment decisions

When projects exceed a certain cost threshold, our Investment Committee must approve the expenditure. The committee's decision considers factors such as environment, health and safety. 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 topical Intranet sites and other articles featuring employees explaining how their work intersects with human rights.

Bioethics

Part of the non-financial report

Bioethics guide us in how to 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 on divisive bioethical issues arising from the explosive progress in science and particularly molecular biology. In light of this situation, we feel the need to clarify our own position on these issues.

Our approach to ethical business conduct

In our work we encounter various bioethical issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. We are strongly committed to conducting this research in an ethical manner. **Patient wellbeing and benefit** is always our number one priority, both during treatment with our drugs and when our products are distributed to academic researchers and the biopharma industry. We carefully evaluate our position on controversial topics so that we can make informed decisions that meet the highest ethical standards.

How we assess bioethical issues

The Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP), co-chaired by a senior executive biomedical expert of our company and the Head of our Global Health Institute, gives clear guidance on bioethical issues, which steers our behavior and entrepreneurial conduct. It consists of renowned international experts in the fields of **bioethics, theology, science, and law**. The MBAP meets once a year and also spontaneously, if required, in response to emerging urgent bioethical issues. We publish a summary of the discussions from each meeting on our internal electronic collaboration platform. Our employees can ask MBAP members for advice and are able to report concerns on ethical issues.

We continuously adapt the organizational structure of the MBAP to reflect the current requirements of bioethical issues in all three of our business sectors. In 2018, two experts from Africa and Asia became standing members, having previously had guest status. This has enabled us to further integrate the important views of these regions in our bioethical discussions.

Our dedicated guidance panels for genome editing and stem cell topics continue to operate under the overarching MBAP. These panels are responsible for the operational implementation of our stance and are empowered to make

decisions about specific questions on individual projects. Since it was formed in 2011, the Stem Cell Research Oversight Committee (SCROC), for example, has been verifying all internal research proposals that employ **human stem cells** and ensuring compliance with our ethical guidelines and any legal requirements. This also includes collaboration with external partners.

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 scope of legislators, which is why we also seek the advice of external experts.

Bioethics Advisory Panel discussions

In 2018, the MBAP addressed, for the first time, the topic of **Artificial Intelligence (AI)** and related ethical issues. The recommendation was to develop a supervisory board that includes roles and responsibilities for the highly sensitive data that is used in clinical and other applications of AI.

Other topics included new developments in [stem cell research](#), [genome editing](#) and [animal welfare](#).

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 (Germany), Boston (MA, United States), Beijing (China) and Tokyo (Japan). Major biotech production sites are located in Martillac (France) and Aubonne, as well as Corsier-sur-Vevey (both in Switzerland), 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 regulatory changes that relate to biotech products and adapt our processes accordingly, thus ensuring we adhere to all statutory requirements.

Using genome-editing techniques

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", which is the use of genome editing techniques in plant cultivation. Statutes in different countries allow for a varying degree of latitude in applying this technique.

Our **Genome Editing Technology Principle** provides a mandatory ethical and operational framework for our employees, setting clear operational boundaries for us both as a supplier of custom targeted nucleases and genetically modified cell lines, and as a user of genome editing technologies for scientific research. This principle includes background information on the topic and explains our current stance on the technology.

In 2018, the MBAP re-examined the current possibilities and ethical boundaries of genome editing systems and agreed that our Principle did not need to be updated. It was determined to understand more fully the advances in genome editing in agriculture, as well as gene drive technologies, and the associated ethical and country-specific legal implications. A number of MBAP members and scientists of our company pooled their insights to co-author a paper entitled, "**Ethical Considerations in the Manufacture, Sale, and Distribution of Genome Editing Technologies**", which was published in the American Journal of Bioethics. The paper shows that we have become a thought leader in the scientific discussion on genome editing innovations and that we are committed to fostering a broader dialogue in a bid to create lasting buy-in and acceptance for this promising technology.

Stem cell research

We currently 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. We do, however, use human embryonic stem cells in our research and offer our customers several select stem cell lines. Thereby, our **Stem Cell Principle** ensures compliance with our ethical approach. All

projects are reviewed and approved by the SCROC before any stem cells are used for research purposes. We only use cell lines approved by the United States National Institute of Health (NIH) and that are allowed under the German Embryo Protection Act and the German Stem Cell Law.

During 2018, the SCROC continued discussions on a new Informed Consent Form for the use of induced pluripotent stem cells (iPSCs), which is expected to be finalized in 2019. iPSCs are identical to embryonic cells and can generate every type of cell in the human body. They are used in many research projects, but, in most cases, do not require specific approval by the SCROC. The SCROC also decided to support the generation of organoids derived from adult stem cells under the precondition that stem cells derived from fetal tissue should be avoided.

So far, we do not support research aimed at producing artificial gametes. Any support on our part would have to comply with the German Embryo Protection Act and our Fertility Principle.

The topic of producing artificial gametes will be revisited by the SCROC in order to follow up on ongoing developments.

Fertility research

We develop treatments for infertility and seek to improve the success rate of in vitro fertilization, and so we are frequently confronted with various related **bioethical issues**. Our legislative point of reference for these issues is the German Embryo Protection Act and we are steered by our **Fertility Principle**, which was developed based on guidance from the MBAP and came into force in October 2017.

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. This may include the **permission to use biospecimens** for further medical research beyond the clinical study through an optional consent. Since 2017, a policy and standard operating procedures have defined our principles and processes of human biosample management during and after clinical studies.

Biological samples, including tissue and body fluids, are stored in biorepositories 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 and all current legislation.

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](#).

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 physi-

cian 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 2018, we included a statement regarding requests on off-label use in the new [compliance policy concerning interactions with patients](#). We only market our medicines within the scope of the drug's marketing approval and we never share information on off-label use for commercial ends but 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 studies generally run for multiple years. Before they begin, extensive preclinical testing must be performed to demonstrate that the drug poses no unacceptable risks. This typically includes procedures such as animal testing.

Our approach 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, and only when the medicines being tested show great therapeutic promise and have a **positive benefit-risk ratio**. In addition, 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 each of the 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 also 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 and we adhere to all relevant international scientific and ethical standards, irrespective of the region or country. 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 the healthcare infrastructure is less developed, we adhere to all relevant scientific and ethical standards at all times. 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.
- 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 being tested will be submitted for marketing

authorization and made available to patients after we have proven 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

Pharmaceutical development and the related governance process are the responsibility of our Head of Global Research and Development, who co-chairs the Development Decision Group (DDG) with the Global Head of Innovative Medicine Franchises. The DDG replaces the former Development Operations Committee (DOC). Decision makers from all relevant functional areas sit on this biopharma committee, thus ensuring a cross-functional approach to the governance of drug development.

Under the umbrella of the DDG, two further committees oversee our clinical studies. The Integrated Clinical Study Committee (ICSC) is responsible for studies in pharmaceuticals that are under clinical development, while the Global Medical Affairs Decision Board (GMADB) is responsible for studies involving approved medicines. Both bodies consist of medical scientific **experts and executives with long-standing experience** in clinical research. The ICSC is also supported by our therapeutic area review boards, which conduct thorough scientific assessments of new drug/pharmaceutical study concepts. Our development and study teams present clinical study concepts to the appropriate committee. Each committee meets regularly to conduct a comprehensive review of the proposed concepts and has to verify that our studies are scientifically sound, have a legitimate scientific purpose and are performed according to the latest standards and best practices.

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. We only take the critical step of a first in-human clinical trial after diligently conducting **extensive preclinical testing**. 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) over-

sees 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](#).

Our commitment: International guidelines and agreements

We have renamed our Clinical Research Policy and extended its scope. The now so-called Human Subjects Research and Development Policy provides the framework for conducting clinical studies and ensures that we adhere to all applicable **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**. These are planned by the Biopharma Research & Development Quality function, based on a quality risk assessment approach to identify areas for internal and external auditing. 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 detailed 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 2018, once again, 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 pharmaceuticals. Potential adverse effects and risks are taken into consideration in an effort to evaluate the benefit-risk ratio of our products and manage any risk. Product information, including the Investigator’s Brochure and Subject Information, is updated accordingly. You can find more information under [Patient safety](#).

Conducting clinical trials in vulnerable populations

The implementation of clinical studies in vulnerable populations, such as children or people with mental disabilities, requires **special attention and care** in order to comply with the highest ethical and scientific standards. As the well-being of the individual is our absolute priority, we involve vulnerable populations only when there is a scientific justification and 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.

The Pediatric Praziquantel program led by our company within a [consortium of partners](#) has been implementing clinical trials in developing countries and involving vulnerable populations. The program aims at developing, registering and providing access to a **pediatric formulation** of praziquantel for treating schistosomiasis in children younger than six years of age. Due to a lack of clinical data and no suitable pediatric formulation of praziquantel, this age group currently goes untreated. Following the successful completion of the Phase I bioavailability studies with healthy adults in South Africa and the swill-and-spit taste study in children aged six to eleven in Tanzania, Phase II was concluded in November 2018 in Ivory Coast with children aged younger than six years. The current results confirm the formulation and the dose that will be pursued by the consortium until

registration. Phase III is due to start in 2019 with children in the target age group in Kenya and Ivory Coast.

The clinical program was designed in line with the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) recommendations for pediatric development. It was planned and is being implemented with the support of regulatory authorities and a panel of international experts, including clinicians from endemic countries. Further details can be found under [Health for all](#).

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.

We have established processes defining the requirements for selection, approval, contracting and oversight-monitoring of CROs. In addition to comprehensive collaboration manuals with a contracted vendor, expectations on the highest quality level of the provided services including roles and responsibilities are specified in detailed quality agreements. Based on a risk assessment approach, vendors are audited regularly against applicable regulations, guidelines and the above-mentioned manuals and agreements. This also applies to study centers (for example hospitals) involved in our clinical studies. In 2018, once again, these audits did not reveal significant non-compliance with the above-mentioned standards.

Close dialogue with patients and advocacy groups

We want to ensure the **voice and needs of patients** are adequately taken into consideration when developing and executing clinical studies. To this end, we have established Patient Advisory Boards (PABs). 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 share their experience and particular perspective related to our clinical trials, plus multiple aspects including but not limited to protocol design, educational materials, and others. This advice and wealth of valuable insight applies to both the design of the clinical trial and its operational implementation. We use this information to render clinical development and clinical studies more patient-centric by sharing the outcomes of the PABs internally. Our Global Clinical Operations organization uses such information in multiple manners with a clear focus on patient centricity in everything we do.

Furthermore, we are involved in the European Patients' Academy on Therapeutic Innovation (EUPATI), a public-private partnership within the Innovative Medicines Initiative (IMI). It initially ran from 2012 to 2017 but we have extended our participation until 2020. EUPATI is a pan-Euro-

pean 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 partnership has created a suite of resources that is available to better inform patients on the **development process** and the importance of their involvement while also offering them a way to incorporate their needs into the development of clinical studies. EUPATI also 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. 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 [ClinicalTrials.gov](#) database run by the United States 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 2018, we provided participants of ten studies 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 and 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 developing **avelumab (Bavencio®)**. This is an investigational anti-PD-L1 (programmed cell death ligand 1) antibody that we initially discovered and developed as a potential treatment for different tumors. 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. As of the end of 2018, more than 9,000 patients have been evaluated within this program.

In 2018, avelumab has continued to gain marketing authorization in several countries including Argentina, Australia, Brazil, Chile, Israel, Lebanon, Mexico, Saudi Arabia, and Taiwan for treatment in patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive form of skin cancer. Previously, we successfully started to market the medicine in the EU, Japan and the USA. Subsequently, avelumab has also been granted regulatory approval in Canada and Israel 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. Positive top-line results were shown in 2018 in renal cell carcinoma.

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 the 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.

Support of independent human subject research

In addition to conducting our own clinical research programs and studies, we also support studies proposed by independent investigators, so-called investigator-sponsored studies (ISS). Our [ISS Principles](#), published on our website in 2018, define an ISS as "an unsolicited request for funding and/or supply of an investigational or marketed product by a third-party investigator/institution that initiates and conducts an independent scientific investigation as the regulatory sponsor." By granting financial or material support for independent human subject research, we seek to stimulate the advancement of clinical and medical knowledge and patient care in our areas of therapeutic interest, and to support the safe and effective use of our products. We give priority to research that is innovative and has the potential to address specific unmet medical or scientific needs. Our principles, framework and standards for granting support for ISS and for our collaboration with independent investigators are specified in our ISS Principle and our corresponding policy and standard operating procedure.

Coming to terms with the past

In the 1950s and 1960s, drugs from various manufacturers were tested on children living in institutions in Germany, often in collaboration with (university) hospitals and general practitioners. In 2015, we made files in our **historical archives** at our global headquarters in Darmstadt (Germany) available to researchers, in order to help understand and come to terms with this episode in the history of science. When their work is completed, their findings can be used to make 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. We enforce stringent animal welfare standards that meet and frequently exceed applicable laws and extend these high expectations to our suppliers, contract research organizations and other partners.

Our approach to animal welfare

Animal studies enable us to test both the safety of our chemical and medicinal products, and the efficacy of our pharmaceuticals. We conduct animal testing within our Healthcare business sector as part of the official drug approval process and for biological quality control. Animal welfare is also a prominent issue for our Life Science business sector, where laboratory animals are kept, for instance, for the production of antibodies. Our subsidiary BioReliance conducts animal testing as part of contract research work for third parties.

Our Group-wide Policy on the Use, Care and Welfare of Laboratory Animals 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 well established and tested methods that ensure high-quality results. We 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

In 2018, we launched our internal 3Rs Award, which is open to all our employees and which further strengthens our commitment to apply and actively promote the 3Rs in our animal research activities.

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

How we ensure animal welfare

Through our Corporate Animal Science and Welfare (EQ-A) unit, we endeavor to create uniform high-quality animal welfare standards. To ensure adherence to these standards, we initiate **animal welfare audits** within both our company and our partners. In 2018, we expanded the

animal welfare auditing team in order to accommodate for increased auditing and AAALAC International reaccreditation demands. All our animal science and welfare officers and experts regularly interact through our global laboratory animal science network. This platform for sharing best practices and lessons learned supports the animal welfare units at our sites as well as all projects and processes related to animal science and welfare.

Our Group Animal Welfare Council is made up of representatives from all our business sectors and convenes twice a year to support and advise the Chief Animal Welfare Officer. This council discusses relevant developments and makes decisions regarding our Animal Welfare Strategy. If an employee identifies an internal issue regarding animal welfare, they can file an incident report which will be sent directly to the Chief Animal Welfare Officer or report it via our SpeakUp Line.

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.

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. As a member of Interpharma, we have joined a continuous dialogue with [Swiss Animal Protection](#) to identify common interests and find synergies regarding the 3Rs.

Our Chief Animal Welfare Officer sits on various committees and takes an active role in order to advocate our position on animal welfare. Moreover, he represents EFPIA on the [AAALAC International](#) Board of Delegates, where he ensures **adherence to European standards**. He has been appointed to the Board of Directors of AAALAC International since the end of 2016 for a three-year term. He is also a member of the German Federal Animal Welfare Commission.

Our commitment: Group-wide methodology and standards

Through our Group-wide [Policy on the Use, Care and Welfare of Laboratory Animals](#), 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 include 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 contracted animal research services we offer third parties such as contract research organizations, academia or partnerships and to those services we contract from these 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, our standard entitled Housing and Husbandry Practices for Common Laboratory Animals also applies to our external partners. In 2018, we implemented the Vendor Qualification Standard, which describes our criteria for evaluating the quality of animal welfare practices in our suppliers and partners.

Legal requirements

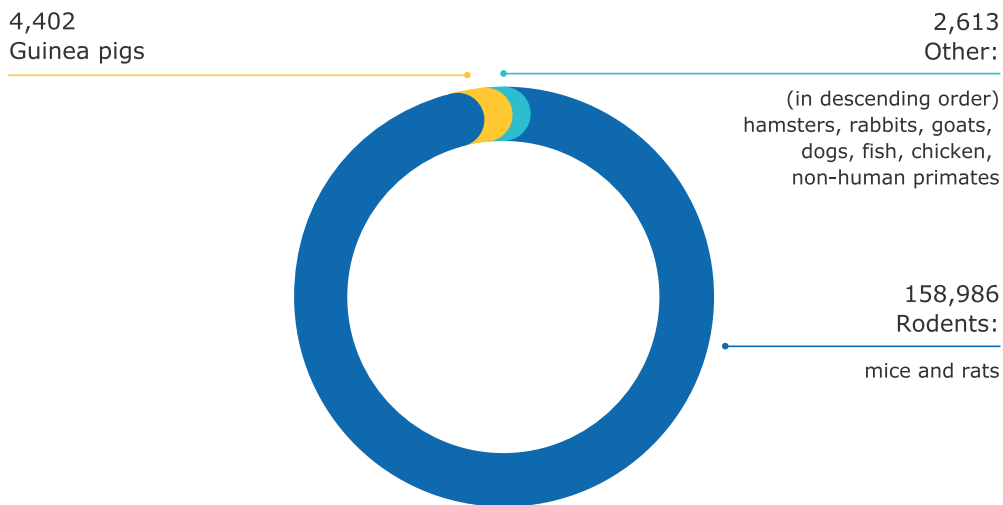
Animal research is only permitted if there are no recognized alternative methods available. In many fields, however,

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

In 2018, around 166,000 animals were used at Merck KGaA, Darmstadt, Germany. This represents a decrease of 12% compared to 2017. The majority (96%) of the laboratory animals we use are rodents (mice or rats). In addition, approximately 10,800 animals were used by contract research organizations (CROs) in our name and in collaborations with academia. Regulatory agencies sometimes require investigational drugs to be safety tested on non-rodent species. This allows researchers to **identify potential adverse effects with the necessary accuracy** and include them in the [risk assessment](#) of a substance.

Animal types



Auditing our research facilities

We perform regular audits on our animal research facilities to ensure adherence to our animal welfare standards. In 2018, ten internal audits and ten authority visits occurred. We have initiated the relevant corrective measures where necessary. No critical shortcomings were identified during these audits.

We adhere to the **highest international animal welfare standards** at all times. All our Healthcare laboratory animal facilities and one of our Life Science laboratory animal facilities in the United States have been accredited to the standards of [AAALAC International](#).

Collaborating with partners and suppliers

We perform the majority (95%) of animal studies ourselves and procure our animals from specialized breeders. 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, to a much lesser degree, academic institutions. However, whenever collaborating with such organizations, we expect them to adhere to comparably 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, conduct audits, typically every three years.

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 worked with other member companies to develop a **cross-company audit concept** that concentrates on those partners that are relevant to the

maximum possible number of companies involved. The results are shared among Interpharma member companies and treated confidentially. Based on the results of the audits, it is up to the discretion of each company whether or not to collaborate with the respective suppliers. In 2018, the association conducted two audits in Denmark, one in France and one in the United Kingdom.

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, international and local legislative requirements. Our employees also regularly participate in external continuing education programs such as accredited laboratory animal science courses offered by the Federation of European Laboratory Animal Science Associations (FELASA), the American Association for Laboratory Animal Science (AALAS), the Society of Laboratory Animal Science, the Laboratory Animal Science Association (LASA) and the Interessengemeinschaft Tierpfleger (Community of Animal Technicians). The respective local, national and international regulatory authorities monitor our activities to ensure compliance.

How we implement the 3Rs

We implement the 3Rs by way of various measures – both within our own company and as part of industry associations. To minimize discomfort and distress to animals before, during and after testing (refinement), in 2017 and 2018 we successfully implemented 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.

Wherever possible we adopt out our animals and employ a special rehoming program using accepted animal welfare organizations that specialize in laboratory animals. In 2018, for example, we closed down our own dog breeding colony and gave the animals away for adoption.

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 improve 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 dedicated to researching and developing new alternatives in animal experimenting, 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 Foundation Board of Trustees.

Our own scientists are also working on developing alternative methods and have received numerous accolades for their efforts, which includes being presented with the 2018 Animal Welfare Research Award by the Hessian government in Germany. One of our Global Research & Development teams was recognized for demonstrating how animal welfare and cutting-edge research can go hand in hand through the use of innovative housing systems for rabbits and rats that are used in legally required animal experiments when developing medication to treat arthritis.

Other awards that our teams have received include:

- 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

In 2018, we also launched an internal 3Rs Award, which is open to all our employees. The **three winning teams** in 2018 were recognized for providing innovative ways of implementing the 3Rs for animal-based research. One of the winning teams is based in Israel. It found a way to produce monoclonal antibodies using an in-vitro method instead of the animal itself, which has the added benefit of achieving higher yields than conventional production methods. A bio-monitoring team in France was awarded for developing a pyrogene test that does not need to use rabbits as test subjects. This project is currently awaiting regulatory approval. We moreover recognized a team from Italy that developed an in-vitro method, which replaces mandatory growth hormone testing on animals.