

products

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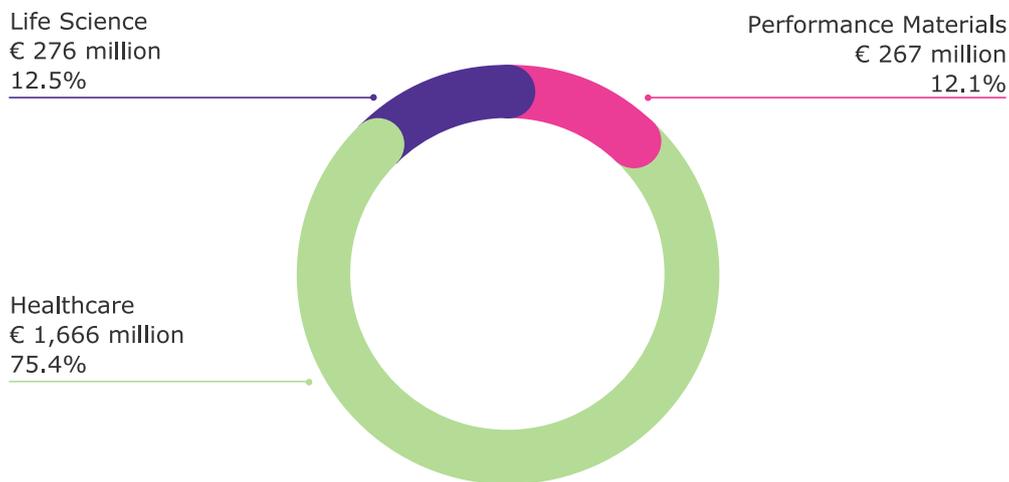
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Innovation and digitalization

Part of the non-financial report

We develop products and technologies that enrich people's lives. To this end, we are constantly on the lookout for groundbreaking developments and trends. Research and development (R&D) and innovation are the cornerstones of our success. In 2019, we spent € 2.3 billion on R&D, corresponding to 14% of our net sales. New technologies, and the advance of digitalization in particular, enable us to create innovative technologies, products, services and pioneering business models. Digitalization also decreases the time-to-market for new ideas, which creates opportunities we intend to leverage.

Research and development costs by business sector¹ – 2019



¹⁾ Not presented: Research and development costs of € 59 million allocated to Corporate and Other.

Our approach to innovation

Our Healthcare, Life Science and Performance Materials business sectors use established strategies to drive new product developments for the benefit of patients and our customers. The diversity of these business sectors provides us with a breadth of technologies and depth of market knowledge, giving us a competitive advantage in developing new products.

At the same time we aim to create new businesses between and beyond our business sectors and the current scope of our activities. When deciding where to focus our activities, we analyze current megatrends to determine the innovation fields in which we see potential for new business. We endeavor to identify innovation projects that transcend

our current portfolio and develop them from the initial idea all the way to market launch. This can only succeed if our business sectors work closely together and if we are open to external momentum. Our **end-to-end innovation process** seeks to achieve exactly that. In the process of integrating Versum Materials and Intermolecular, which we acquired in 2019, we are reviewing the existing innovation process, making adjustments as necessary.

We also create and **foster innovation ecosystems** in order to bolster our overall innovative power in several areas. We incubate viable technology companies through our Accelerator programs in Europe and China. Furthermore, we partner with key universities on several development programs, focusing on the fields detailed below.

INFO

OUR THREE INNOVATION FIELDS TO DRIVE INNOVATION BETWEEN AND BEYOND

Bio-sensing and interfaces

Focusing on the interface between the biological and digital world, the goal of this field is to utilize data analytics tools to enable faster and more accurate (remote) monitoring and medical treatments in numerous areas.

Clean meat

This field concentrates on the biotechnology required to produce real meat grown in vitro. This is expected to enable the production of animal protein that is healthier, more ethical and environmentally sustainable.

Liquid biopsy technologies

This area focuses on non-invasive alternatives to traditional tissue-based diagnostics, such as liquid biopsy, thereby reshaping methods of detecting and managing various diseases.

We drive promising projects as quickly as possible from the brainstorming and idea generation stage to an incubation and growth phase, where we provide project teams with a suitable environment to develop their business models and scale up their ideas. Projects are monitored in a lean process in which they prove their commercial relevance at different gates. All activities are **supported by experts** in business model design, business development, market research, and agile methodologies. The objective is for the new products or services to make a measurable contribution to our business success once they have been launched.

Our approach to driving digital innovation

A major focus of our innovation efforts is digitalization, and we leverage related opportunities to boost our business performance. We are therefore increasingly forming new **strategic partnerships** with organizations offering different perspectives. We expect to see progress in:

- **Research and development:** Digital technologies enable us to access and analyze large volumes of data rapidly, thereby accelerating our research and development activities. This is particularly the case in our Health-care business sector, where we are working to advance the development of new drugs to provide patients with faster access to effective medicines.
- **Supply chain management:** Digital technologies help us to better manage our supply chain. Centrally collating all data gives us access to crucial real-time data. This enables us to predict supply bottlenecks around the world

and respond promptly to make sure medicines reach their destination when needed.

- **Production:** We set up the infrastructure to capture data throughout all stages of our production processes and apply advanced data science methods to optimize our manufacturing methodologies. To improve the efficiency and reliability of our production processes, we leverage in-silico methods, which means that we simulate molecule properties or chemical reactions on a computer.
- **Digital product innovations:** Digitalization enables us to broaden our existing product portfolio to include offerings such as new digital services. We also promote health awareness and improve disease awareness and patient treatment through innovative e-health offerings such as our Diabetes Online Risk Assessment (**DORA**).
- **Interactions with customers:** Thanks to modern data collection and analysis methods, we can make more efficient use of customer-relevant data. This information allows us to adapt our products and services where necessary.

You can find more information on research and development in our [2019 Annual Report](#).

How we drive innovation

The organizational setup of our research and development (R&D) activities reflects the overall structure of our company. All three of our business sectors operate independent R&D units, which pursue their own individual innovation strategies.

Our Group Strategy and Transformation function facilitates innovation between our individual business sectors and beyond our current business scope. It oversees an **end-to-end process** that ranges from setting the innovation direction through project ideation, incubation and growth to establishing long-term new businesses for our company.

Projects of this kind are developed through our **Innovation Center** at our global headquarters in Darmstadt (Germany), our **China Innovation Hub** and our **Silicon Valley Innovation Hub**.

In addition to identifying innovation fields at a global level, we have also introduced a China Innovation Hub, which is mainly centered on AI-enabled health solutions. In this **innovation field focused on China**, we are exploring new AI-based technologies, products and services that could impact the medical or healthcare industry across the value chain by, for example, increasing efficiency, saving costs or improving customer experience.

Many potential partners for innovation projects are based in Silicon Valley (United States). Through our Silicon Valley Innovation Hub in Menlo Park, California, we aim to uncover new technological opportunities and establish partnerships and projects within our three innovation fields.

Our Innovation Committee (IC) oversees the implementation of innovation projects both between and beyond our business sectors. It is tasked with reviewing the progress of ongoing efforts and with ensuring that the decision-making process for selecting innovation projects is both transparent and consistent. The committee consists of leaders from our Group functions and our three business

sectors. For projects requiring larger-scale investments, the IC consults our Executive Board.

Leveraging data science capabilities

We employ a Global Data Science Team of around 30 data scientists to leverage the significant potential in **advanced analytics and machine learning**. For example, this team works with external and internal data to provide insights to sales teams in Life Science, uses image recognition techniques to support the work of clinicians and researchers in our Healthcare business sector, and assists in the research and innovation process in Performance Materials. The team is part of our Digital Organization, which focuses on providing significant business value by challenging conventional scientific methods and implementing technology to create faster processes.

Investing in promising ideas

M Ventures is our strategic corporate venture capital arm. It invests in innovative technologies and transformational ideas with the potential to significantly impact our core business areas. With a € 300 million fund, M Ventures has a focus on **early-stage investing and start-up companies**, including the creation of spin-offs to leverage our science and technology base. M Ventures takes an active role in its portfolio companies and has a mandate to invest in the areas of Healthcare, Life Sciences, Performance Materials, and New Businesses.

Our commitment: Protecting innovative ideas

We are committed to ensuring the confidentiality of sensitive information, particularly of intellectual property in digitalization projects, and to protecting our innovative ideas. Our Policy for Personal Data Protection and Personal Data Privacy defines the standards that govern how we process, save, use and transfer data. You can find more information on data protection under [Compliance](#).

Our Innovation Center: Growing ideas into business

Located in Darmstadt (Germany), our Innovation Center offers our employees and external partners an optimal environment to **cultivate their ideas** and scale them up to viable new businesses. We provide the infrastructure needed to advance cutting-edge projects, along with state-of-the-art methods and tools.

The Innovation Center team holds regular events, workshops, seminars and webinars. Through these channels, we introduce our employees to creative methods that help generate innovative ideas. In 2019, our Innovation Center received several [awards and accolades](#) for its unique concept of driving innovation.

Igniting and nourishing internal ideas

We seek to maximize the innovative power within our company, giving our employees around the world the opportunity to present their ideas via diverse channels. Our **Innospire** initiative encourages employees to submit ideas for new products, services and business models. Through a multi-stage process, we develop the best suggestions into business plans. In 2019, employees submitted a total of 406 project ideas related to either our three innovation fields or our freestyle category. After assessing their viability, we will announce the most promising projects in May 2020.

Our **Innovator Academy** strives to unlock the innovation potential of idea givers, internal project teams and members of think tanks and start-ups. It provides a wide range of development programs and methodologies, along with online and classroom training courses. We also offer webinars, introducing employees to Innovation Center topics and content through practical examples.

Project example: Mapping the technology and knowledge landscapes of companies

The R&D world in large global organizations is very complex and highly dispersed over many sites, countries and sectors. Finding the right expert or the capabilities needed to start or run projects can therefore become a cumbersome exercise. In addition, building the most efficient R&D strategy for an enterprise requires a comprehensive overview of the available technology platform portfolio.

We have created a **digital solution** to map the entire technology and knowledge landscape within our company – across sites, sectors and countries. This makes the information created by every knowledge node across the organization instantly available to R&D managers, experts, technology scouts and strategists across the business. A next step is to commercialize this software, making it available to other companies.

Opportunities for university students

In June 2019, we launched the Innovation Summer School of Merck KGaA, Darmstadt, Germany, a three-month intrapreneurship program giving students a unique opportunity to learn about intrapreneurship, meaning innovation in a corporate environment. The students were to grow a seed idea **into a pitchable innovation concept**. They were tasked with exploring our innovation fields and proposing ideas for potential new innovation projects in the Innovation Center. Our expert jury selected two promising ideas, and we offered the winning teams seed funding to further shape their ideas into an initial business plan at our Innovation Center.

Silicon Valley Innovation Hub: Looking for the food revolution

The Silicon Valley Innovation Hub has a strong focus on our Clean Meat innovation field. Besides other initiatives, we began sponsoring the **Alternative Meats X-Lab** at the University of California, Berkeley (USA) in 2019, to help entrepreneurs and researchers investigate the **next generation of foods**. The sponsorship offers an opportunity to engage with a prolific research community within the Clean Meat industry that is interested in ideation, problem-solving and driving the research agenda.

We also partnered with the Institute for the Future (IFTF), a not-for-profit think tank based in Palo Alto (California, USA). This relationship will give us access to recent research on the **future of food** and allow us to collaborate with one of the most highly regarded and successful think tanks in the world on topics within our innovation fields.

China Innovation Hub: Strengthening our innovation footprint

Our China Innovation Hub has locations in Shanghai and Guangdong, which were inaugurated in October and November 2019, respectively. Their role is to use a **national-wide innovation network** to scout, incubate and invest in innovative opportunities in healthcare, life science, performance materials, and related fields between and beyond our existing businesses.

In addition, we launched a **China-specific program** for our **Accelerator** via the China Innovation Hub. Six start-ups completed their three-month acceleration journey, with half of them forging partnerships in business sector and innovation fields of our subsidiary in China.

Synergizing external ideas: Start-ups and cross-industry collaboration

Numerous start-ups around the world are working on new technologies and innovative business models. Our **Accelerator** supports select enterprises in their development through programs at our global headquarters and in China. This helps us gain insights into innovative start-ups, which supports our efforts to identify emerging market trends early on. Our primary goal is to link these start-up companies with our innovation projects or our business sectors for future collaboration. In 2019, we accepted ten start-ups into the Accelerator at our Darmstadt headquarters. Following the end of this three-month program, we initiated collaborations with 30% of the participating start-ups. We are in discussions with another 60% on potential partnerships.

We accepted a total of 18 start-ups from more than 610 applications for the next Accelerator intake at both our global headquarters and in China.

Accelerating innovation

In 2019, we extended our Accelerator Satellite program, making it also available in the United Kingdom. In Africa, it is now run through a public-private partnership with **Make-IT in Africa**, a tech entrepreneurship initiative initiated by the German Gesellschaft für Internationale Zusammenarbeit (GIZ) in Kenya, Nigeria, South Africa, and Tunisia. This enables us to **connect with African entrepreneurs** and identify cutting-edge start-ups for our Accelerator program.

Through this African satellite program, we aim to **contribute to UN Sustainable Development Goal 3**, "Ensure healthy lives and promote well-being for all at all ages", by identifying innovative African start-ups and offering them partnership and support to help them scale up. We focus on areas close to our business and innovation fields such as bio-sensing and interfaces and liquid biopsy technologies.

In June 2019, we opened the Innovation Lab of H. Spectrum & Merck KGaA, Darmstadt, Germany in Taiwan – an incubator that aims to support start-ups in **generating patient-centric solutions**. We selected four start-ups to participate in the program, working under pre-defined innovation topics: Liquid biopsy, Bio-sensing and interfaces, Patient journey, and Right drug to right patient. The select start-ups gain access to expertise and networks while we engage with new ideas that help drive innovation for technology-based healthcare solutions.

Rewarding inclusive innovation

For the second time, we hosted the European final of the Inclusive Innovation Challenge in Darmstadt (Germany) in October 2019, acting as the exclusive European partner. The competition was initiated by the Massachusetts Institute of Technology (MIT) **Initiative on the Digital Economy** and aims to **accelerate technology-driven solutions** that enable greater economic opportunities for medium- and low-income earners. Organizations and companies from around the world can take part with technological solutions that shape the future of work. The challenge awards over US\$ 1 million in prize money. We invited the expert judges involved in selecting the winners to take part in an advisory board on the topic of digitalization and the future of work at our company.

Fruitful strategic partnership

Through our strategic partnership with **Palantir Technologies**, a company based in California (United States), we are able to use their data analysis capabilities to improve and accelerate the development, commercialization and delivery of new medicines. The access to Palantir technology enabled us to create tools that help to improve patient retention, increase the efficiency of sales representatives and aid in strategic targeting to deliver effectively on our product launches. We can also integrate and analyze large amounts of data to **improve our operational excellence**.

Syntropy is a joint venture formed by our company and Palantir Technologies. The partnership aims to give scientists and research centers **access to a technology platform** that integrates and centralizes various organizations' data. Advances in medical research over decades have created a wealth of knowledge about diseases and how to treat them. This includes biomedical data. A substantial amount of this data is inaccessible to the scientists and clinicians who need it to advance their research. Syntropy will create a network that drives discovery and improves human lives.

Promoting visionary research

In 2018, on the occasion of our 350th anniversary, our company launched the **Future Insight Prize** to honor and promote groundbreaking scientific and technological innovations that stand to **benefit humanity** in the fields of health, nutrition and energy. We presented the award for the first time in 2019 and offered a € 1 million research grant to the winners: U.S.-based scientists Pardis Sabeti and James Crowe. Pardis Sabeti from the **Broad Institute** was recognized for identifying innovative genetic technologies used in the detection and therapy of infectious diseases. James Crowe from **Vanderbilt University Medical Center** received the prize for uncovering the mechanisms necessary for creating therapeutics and vaccines. Their research may enable the development of a "pandemic protector" technology that would help protect people worldwide from pandemic viral diseases.

At the 2020 Curious Future Insight Conference, we will award the next Future Insight Prize in the **Multidrug Resistance** category.

sustainable products

sustainable product design

Respect for the environment is at the heart of sustainable conduct. We see it as our duty to not only conserve resources when developing our own products, but to also help our customers increase the sustainability of their products. Our Life Science business sector develops solutions to make research and biotech production simpler, faster and more efficient, while our Performance Materials business sector focuses on solutions for the electronics market, for example semiconductor or display materials.

Our approach to sustainable product design

Our individual business sectors take different approaches to sustainable product design. In our Life Science business sector, we aim to reduce the impact of our products on health and the environment. This applies to **the entire life cycle**, from manufacture and use to disposal. At the same time, we seek to make our products more efficient and user-friendly. We ask ourselves right at the start of product development how to best reconcile these requirements.

Our Performance Materials business sector develops and produces numerous intelligent materials that help our customers manufacture high-tech products. Many of these materials allow people to save energy in their everyday lives. The avoidance of hazardous materials is a principle that is embedded in the product development process.

How we include sustainability in product design

The Life Science business sector works across its three business units to drive product-related sustainability. This includes our Design for Sustainability (DfS) program for eco-friendlier life science products as well as DOZN™, a web-based tool for assessing greener alternatives.

Our Performance Materials business sector has its own CR Committee. It comprises representatives from all Performance Materials business units and other relevant internal units.

The responsibilities described here also apply to product **packaging and recycling**.

Integration of Versum Materials and Intermolecular

In October 2019, Merck KGaA, Darmstadt, Germany acquired the two companies Versum Materials and Intermolecular, broadening the Performance Materials product portfolio in the semiconductor solutions field.

In the course of the integration process, we evaluate their activities and then include them in our reporting as of 2020.

Our commitment: Chemicals and product policies

In order to meet the product safety regulations relevant to our company, our Regulatory Affairs Group Policy details **Group-wide processes** for managing and implementing

product safety, including the necessary management structures.

Our processes for sustainable product design

Within our Life Science business sector, a strategic platform founded on a transparency-based, **data-driven approach** helps our experts to drive sustainability improvement during the development of products and packaging. Our Design for Sustainability (DfS) program, a comprehensive approach to increase the sustainability of our products, focuses on three areas:

- Our **DfS: Development** pillar focuses on embedding sustainability at the beginning of the R&D process.
- Our **DfS: Consultancy** pillar focuses on working with our customers to solve specific sustainability and/or green chemistry challenges they face.
- Our **DfS: Reengineer** pillar focuses on our established portfolio of products and on looking at how we can improve the environmental footprint of these products through application of the 12 Principles of Green Chemistry in our process. We then use our proprietary web-based tool **DOZN™** to assess the improvements. We have now extended the tool to our customers to aid them in assessing their own products and processes.

Within our Performance Materials business sector, our raw materials for the cosmetics industry meet the high standards of the EU Cosmetics Regulation and are produced in line with Good Manufacturing Practices for Cosmetic Ingredients (**EFFCI GMP**).

Sustainable product design in the Life Science business sector

Through our DfS program, we have developed a comprehensive approach to increasing the sustainability of Life Science products. The "DfS: Development" program provides our product developers with a **range of tools** that enable them to analyze the impact of a product regarding materials used, energy and emissions, waste, water, packaging, usability and innovation. We have developed sustainability criteria that can be used to rank a product's performance in each of these areas. When developing a new product, our aim is to improve on as many of these criteria scores as possible.

To understand the potential environmental impacts throughout the product life cycle, we conduct streamlined product life cycle analyses. The findings from these analyses inform our efforts to improve our products and are incorporated into subsequent development stages. Experts from R&D, Product Management, Quality, Procurement and other departments collaborate along every step of the process. By the end of 2019, 32% of such product development projects had met three or more product sustainability criteria.

In 2019, we successfully developed further our DfS program in order to better account for environmental impacts during the product development process and to improve our **communication of sustainability attributes** to our customers. We developed new elements of the program, including a scoring system and we initiated a pilot phase during which we test and optimize these elements prior to global implementation.

We also continued to run a product development pilot project with the goal of encouraging our suppliers to participate in the Together for Sustainability (TfS) industry initiative. Ten of our suppliers of consumables took part in the project. More than 85% of product manufacturing costs are attributable to them.

Green chemistry assessment tool

Through our "DfS: Reengineer" initiative, our Life Science researchers are developing innovative solutions in line with the 12 Principles of Green Chemistry developed by chemists Paul T. Anastas and John C. Warner. These aim to make research **as environmentally compatible as possible** and to minimize negative impacts on human health.

Our proprietary web-based tool DOZN™ enables us to assess sustainable alternatives for various chemicals and to provide transparency to our customers. DOZN™ provides a **framework for rating our products** in the three stewardship categories "Improved resource use", "Increased energy efficiency" and "Reduced human and environmental hazards." The system calculates scores on each substance based on a range of data that includes the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as well as Material Safety Data Sheet information. To date, we have used this matrix to assess and improve more than 45 products.

In 2019, we introduced a new customer-facing version of DOZN™ 2.0. It allows customers to compare products and/or processes in a secure environment while utilizing the power of our system. DOZN™ 2.0 brings new possibilities of sustainable product design to our customers to make more **environmentally friendly choices** in their development processes.

More than 830 greener alternatives to conventional products have been made available to date across our platform of solutions.

Responsible use of natural resources

We are committed to implementing the **Nagoya Protocol**, an international supplementary agreement to the UN Convention on Biological Diversity (CBD), which has been transposed into EU law and was implemented in German law on July 1, 2016. We support the general principles set

forth in the CBD, and especially the third objective: the fair and equitable sharing of benefits arising from the utilization of genetic resources and traditional knowledge, in accordance with the Nagoya Protocol's terms and conditions. A key element is access and benefit sharing, which ensures that countries providing genetic resources and knowledge also benefit from their use. The Nagoya Protocol plays a key role in our product development efforts and we apply the agreement's requirements when using genetic resources originating in countries covered by the protocol.

In 2019, we adopted a Group-wide standard entitled Access to Genetic Resources. Its objective is to define **requirements, roles and responsibilities** in order to ensure compliance with the Nagoya Protocol under applicable legislation. We carried out comprehensive trainings on the standard across relevant units.

Where appropriate, we ensure that genetic resources and traditional knowledge are obtained with the prior informed consent of the relevant Nagoya Protocol member state. Their use is governed by **mutually agreed terms**. If applicable, for example when introducing a new product on the market, we disclose appropriate due diligence declarations and keep all associated records as required by relevant legislation.

Each business sector defines specific procedures to help ensure that the requirements set out in the Group-wide standard are met.

Tracking 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 434 kilotons of material in 2019 (2018: 488 kilotons). We only record the weight of the materials that are directly used in our pharmaceuticals and chemicals.

Wide range of solutions

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

Greener solvents

Our greener, bio-based solvents utilize non-food, **renewable resources**, making them more environmentally friendly. Our solvent Cyrene™ is derived from waste cellulose and is used as a more sustainable alternative to substances such as NMP and DMF, which are classified as toxic to reproduction. Through Cyrene™ and other greener solvents, we are helping our customers to make their production processes safer and more environmentally sustainable. Cyrene™ was named "Environmental Product of the Year" at the **Environmental Leader Awards 2019**.

We expanded our greener solvent portfolio by launching another solvent, Dimethyl Isosorbide, in 2019, with further solvents to be launched until 2022.

Eco-friendly lab water use

Our Milli-Q® IQ 7000 lab water purification and monitoring system uses mercury-free UV oxidation lamps and has a hibernation mode to save energy while still preserving system water quality. Compared to previous versions, we reduced the size of the system by 25% and the size of the purification cartridges it is equipped with by 33%. These measures helped to cut down on the amount of plastic used, on packaging and transportation as well as on waste levels.

Less plastic in cell culture creation

The amount of plastic waste generated by creating cell cultures is high, due to the need for single use, sterile products. We estimate that globally, between all providers of filters, approximately seven million units are used each year just for sterile filtration. This does not include flasks, pipettes and other plastic used. This plastic is a biohazardous waste and cannot be easily recycled.

Under our Design for Sustainability approach, we created a greener version of our current Stericup sterile filtration system, thereby reducing the amount of plastic entering the laboratory and waste stream.

The new Stericup E was designed so that customers can connect the bottle containing the sample to be filtered directly to the Stericup E filtration unit, avoiding the use of a plastic funnel. Depending on the product version, the new Stericup E design can **reduce the amount of plastic** used by up to 48%. This also reduces the amount and size of plastic and corrugated packaging by up to 73%. The unit of sale is then lighter and smaller, which leads to a reduction of CO₂ emissions during transportation. Storing the product at our distribution centers and at customers' sites requires less space and reduces the volume and cost of waste disposal (including biohazardous waste) for our customers. This new design leads to a reduction of the global warming potential of the product of up to 46% from design to end of life.

Optimizing the ethylene oxide sterilization process

Some of our products are sterilized with ethylene oxide (EO). In 2019, we successfully completed our three-year project to improve the efficiency and reduce the environmental impacts of the EO sterilization process for products manufactured at our Life Science site in Molsheim (France). This encompassed 25 of our product families. A multidisciplinary team successfully developed and implemented the new process in line with the ISO 11135 standard on the sterilization of healthcare products. The new process allows us to sterilize different products in the same cycle, resulting in an optimized truck fill rate for transportation from our site to the sterilization partner. The number of trips has thus been reduced by half, enabling us to reduce our emissions by 200 metric tons of CO₂eq annually.

Current product examples from the Performance Materials business sector

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

Colloidal silica

Over the past decade, our semiconductor customers have transitioned to using more environmentally sustainable materials in their chip manufacturing, while simultaneously delivering advanced computer chips at lower costs. We have responded to this challenge by developing **next-generation products** using a minimum of 30% less colloidal silica to save process costs for our customers, while also reducing our freight, packaging and processing costs. We successfully launched a next-generation product that meets these technical and commercial targets. We can therefore reduce the need for ocean containers by approximately 180 units annually. We also optimized the production process, reducing process water consumption by over 14 million gallons (53 million liters) compared to our standard product. The availability of this product in concentrated form means that our customers can also save costs on waste treatment and reduce the number of plastic drums used.

As a result of the acquisition of Versum Materials, we obtained a significantly sized CMP business, in which we aim to explore options for applying the approach outlined above.

NMP-free removers

The production process for semiconductor devices requires numerous cleaning steps to remove the organic material used to pattern the circuit design. These cleaning methods require complex solvent chemistries that selectively remove organic material without damaging the sensitive electronic components. However, the most effective solvents pose a significant environmental hazard. NMP, a mainstream solvent common in wafer cleaning processes, is highly toxic and, in 2020, will be classified as a restricted chemical under the European Union's REACH regulation. We are continuously working on developing **new cleaning chemistries** and already launched new products in 2019. As a result, not only more sustainable solvents, but also more efficient solvents are utilized by our customers. By designing custom solvent systems for our customers' cleaning applications, hazardous chemistries can be avoided and the volume of material used is reduced, as is waste.

Switchable windows

Windows that can be darkened in a matter of seconds are now a reality, thanks to our **liquid crystal window (LCW)** technology. These darkened windows regulate the heat generated by direct sunlight. The LC material was commercialized under our **licrivision®** and **eyrise®** brands. New estimates based on planned customer projects show that this technology can lower the energy consumed by building climate control systems and lighting by up to 10%, thereby replacing conventional shading.

Life cycle approach to benefit our customers

At the manufacturing plants where our effect pigments are produced, we focus on saving energy and reducing CO₂ emissions. This is especially relevant for customers who want to reduce their upstream supply chain CO₂ footprint. In 2019, we achieved a 11% overall CO₂ reduction for plants producing pigments for our Surface Solutions portfolio compared with 2018.

Shifting to more natural-based cosmetics

Consumers are increasingly scrutinizing brands and companies for environmental and social aspects. Responding to this trend and the ever-growing popularity of natural cosmetics, we are working closely with our customers in the cosmetics industry to find solutions for more natural-based cosmetics. The resulting cosmetic formulations comply with strict criteria and, by the end of 2019, 73 of our cosmetic pigments and active ingredients had been certified to Ecocert's COSMOS standard for organic and natural cosmetics. We have also obtained **halal certificates** for over 50% of this product portfolio, including broad parts of the pigments portfolio, our **Eusolex T** and UV-Titan product ranges. Our aim is to develop more natural-based raw materials for use in cosmetics in the future.

Alternatives to microplastics in cosmetics

Functional fillers play a crucial role when it comes to the look, feel and quality of cosmetics. For example, beauty products containing effective functional fillers are easier to apply, wear well and help mask imperfections or skin discolorations.

Microplastics are often used in cosmetics and functional fillers. However, they are highly resistant to environmental biodegradation, fragment into ever smaller pieces and do not dissolve in water. Wastewater treatment plants are able to filter out only 90% of microplastics.

We offer effective and scientifically proven alternatives to microplastics. Our **RonaFlair®** portfolio of functional fillers offers environmentally friendly mineral ingredients that deliver a variety of cosmetic properties.

packaging and recycling

Packaging protects our products from external influences and helps to ensure that they reach the customer undamaged. Packaging must remain intact across the entire product life cycle. We are working to reduce the amount of material we use as well as to increasingly utilize eco-friendly materials. We also help our customers to take a more sustainable approach to disposing or recycling our products and packaging.

Our sustainable packaging strategy

We aim to deliver our products in packaging that is safe and easy for customers to handle. We also try to make it as sustainable as possible. With more than 300,000 products in our Life Science portfolio – ranging from biochemicals to lab chemicals and from filter materials and systems to instruments – we face a variety of challenges when it comes to packaging. We strive to improve the sustainability of this packaging to help both us and our customers reduce its environmental impact. In 2019, we therefore officially launched SMASH Packaging, a sustainable packaging strategy for Life Science. The strategy is built on three pillars: optimizing resources, using more sustainable materials and designing for a **circular economy**. We have set four goals that support these pillars.

- **Shrink:** reduce amount of packaging
- **Secure:** achieve zero deforestation
- **Switch:** improve plastic sustainability
- **Save:** maximize recycling

We have also defined targets for the years up to 2022 relating to these goals. The targets address the development of new product packaging and the improvement of existing product and distribution packaging.

New product packaging is where we can make the biggest impact. Our approach consists of implementing **new standards and guidelines** development teams can apply to create more sustainable packaging. In the future, we will assess the sustainability characteristics of new product packaging based on our **Design for Sustainability** scorecard that is being redesigned.

Making packaging more sustainable

A large proportion of our packaging consists of fiber derived from wood. We work continuously to increase the amount of recycled material and the proportion of corrugated cardboard boxes certified to the standards governing **sustainable forestry**, including the Sustainable Forestry Initiative (SFI), the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC). We want to reach our zero deforestation goal by ensuring that none of our wood and fiber-based packaging materials contribute to deforestation. In this connection, we conducted a survey in 2019 to better understand the practices of our suppliers and the characteristics of our packaging and to identify opportunities for improvement. We collected information from our strategic direct suppliers who represent 80% of our fiber-based packaging materials spending. Overall, by volume, 75% of corrugated packaging supplied by these companies is certified by at

least one of the three sustainable forestry standards or are made of recycled material.

Cellulose as an alternative to polystyrene foam

In the past, we used expanded polystyrene (EPS) molded foam to secure glass reagent bottles and prevent them from breaking during transport. While EPS, also known as Styrofoam[®], is an excellent cushioning material, it is manufactured from non-renewable petrochemicals and difficult to recycle. By contrast, molded pulp components can be easily recycled with other paper materials and **compacted together** for storage and transport. We are replacing EPS wherever possible with molded components made of cellulose and recycled paper pulp.

We use molded pulp inserts to pack a variety of liter bottle configurations in shipping boxes, thereby replacing around three million EPS parts per year. We are currently conducting safety tests on new pulp designs for shipping other bottles of various sizes. Overall, we used approximately 1,000 metric tons of molded pulp packaging material in 2019.

More sustainable bulk packaging solution

We seek **eco-friendly alternatives** to ship our products safely, which is why we are partnering with a biotech company to jointly develop a more sustainable bulk packaging design for the transport of our Millistak+[®] Pod Disposable Depth Filters. A life cycle assessment showed that we achieved a 24% reduction of corrugated cardboard used, which translates to a 17% decrease in greenhouse gas (GHG) emissions throughout the life cycle of the packaging materials. This translated to a total of around 4 tons of corrugated cardboard that was saved in 2019. Moreover, our customers require 70% less time to process our products and their packaging.

More cardboard instead of plastic

Solvents are usually supplied in plastic bottles. We use Titripac[®] because it offers a more eco-friendly alternative. The cardboard carton and plastic liner with an integrated withdrawal tap have made the packaging **more recyclable** and reduced its weight by more than 50%. As a result, the greenhouse gas emissions arising across the entire product life cycle are 61% lower compared to plastic bottles. Since the withdrawal tap protects the product against contamination, contents can be used to the very last drop. This helps reduce chemical waste.

Reusing EPS boxes

Many of our Life Science products need to be kept cool during shipping and are therefore packed in special EPS

boxes. To **mitigate waste**, we offer our customers in the United States the option of returning these boxes to us. If they are still fully functional, we reuse them. In 2019, this amounted to more than 11,500 boxes that were reused at least once, representing around 4% of the shipments leaving the three distribution centers where this type of packaging is being used.

Sustainable membrane packaging for cut disc filters

In 2019, we launched a redesigned membrane box packaging. All customers who order cut disc filters now receive their order in the new packaging design.

The new membrane box packaging is manufactured using 22% less plastic than the previous design. Moreover, it replaces polystyrene with polypropylene that has a 43% lower global warming potential in its production phase than polystyrene. Other environmental impact enhancements include the elimination of foam inserts and local sourcing of materials, resulting in less transportation and fewer emissions. This new design also **reduces GHG emissions** by 200 metric tons per year across the entire product life cycle. A life cycle assessment conducted on this new packaging design features the following sustainability improvements over the previous design:

- 22% reduction in weight of product packaging
- 33% reduction in GHG emissions
- 27% reduction in non-renewable energy.

Introducing recyclable plant-based coolers

In the past, we used insulated containers made of expanded polystyrene (EPS) for the shipment of our temperature-controlled products. While EPS offers good insulation and cushioning properties, it is a petroleum-based material that takes hundreds of years to decompose. As the options for recycling EPS are limited, it is generally incinerated or landfilled. It can also cause environmental pollution, notably when it enters the marine environment. We have set ourselves the target to **reduce the use of EPS by 20% by 2022**. This target is part of our SMASH Packaging strategy.

In 2019, we investigated several technical solutions in order to find an **alternative cooler** that would meet our standards for effective cold chain transportation with a lower environmental footprint than an EPS cooler.

In early 2020, we started implementing this new cooler at one of our distribution centers in the United States. We

use it for our products that are shipped with dry ice at a temperature of 2°C to 8°C. We plan to progressively deploy these new coolers in our main distribution centers in North America.

Reducing the amount of packing material used in distribution

Packing or padding material is used to safely store and transport products to our customers. We want to **increase its sustainability characteristics** as part of our SMASH Packaging initiative. In 2019, our distribution teams in Germany and India conducted projects to optimize the use of packing materials for the shipment of our products.

In our distribution center located in Darmstadt (Germany), we reduced the grammage of kraft paper used as packing material from 100g/m² to 80g/m². This initiative allows us to save 14 tons of paper annually, while maintaining the **same level of performance** in protecting our products.

In our Jigani (India) distribution center, we replaced plastic air pillows with shredded corrugated cardboard for packing. We also implemented a corrugated box shredder. Thanks to this machine, we are able to **reuse the inbound corrugated packaging waste** as shredded corrugate for packing, avoiding the additional purchase of packing material.

Our recycling program

In cooperation with a waste management company based in Massachusetts (USA), we employ a comprehensive recycling program for our Life Science customers in the United States. Product waste from their research labs and biopharmaceutical manufacturing operations is collected, sanitized and **recycled into plastic panels**. This material can be used in many industries, such as construction, landscaping, transportation and marine construction. The program includes our **Biopharma Recycling** and Ech2o Collection recycling programs.

We continue to expand this program throughout the United States and are exploring options in other regions such as Europe and Asia. The program now serves 12 major biopharma manufacturing customers. Since launching the program in 2015, we have recycled 4,167 metric tons of waste generated from the use of our products, including 1,466 metric tons in 2019 alone.

Health for all

Global strategy

Two billion people across the globe do not have adequate access to health. We are striving to make health solutions affordable, raise awareness of diseases and help people learn how to manage them. We work with committed partners to tackle this complex challenge by researching innovative solutions, developing new approaches and improving existing programs to help people at the point of care.

Our approach to improving healthcare for underserved populations

Our aim is to create a healthier future for all: for individuals, communities and countries. We want to use innovation in science and technology to help improve the health of underserved populations in low- and middle-income countries. To achieve this, we leverage our expertise from all business sectors and collaborate closely with a wide range of partners. We also participate in industry-wide initiatives to develop new approaches.

Our **Global Health strategy** is designed to overcome access barriers for underserved populations and communities in low- and middle-income countries in an economically viable and sustainable manner, thereby creating shared value. For us, this means developing business models that increase the value and competitiveness of our company while solving unmet health needs and strengthening health systems. This leads to a win-win solution for our company and society as a whole.

We follow three core operating principles:

- **Developing innovative solutions:** We take a leading role in the elimination of schistosomiasis, and we create new integrated drug, diagnostics, technology and vector control solutions for schistosomiasis, malaria and other infectious diseases.
- **Engaging with cross-sector partners:** We participate in multi-stakeholder global health platforms to help achieve the UN Sustainable Development Goals. We define partnerships for research and development programs, utilize access alliances and create locally-based opportunities, where possible.
- **Creating business opportunities via a shared value approach:** We help to sustainably improve the health of underserved populations by utilizing our portfolio from across all three of our business sectors.

Using **focus programs** to address our priority areas, we want to be instrumental in the elimination of schistosomiasis while fighting malaria and other infectious diseases. Furthermore, we help build local capacity across the value chain and position our company as a leading and reliable partner.

Our global access to healthcare strategy rests on four major pillars that guide our access activities:

- **Availability:** We research, develop and refine health solutions that address unmet needs, tailoring them to local environments. For example, we are committed to delivering on our **R&D portfolio** of projects by developing and providing access to innovative health solutions that help tackle infectious diseases.
- **Affordability:** We seek to provide assistance to those who are unable to pay for the health solutions they need, for example through our **patient access programs**. This also includes addressing challenges regarding pricing and intellectual property. Furthermore, we are working on innovative access paths for health solutions to fight NTDs. For instance, we aim to ensure the future affordability of our new **pediatric drug** to treat schistosomiasis.
- **Awareness:** By empowering medical professionals, communities and patients to make informed decisions, we help raise awareness for diseases and therapies through efforts such as our **global awareness campaigns**.
- **Accessibility:** We promote initiatives that control the cost of goods during product development and production and allow for localized health solutions. We also strive to strengthen our supply chains to help ensure that medicines reach the people who need them quickly and safely, as demonstrated by our **NTDeliver project**.

How we are improving access to healthcare

Our Global Health unit coordinates the implementation of our strategy for global access to healthcare. Multiple teams work on ways to investigate and reduce the barriers that prevent underserved populations from receiving adequate healthcare.

This unit is also responsible for Group-wide initiatives, programs and sponsorships relating to global health topics. Our experts collaborate closely with the Healthcare, Life Science and Performance Materials business sectors to leverage their strengths and competencies effectively.

Our **Global Health Institute** develops and implements a portfolio of projects for transformative treatments, diagnostics, technologies, and preventive measures against infectious diseases. The institute also seeks to provide **research and development capabilities** by engaging in activities to help strengthen health systems in low- and middle-income countries. It operates as a social business enterprise to deliver innovations for the most vulnerable members of society, namely women and children in low- and middle-income communities.

Our Access to Health unit investigates the factors that prevent underserved populations from receiving healthcare and coordinates with multiple partners to identify and develop solutions.

Our Schistosomiasis Elimination Program leads our efforts to **eliminate schistosomiasis** in close collaboration with several external partners.

Our commitment: Providing a solid basis for access to healthcare

To demonstrate our commitment to expanding access to healthcare, we publish a dedicated **Access to Health Charter** on our website. We updated the charter substantially in 2019 to reflect our strategy and approach in response to the latest developments in global health and access. This charter sets out guidelines on the following:

- **Our approach** (updated in 2019)
- **Pharmaceutical product donations** (updated in 2019)
- **Fake medicines**
- **R&D for infectious diseases** (updated in 2019)
- **Pharmaceutical product pricing**
- **Intellectual property rights** (updated in 2019)

Every two years, the **Access to Medicine Foundation** publishes the **Access to Medicine Index**. It benchmarks 20 of the world's largest research-based pharmaceutical companies on activities and initiatives that experts consider most relevant for access to medicine, ranging from donations made and patents registered to capacity building. We use the ranking to inform and, in certain cases, guide our access to health strategy and approach. In 2018, we were ranked in **fourth place**, retaining our previous position. This was in recognition of our company's integrated strategy on access to medicine, our efforts to address the needs of unserved and underserved populations across the entire value chain and our commitment to creating shared value.

We continue to endorse the **London Declaration on Neglected Tropical Diseases**, through which participating companies, governments and private organizations promise

to help control and ultimately eliminate the top ten most prevalent infections. We are particularly engaged in the fight against schistosomiasis.

Partnering to build research capacity and clinical skills

Following our integrated approach to fighting infectious diseases, we have continued implementing a series of research programs on malaria and schistosomiasis. These programs mainly took place in Africa and involved post-doctoral and PhD fellows and local scientists. We also developed a training course for laboratory experts.

By acting as a host organization for the European and Developing Countries Clinical Trials Partnership (**EDCTP**) Fellowship Scheme, we are helping to **empower African research fellows** and enhance their clinical trial practices and management skills.

Engaging stakeholders

Partnerships and dialogue are vital to improving access to healthcare, and we aim for stakeholder dialogues with a relevant and scalable, far-reaching impact. Our partners include multinational organizations, government agencies and NGOs, as well as academic institutions, health industry associations, companies, and independent global health experts.

Alliances for better access to health

We are a member of the Business for Social Responsibility (**BSR**) initiative and endorse the **BSR Guiding Principles on Access to Healthcare**, which provide a framework for us to refine and enhance our Global Health efforts.

Together with 21 other leading pharmaceutical companies, we host the global **Access Accelerated** initiative, which seeks to improve both the treatment and prevention of non-communicable diseases in low- and middle-income countries. We also joined forces with advocacy groups such as the **Swiss Malaria Group**, which aims to positively influence access paths.

Our **Access Dialogue Series** is a multi-stakeholder platform for sharing information and **exchanging best practices** on broadening access to healthcare. We harness the ideas shared through the series to inform and drive our access strategy, plan of action and engagements. In this way, we create transparent, insightful and critical dialogue on how we and our partners can best use our respective capacities, experience, expertise, and competencies to sustainably address access barriers. In 2019, we hosted an event on supply chains and delivery where we met with internal and external experts to share information and discuss our company's engagement.

Discussions at a global level

We take part in many events with a global reach or relevance in order to participate in and advance global health discussions. We engage with major stakeholders in a dialogue on infectious diseases and deepen collaborations with the scientific community through publications and by taking on leading roles at international scientific conferences and events.

In 2019, we participated in multiple events and initiatives, some of which are listed below:

- **Conference on Tropical Medicine and Global Health** in Munich (Germany), April
- **World Malaria Day**, April
- **72nd World Health Assembly** in Geneva (Switzerland), including the side event "Leaving no one behind: from philanthropy to sustainable health solutions. How can local manufacturing be part of an integrated approach to tackling NTDs and advancing Universal Health Coverage?", May
- **7th International Conference on P.Vivax Research** in Paris (France), June
- High-level meeting between CEO Healthcare (Executive Board member of Merck KGaA, Darmstadt, Germany) and the Director-General of the World Health Organization (WHO), July
- **74th Session of the UN General Assembly** in New York (USA), September
- **Access Dialogue Series of Merck KGaA, Darmstadt, Germany: Supply Chain & Delivery**, September
- **COR-NTD on Female Genital Schistosomiasis** in Liverpool (UK), September
- **11th European Congress on Tropical Medicine and International Health** in Liverpool (UK), September
- **Annual NTD NGO Network Meeting** in Liverpool (UK), September
- **WHO-WIPO-WTO Trilateral Symposium on "Cutting-Edge Health Technologies: Opportunities and Challenges"**, October
- **Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers** in Copenhagen (Denmark), December

FOCUS PROGRAMS

Neglected tropical diseases occur almost exclusively in impoverished populations in low- and middle-income countries. Barely known in industrialized nations, they attract little public attention and research funding. One example is schistosomiasis. Our aim is to help take urgent action to prevent and control this neglected disease as well as more familiar infections such as malaria.

Strategy for preventing and treating infectious diseases

Working hand in hand with our external partners, we seek to improve the health of underserved populations in low- and middle-income countries through our science and technology innovation. Our strategy is to develop and provide medicines, improve diagnosis, counter disease transmission, increase disease control, expand access to healthcare, and strengthen local health systems.

Our priority areas are eliminating schistosomiasis, developing health solutions for malaria and infectious diseases, expanding access to healthcare by strengthening health systems, and promoting capacity building along the value chain.

Our fight against schistosomiasis

Schistosomiasis, a tropical worm disease also known as bilharzia, is one of the most prevalent parasitic infections in Africa, placing a significant burden on public health and the local economy. The disease affects **almost 240 million people** worldwide, with more than 90% of cases occurring in sub-Saharan Africa. School-aged children are particularly vulnerable to infection. An estimated **200,000 people** die every year from the long-term effects of schistosomiasis, such as liver and kidney infections, bladder cancer and anemia.

Our ultimate aim in all our schistosomiasis-related work is to eliminate the disease. To help achieve this goal, we adopted an integrated schistosomiasis strategy in early 2019 that we are implementing in close collaboration with multiple partners worldwide. The new approach focuses on five areas:

- **Supplying medicine:** We donate up to 250 million tablets of praziquantel per year to **WHO**. Nearly 50 years after its invention, praziquantel still remains the standard of care for the effective treatment of schistosomiasis around the world.
- **Researching new solutions:** We are collaborating with research institutions and through public and private sector partnerships to develop a new formulation of praziquantel for children under the age of six and identify diagnostics and vector control approaches.
- **Working with partners:** Collaborating with partner organizations through the Global Schistosomiasis Alliance (**GSA**), we are accelerating the progress towards schistosomiasis control and elimination.
- **Improving water, sanitation and hygiene:** We support WASH projects to prevent transmission of the disease through the development of infrastructure.
- **Education and behavior change:** We invest in education and behavior change projects and participate in health education initiatives that raise awareness of the causes and dangers of schistosomiasis and teach people how to prevent it.

Our fight against malaria

According to World Health Organization (WHO) estimates, nearly half of the world's population is at risk of contracting malaria. More than **200 million cases of malaria** and over 400,000 related deaths are recorded every year, with 70% in children under five years of age. Around 90 different countries are affected by the disease, with approximately 90% of deaths occurring in Africa.

There is an urgent need for new products to overcome the problem of increasing drug resistance and to achieve our goal of complete elimination. Through our company's Malaria program, we are helping to deliver integrated and sustainable health solutions entailing treatments, diagnostics and prevention methods to fight malaria in endemic countries.

Schistosomiasis: Over one billion tablets donated

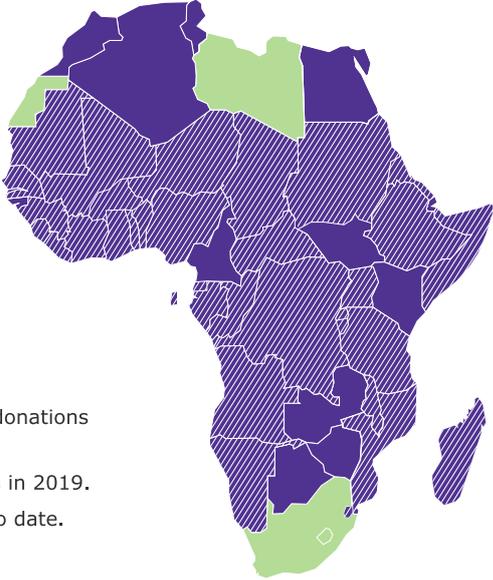
As part of our longstanding partnership with WHO, we have renewed our commitment to make annual donations of praziquantel tablets for distribution in 47 endemic African countries to treat school-aged children. In 2019, we donated approximately **233 million tablets** for distribution in 35 countries, 32 of which in Africa. Also, we maintained our commitment by ensuring that we have sufficient production capacity to manufacture up to 250 million tablets a year. The latest numbers from WHO show that in 2017, 72% of all school-aged children in need of treatment in sub-Saharan Africa were treated.

Countries that have received donations of praziquantel tablets

Since 2007, we have donated over **1 billion** tablets of praziquantel, which is enough to treat around 400 million school-aged children.

- African countries that have been receiving tablet donations from us since 2007*.
- ▨ African countries to which we also donated tablets in 2019.
- Countries that have received no donated tablets to date.

* Launch of our Praziquantel Donation Program.



Schistosomiasis health education project

Through our joint health education project with the **NALA** Foundation, we are investing nearly € 300,000 over a three-year period. Since the end of 2017, we have reached 250,000 people in southwestern Ethiopia, almost half of whom are school-aged children. The education programs will help promote long-term behavioral change in the drive to **eliminate schistosomiasis** and other neglected tropical diseases.

In 2019, we expanded the project to two further districts in Ethiopia and reached around 188,000 people, almost 40% of whom were school-aged children. To deepen our understanding of the knowledge, attitudes and practices of primary school children with respect to **safe water, sanitation and hygiene**, we conducted a survey that revealed that 58% of the children taking part had never heard of parasites that can infect the intestines. This prompted us to create a series of educational training sessions.

Thanks to our financial support, our on-the-ground partners were able to conduct training sessions in schools and among local communities, with the majority of the schools setting up hand-washing stations. Clean water and latrines are now available in these stations throughout the school year. Teachers also reported major improvements in students' personal hygiene and general levels of cleanliness in the participating schools.

Central platform in the battle against schistosomiasis

The Global Schistosomiasis Alliance (**GSA**) is a coordinated, multi-sectoral effort to combat the complex disease schistosomiasis. In 2019, the GSA recruited additional international stakeholders as new members and contributed to WHO's consultations ahead of the new NTD Roadmap expected to be passed by the World Health Assembly in 2020. The GSA took part in various projects aimed at driving local efforts to combat schistosomiasis as well as organizing several

conferences and key meetings. The alliance is also helping to promote and support an **international action plan** to progress schistosomiasis control and ultimately eliminate the disease. The GSA continues with its efforts to raise awareness through coordinated campaigns.

Partners in schistosomiasis research

Over time, we have developed a portfolio of **R&D projects on schistosomiasis**. These include a new pediatric formulation of praziquantel to treat children under the age of six, identifying new drugs to prevent and treat schistosomiasis, developing innovative and highly sensitive **schistosomiasis diagnostic methods**, and defining approaches for vector control.

Praziquantel is an effective and well-tolerated drug, but it does not work in all developmental stages of the parasite. We continue to collaborate on research activities with many partners in developed and low- to middle-income countries. This work aims to discover new, long-lasting compounds to **treat juvenile forms** of the parasite, thereby improving efficacy and preventing reinfections. In 2019, we obtained **promising assets** from **Salvensis** and the **London School of Hygiene & Tropical Medicine** to identify potential new candidates for preventing infection and curing patients affected by schistosomiasis.

The need for more sensitive diagnostics is crucial in the fight against schistosomiasis. Since 2017, we have been collaborating with the Australian Institute of Tropical Health and Medicine at **James Cook University** in Townsville (Queensland, Australia) and with the **Baylor College of Medicine** in Houston (Texas, USA) on researching new biomarkers in order to develop diagnostic tools for schistosomiasis. The program achieved the preliminary identity of new schistosomiasis biomarkers for novel diagnostics.

As of early 2019, we also initiated our **collaboration** with the Foundation of Innovative New Diagnostics (**FIND**) and the **Bill and Melinda Gates Foundation** to develop a sensitive

rapid diagnostic test (RDT) to improve mapping and case detection for schistosomiasis.

Beyond these efforts, we continued to explore technologies that control transmission factors through basic research activities, for example the elimination of the infectivity of snails through gene editing, or through access-to-water programs in Senegal. In 2019, we implemented initiatives to address female genital schistosomiasis (FGS), a major challenge to women's health in Africa, and its impact on HIV/AIDS. In particular, we began supporting a trial to **optimize therapeutic treatment for women** suffering from FGS in Madagascar and conducted advocacy initiatives through workshops and training sessions.

Consortium for the development of a pediatric praziquantel formulation

If left untreated at a preschool age, schistosomiasis can have long-term effects on children such as anemia, stunted growth and impaired learning. It can seriously affect their lives and potentially cause chronic diseases, including bladder cancer or genital schistosomiasis. We are working with the **Pediatric Praziquantel Consortium**, which includes both public and private sector representatives, to develop and provide access to a pediatric formulation of praziquantel to children under the age of six.

Following initial Phase I studies and a taste evaluation, we completed the Phase II study in Ivory Coast in 2018. It assessed the efficacy and safety of two different formulations of orodispersible tablets (ODT) in schistosomiasis-infected children under the age of six. The results indicated that both formulations are well tolerated and helped us to identify the optimal formulation and dose to pursue until we can register the drug.

In 2018, **two new partners** joined the **Pediatric Praziquantel Consortium**: the Kenya Medical Research Institute (KEMRI) and the Université Félix Houphouët-Boigny in Ivory Coast. Both play important roles in implementing the **Phase III trial** that started at the Homa Bay clinical center in Kenya in September 2019. This pivotal trial is designed to evaluate the efficacy and safety of the new **child-friendly praziquantel ODT formulation** in children three months to six years of age who are infected with schistosomes. The trial is being conducted in Kenya and Ivory Coast, and is co-funded by the consortium, the European & Developing Countries Clinical Trials Partnership (EDCTP) and the Global Health

Innovative Technology (GHIT) Fund. The study represents the last step of the clinical development program, which, should it produce a positive outcome, will allow the clinical data package needed for registration to be completed. We expect the product to be available to the first endemic countries in Africa in 2022. Together with international key stakeholders, we are working on designing an innovative access path to ensure future affordability, availability and adoption of the new medicine.

Malaria: Enabling the treatment of children

As part of our company's Malaria program, we are developing a new innovative drug (M5717) for the treatment of malaria in children. In 2019, we assessed the safety of the compound and gathered data to support clinical proof of principle by conducting a Phase I/Ib study in healthy volunteers in Australia. The program is progressing towards the next phase, where we will explore opportunities to develop the compound in combination with another anti-malarial compound to potentially serve as a single-dose treatment to cure or prevent malaria.

Developing new lead programs for antimalarials

In 2019, our strategic collaboration with the **University of Cape Town** in South Africa and the **Medicines for Malaria Venture** continued its screening activities with the aim of identifying new therapeutic solutions for malaria and building research capacity in and for Africa. Co-funded by the **German Federal Ministry of Education and Research**, this program continues to leverage our proprietary chemical library of nearly 100,000 compounds to identify new lead programs for the treatment of malaria. It targets liver-stage forms of the parasite and focuses on long-lasting compounds to **improve post-treatment prophylaxis**. Together with our partners, we have identified a promising chemical series to help declare potential lead candidates for drug discovery and development activities.

Through a collaboration with the Instituto de Biologia Experimental e Tecnológica (iBET) and the Instituto de Medicina Molecular (IMM) in Portugal, we made progress in developing a new cell model of liver-stage malaria infection. This new cell model could serve as a screening tool for novel anti-malaria drugs. The results have been published in peer-reviewed scientific journals.

Preventing and controlling malaria transmission

To help prevent the spread of malaria, we are working to improve access to insect repellent as a vector control method. Through internal and external collaborations, we are working towards demonstrating the efficacy of IR3535® against malaria in Africa. IR3535® is used in insect repellents for complementary prevention of vector-borne diseases such as dengue and Zika fever, Chikungunya and Lyme disease. The repellent is safe for all age groups, including children, pregnant women and nursing mothers.

We are partnering with the **Infanta Malaria Prevention Foundation** to support the Ghana Health Service's National Malaria Control Program by exploring potential IR3535®-based solutions for malaria prevention in vulnerable communities. In 2019, we helped to broaden the scope of this initiative through an **integrated, country-level approach**, working with an established network of partners in Ghana. Through these efforts, we aim to improve health

worker capacity to detect malaria cases through microscopy and continue our work to deploy IR3535® as a malaria preventive method for women and babies. Furthermore, we will increase our knowledge of the prevalence of asymptomatic patients suffering from malaria via an innovative pan-African network that maps the pathogenic parasite *P. vivax*.

Technologies to combat antimicrobial resistance

We have implemented new collaborative programs to assess the degree of resistance of identified bacterial pathogens. We have also focused our efforts on the development of new technological platforms to accelerate the assessment of infection types and test the validity of drugs. Since 2018, we have been **partnering with Boston University** to test, validate and optimize a new user-friendly technology to identify and quantify the active pharmaceutical ingredients of medicines sold in hospitals, health centers and pharmacies. This helps us in detecting fake medicines.

open innovation sharing

We consider it our duty and responsibility to share core technological advances to improve global access to healthcare. However, this level of transparency requires a solid, transparent and reliable legal framework that protects the intellectual property rights of pharmaceutical companies and enforces patents in order to provide the opportunity to balance the initial investment in research and development.

Our approach to sharing and protecting intellectual property

The approach that we and other pharmaceutical companies take to our intellectual property impacts access to healthcare. We often refrain from filing or enforcing patents in low- and middle-income countries. In markets where we do register product patents, we are transparent and committed to sharing data to the greatest possible extent and to improving public access to clinical study data. We report on the patent status of our products via a publicly accessible [database](#). Furthermore, we support voluntary licensing agreements of all kinds, including non-exclusive voluntary licenses, legally binding non-assertion covenants and clauses that aim to widen access to health. Moreover, we support the concept of patent pools, but believe that these should be structured in such a way that they improve access to medicines, prevent anti-competitive behavior and overcome geographic limitations. We consider joining patent pools when they are relevant to our portfolio and meet all our efficacy, quality and safety requirements.

The responsible treatment of intellectual property does not pose a barrier to health, but rather guarantees **safety and high quality** for patients worldwide. Nearly all medicines that address the highest burden of disease in low- and middle-income countries are not protected by patents. Studies found that between 90% and 95% of the [WHO Model List of Essential Medicines](#) are off-patent. We provide 46 essential medicines and products, 27 of which are on the WHO Model List of Essential Medicines and 29 of which are considered to be first-line treatments.

We provide access to patent information through our Access to Health initiatives and partnerships. In some cases, we even give access to parts of our chemical compound libraries. This is true for open innovation research projects and collaborative research programs that develop novel R&D platforms in search of new active substances.

How we organize access to and control of our intellectual property

Our [Open Innovation](#) initiative is a collaborative and cross-functional effort led by our Access to Health and Patents Healthcare units. It aims to **mitigate affordability issues** by sharing our intellectual property, thus accelerating early discovery in diseases with high unmet needs where we do not have expertise. We hope to foster the discovery of new generations of health solutions that will tackle the needs of the most vulnerable populations, with a primary focus on neglected tropical diseases (NTDs).

Our Open Innovation Committee provides technical expertise, strategic guidance and decision-making regarding our open innovation strategy, activities and collaborations. Co-chaired by the heads of our Access to Health subunit and the globally acting Patents Healthcare unit, the Open Innovation Committee is part of our Open Innovation Initiative.

Our commitment: Supporting transparent and reliable frameworks

We support [TRIPS](#), an international agreement administered by the World Trade Organization (WTO) that addresses trade-related aspects of intellectual property rights, along with TRIPS addenda such as the Special Declaration on the TRIPS Agreement and Public Health (also known as the 2001 DOHA Declaration). This extends the deadline for low- and middle-income countries to apply TRIPS provisions to pharmaceutical patents until 2033.

Initiative improves access to patent information

We are a founding member of the Patent Information Initiative for Medicines ([Pat-INFORMED](#)), which was established by 20 leading research-based biopharmaceutical companies. Pat-INFORMED acts as a global gateway to medicine patent information, offering tools and resources that help determine the existence of patents relevant to products sought by national and international drug procurement agencies. This transparency should make it easier for drug procurement agencies to access a basic body of patent information needed for implementing **disease management strategies** and other activities that address public health needs. Pat-INFORMED features patent information for small-molecule drugs within cardiovascular, diabetes, hepatitis C, HIV, oncology and respiratory therapy areas and any products on the [WHO Model List of Essential Medicines](#) that are not within these therapy areas. The initiative is backed by the World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Pat-INFORMED currently houses information on over 14,000 individual patents for 600 patent families and 169 INNs, unique names that are globally recognized and used to identify pharmaceutical substances or active pharmaceutical ingredients of medicines that cover a wide range of conditions.

Open innovation collaboration through WIPO Re:Search

We continue to take part in the **WIPO Re:Search** public-private partnership, whose mission is to accelerate the discovery and development of medicines, vaccines and diagnostics. This initiative aims to create **new solutions** for people affected by neglected tropical diseases, malaria and tuberculosis by making intellectual property and knowledge available to the global health research community. Our latest collaboration under the WIPO Re:Search platform is with the University of Yaoundé I in Cameroon (Africa) to combat the infectious disease known as Buruli ulcer. Furthermore, we are working on extending our collaboration

with the **University of California San Diego** (United States) to find potential cures for onchocerciasis, leishmaniasis, Chagas disease and African sleeping sickness.

Drugs for Neglected Diseases initiative

In partnership with the Drugs for Neglected Diseases initiative (**DNDi**), we are involved in the Drug Discovery Booster project for neglected tropical diseases, pursuing an open innovation approach through which the participating companies can simultaneously search for new treatments for leishmaniasis and Chagas disease. We are joined in this project by seven other companies: AbbVie, Astellas, AstraZeneca, Celgene, Eisai, Shionogi, and Takeda).

pharmaceutical supply chain

In many parts of the world, medicines are not always available where and when they are urgently needed. We want patients in low- and middle-income countries to have fast, safe and affordable access to our products and believe this can be accomplished through efficient supply chain management and by utilizing local manufacturing.

Our approach to local supply chain solutions

During product development and manufacturing, we favor approaches that enable us to control the cost of goods and allow for local manufacturing and supply chains that help to strengthen the local economy. We apply this model in our work with the **Pediatric Praziquantel Consortium**, for instance.

We partner with pharmaceutical companies and other supply chain stakeholders to help strengthen supply chains in low- and middle-income countries and to guarantee the targeted supply of medicines. We manufacture some of our products directly in the regions where they are needed in order to **build local capacity**, increase service quality and flexibility through reduced travel times and distances, and to achieve cost savings that can be passed on to the consumer.

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

How we organize our supply chains

Our Global Planning unit is responsible for our efficient medicine supply chains and is part of Biopharma Supply Network Operations within our Healthcare business sector. Global Planning collaborates with our **Global Health unit** and markets supply chain representatives for efficient demand management. It also consults experts from other business sectors as needed.

Our commitment: High quality standards for pharmaceutical production

All our pharmaceutical production plants operate to the same high standard of quality worldwide. This ensures full compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) for us and our contract manufacturers.

Our Right First Time (RFT) concept aims to reduce the number of temperature excursions that occur during transportation worldwide. We also encourage shipping sites and receiving units to work with freight forwarders and carriers to improve their processes.

Our **uniform quality assurance system** helps to ensure that our quality standards are universally respected.

It comprises training courses, quality control monitoring and technologies tailored to each site. The results of all audits conducted by health authorities are published Group-wide, allowing the respective units to share lessons learned and to benefit from the improvements made by others.

Through our Virtual Plant Teams, we support our contract manufacturers in complying with quality standards. We assign a production expert to our external partners in Africa, Asia and Latin America to act as a virtual site leader and to provide guidance.

Leveraging technological possibilities for efficient market access

Accurate business forecasts are the foundation of efficient supply chain management. We use harmonized biopharmaceutical business planning processes across our Group, including a special software platform that enables us to plan centrally for specific demands for medicines. The data generated by the software platform is provided to the regional affiliates so that they can add their market intelligence. The received forecast is then used to manufacture and deliver medicines according to demand, which allows us to prevent local inventories from running out or expiring.

We employ a software-based solution that provides **continuous access** to our e-shop for our customers in northwestern Africa, enabling them to quickly and easily order medicines approved by the respective regulatory authorities. The system makes demand more transparent while reducing lead times and miscommunication. Both systems combined enable us to react more quickly to local demands than ever before, even in low- and middle-income markets.

In 2019, we extended the integrated business planning process and platform to other functions within the Healthcare business sector. In this way, we can further improve our understanding of market demand across all our functions, helping to ensure that supply is better balanced with demand.

We also deployed our innovative global production planning tool to the manufacturing sites in Darmstadt (Germany), Mollet (Spain) and Semoy (France). The tool takes the sites' capacity constraints into account when generating production orders. As a result, we are better able to match the distribution plan with feasible production orders and can provide a much better visibility of the supply to markets.

Working with partners to achieve more

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

Shared data platform for medicine donations

NTDeliver is our digital information tool for improving transparency in medicine donation supply chains created through public-private partnerships. Deliveries sent by companies running donation programs are clearly displayed – from purchase orders made by the World Health Organization (**WHO**) through to delivery to the first warehouse in the destination country. The tool improves the coordination of our efforts and provides WHO, local experts and our company with a more **transparent overview** of the in-country inventories. We added new features to the tool in 2019, such as an alarm that informs key stakeholders about upcoming expiry dates of medicines that may still be in their inventory.

In Kenya, where schistosomiasis poses a significant challenge to school-aged children, we are collaborating with approximately 12,000 teachers across the country to support a deworming program designed to help prevent and treat instances of schistosomiasis among children. We deploy our **NTDeliver** tool to monitor the volumes of **medicines reaching schools**, particularly those of last-mile deliveries to remote, rural locations in Kenya. In addition to tracking the efficiency of schistosomiasis medicine supply chains, we are stepping up our monitoring to understand the positive impact of these supply chains on children's lives. For instance, we track the number of children treated. In 2019, we further improved this tool and firmly established it as an essential part of the program. Building on this experience, we are reviewing the best way to retrieve unused medicines from the field and store them centrally for upcoming deworming campaigns. We are also considering how best to expand the use of this tool to other countries.

Further partnerships

We are a founding member of the Accessibility Platform, which meets to discuss local supply chains during our **Access Dialogues**. Spearheaded by the private sector, the platform seeks to raise awareness of the importance of improving supply chain efficiency when expanding access to healthcare worldwide. In particular, it aims to increase the **sharing of knowledge** and information through open, multi-stakeholder dialogue and to identify opportunities for collective action. We also share best practices with other companies and partners on efficient, secure end-to-end supply chains.

Access Delivery Mentorship

As part of our work to innovate and strengthen health systems, we are working on a **supply chain capacity-building** and mentorship program in Tanzania, with the aim of helping to build a strong and resilient private sector distribution network. We are doing this in collaboration with Business for Health Solutions (**BHS**) and Bahari, one of Tanzania's largest medical and health supplies distributors. We have successfully launched and implemented the first pilot program, which brings together our supply chain experts and our partners' procurement teams to better manage stocks of medicines, thus preventing facilities from running out in times of need.

Promoting local production

In India and Indonesia, we manufacture drugs for diabetes, cardiovascular conditions and diseases of the lower respiratory tract. These capacity-building efforts support local economies and allow us to supply medicines more rapidly and affordably to these and neighboring countries, such as Sri Lanka and Myanmar. We also serve local markets in China and Russia through local production, for example via contract manufacturing organizations (**CMOs**).

CURAFATM Points of Care

We aim to address inequalities regarding primary healthcare access in emerging economies and to enable accessibility, availability, awareness, and affordability of primary healthcare in order to fulfill our vision of primary healthcare for everyone, everywhere.

Five facilities within the **CURAFATM** initiative are operational in underserved, low-income communities in the outskirts of Nairobi, Kenya. They serve as points of care for **integrated primary healthcare services**. Each facility is run by local pharmacists and nurses who provide pharmaceutical and clinical services, medicines, digital health solutions, health education, insurance, and financing solutions to their communities. These teams are supported by modern facilities that include Wi-Fi access and cell-phone charging stations, tablet computers, televisions, and refrigerators for cold chain medicines that are solar powered. In 2019, the five sites collectively served over 2,000 patients every month. We implemented a patient management platform and acquired a telemedicine solution in 2019 to improve patient outcomes.

The overarching objective is to further develop the primary healthcare service model, resulting in a sustainable business model. The first achievements towards scale-up were the development of a franchising manual and the **CURAFATM** replication request by the Guinean Ministry of Health and Public Hygiene.

In recognition of this work, we received a grant from the UK Department for International Development (**DFID**).

Fight against falsified medicines

According to a [WHO report](#), more than 10% of all medicines in developing and emerging countries are counterfeit or substandard, a situation that creates a major health risk. For more than 20 years, the Global Pharma Health Fund ([GPHF](#)), a non-profit initiative funded by our company, has been fighting falsified and substandard medicines with its unique portable, compact laboratory, the GPHF Minilab™.

The GPHF Minilab™ fits into a tropics-resistant flight case and can detect falsified medicines rapidly and cost-effectively. Largely used in Africa and Asia, and [cited by WHO](#) as one of the most important tools for detecting substandard and falsified medicines, it enables scientists and clinical staff to verify the content of some **100 active pharmaceutical ingredients** for authenticity. The GPHF develops the Minilab's method inventory, supplies the portable laboratories at cost and provides training on how to use

them. In 2019, the GPHF consolidated all 100 test methods within a single manual in English, with translations into French and Spanish due to become available in 2020.

More than **850 Minilabs** are currently in use. In 2019, 21 Minilabs were supplied. 15 were given to the Philippines and the others to Bangladesh, the Democratic Republic of the Congo, India and Mongolia.

In November 2019, we engaged in discussions on the topic of detecting falsified medicines. At the National Consciousness Week Against Counterfeit Medicines ([NCWACM](#)) in the Philippines we discussed challenges and solutions for the fight against counterfeit drugs with local regulatory representatives and government officials. We presented our collaboration with [Boston University](#) on the development of a new user-friendly tool to assess the validity of drugs.

prices of Medicines

Part of the non-financial report

In OECD countries, prescription drug costs accounted for **between 6% and 29%** of total healthcare spending in 2017. However, advances in the research and development of innovative medicines are significantly transforming the healthcare landscape, allowing chronic diseases – the greatest cost drivers – to be treated more effectively and affordably.

Our approach to pricing medicines

We want to help ensure that all patients have access to the most effective medicines for their needs, which is why we are working to prevent cost from becoming a barrier to treatment. We are committed to **flexible and fair pricing** – both within and across countries. We therefore adapt our prices based on local market access, taking into account factors such as health system capacity and financial standing, geographic circumstances and existing infrastructure, statutory requirements, unmet medical needs and socioeconomic aspects, such as the patients' ability to pay. This approach involves working closely with governments and other stakeholders. In addition to these considerations, we continuously monitor dynamic healthcare environments and markets, pricing and reimbursement systems and legal and regulatory guidelines, adjusting our prices as necessary.

We review our prices on an annual basis to ensure they meet patient access needs. We use a consistent, **data-driven approach** to monitor our local pricing. We also make our products affordable to patients in certain countries by participating in government tenders, establishing low-price secondary brands or branded generics and by operating patient access programs.

Moreover, we support risk-sharing agreements and are working to improve data efficiency in health systems, in order to achieve an optimal distribution of funds and resources.

Setting medicine prices

Our Global Pricing and Market Access unit sets market launch prices in coordination with the respective franchises. The team reports directly to a member of our Healthcare Executive Committee. Our individual subsidiaries are responsible for managing prices and continually adapting them to local conditions.

Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition, which includes **increasing accessibility**, availability and awareness. Our medicine pricing adheres to the stipulations of our overarching **Access to Health Charter** and is defined in detail by our **Pricing of Medicines guideline**. Additionally, our Patient Access Programs Policy sets out standards for offering medicines at reduced prices.

Customer-centric contracting models

We are dedicated to advancing value-based healthcare through pricing and contracting mechanisms that fully comply with all local laws. In collaboration with payers, such as health insurance companies, we developed various product- and market-specific reimbursement and contracting models. These help to provide patients with prompt **access to our innovations**. For instance, in the United Kingdom and Ireland, we entered into a risk-sharing agreement that provides immediate access to Mavenclad[®] for patients with multiple sclerosis (MS). Under this agreement, the National Health Service only has to reimburse medication costs for patients who respond to the drug. If treatment has to be switched from Mavenclad[®] to another product, a partial rebate is paid to the National Health Service. Around 1,300 patients in the United Kingdom and around 250 patients in Ireland had been reimbursed for the cost of the drug under this program as of end of 2019. Since October 2018, we have been using a similar pay-for-performance contract for Mavenclad[®] together with GWQ ServicePlus AG, a network of around 60 health insurers with 11 million patients in Germany.

We have also established contracting models for our oncology drug Erbitux[®], our MS drug Rebif[®] and our growth hormone Saizen[®], to make it easier for patients to access these medicines. Similarly, we have capped per-patient costs and formed risk-sharing agreements in certain countries.

Pricing schemes to serve low-income patients

We work in close partnership with governments and other stakeholders on innovative, differential medicine pricing schemes and we supply products at reduced prices to certain countries in Africa, Asia, Latin America, and the Middle East. In India, for instance, we cooperate with public sector representatives, such as Bharat Heavy Electricals Limited (BHEL) and the Oil and Natural Gas Corporation (ONGC), to offer **discounted prices** for certain general medicine and endocrinology products to patients with a limited ability to pay.

Moreover, we regularly participate in government tenders for products that are used in public hospitals serving low-income patients. Many of these tenders take place in low to middle-income countries.

Low-price second brands

For some of our existing brands, we have created low-price second brands, particularly in countries with a large percentage of patients with very low incomes. In Brazil, for instance, 11 of our products are available in a lower-priced format. We have also established low-price second brands in countries including Mexico, the Philippines, Poland, and South Africa.

Generics

Together with our partners, we offer branded generics particularly in low- to middle-income countries. This helps meet the urgent need for affordable, high-quality medicines required to treat endemic diseases. In doing so, we help to ensure better access to consistently high-quality medicines at lower prices. To date, we have launched four branded generics in the Philippines and three in Angola. We also launched a branded generic product in Brazil and Mexico.

Patient access programs

Worldwide, we operate patient access programs that allow us to offer certain products at more affordable prices in several countries. Examples include efforts to expand

access in China to Erbitux[®], our oncology medicine used for instance in the treatment of colorectal cancer. Geared primarily toward low-income patients who receive the drug free of charge, our Erbitux[®] donations have benefited around 12,900 patients in China since October 2012. The program ended when Erbitux[®] was added to China's national healthcare reimbursement catalog, which now gives patients **immediate access** to the product.

We run similar assistance programs in other countries such as India, where we also offer a patient access program for Erbitux[®], providing treatment cycles for free under certain conditions. Around 2,300 patients participate in the initiative each year. In nations such as China and Peru, we offer a free-of-charge biomarker screening that determines whether Erbitux[®] would be a suitable treatment. In China, around 40,800 patients have benefited from this program since 2014.

In addition to our oncology initiatives, we offer access programs for our drugs Rebif[®], Gonal-f[®] and Saizen[®]. In China, for instance, we operate the Gonal-f Baby Fund, an access program that provides financial assistance for fertility treatments to low-income couples having difficulty conceiving.

Health awareness

Many people suffer from certain conditions but do not realize it. This results in individuals either not receiving treatment or not receiving it in time, although effective medicines and therapies are available. To try and prevent this occurrence, we conduct global campaigns that raise awareness and improve knowledge of diseases, their symptoms and treatment options. Ultimately, healthcare professionals and patients can only make informed decisions if they have proper knowledge and the right information.

Our approach to raising health awareness

Awareness plays a key role in our approach to improving **access to healthcare**. We seek to empower communities, medical professionals and patients with appropriate tools, information and skills so that they can make **high-quality, informed decisions** on prevention, diagnosis, treatment, care, and disease management.

We often join forces with committed partners to conduct educational campaigns for prevention, early diagnosis and awareness. This also helps build the capacities of medical professionals working in the fields of research, technology and healthcare.

How we build health awareness

The strategic direction and output of all awareness activities are aligned with our respective businesses. Our diverse business units plan and implement our awareness projects either on a global level or through their local offices, with projects organized according to the **specific needs of the local community**. The offices are also responsible for local mobilization during our global campaigns.

Our commitment: access to health through awareness

Our strategy for addressing access to healthcare incorporates the topic of awareness and is laid out in our **Access to Health Charter**, which we revised in 2019. Our awareness campaigns are also subject to the respective **marketing principles** set out in guidelines such as our "Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations." In addition, our campaigns are governed by internal policies and guidance for reviewing our interactions with **health systems** and by the review processes for communication materials as well as further global, regional and local rules and regulations.

Global awareness campaigns

We regularly conduct campaigns to raise awareness of various diseases across the globe, often in collaboration with patient advocacy groups. We focus on diseases that align with **our core competencies**, expertise and experience along the health value chain. These are, in particular, cancer (specifically colorectal as well as head and neck cancer), thyroid disorders, diabetes and multiple sclerosis.

Awareness and knowledge transfer for thyroid disorders

Throughout 2019, we continued our work to raise awareness of thyroid disorders. At the global level, we supported the International Thyroid Awareness Week in May 2019

for the 11th consecutive year. This annual awareness campaign, which we founded together with the Thyroid Federation International (TFI), aims to highlight some of the **lesser-known aspects** of thyroid disorders.

We hosted numerous events during the week, including events specifically targeted at healthcare professionals. The campaign reached people in many different countries via the events as well as press coverage and social media. We also introduced the world's first-ever series of thyroid emojis or "thyrojis", tapping into a popular trend of the 21st century with a series of customized emojis representing the many faces of thyroid disorders.

Awareness campaigns for head and neck cancer

In 2019, we supported two key head and neck cancer awareness events: World Head and Neck Cancer Day (WHNCD) on July 27 and the European Head and Neck Cancer Awareness Week from September 16-20. Activities focused on aligning with the UK-based patient advocacy group The Swallows to create an emotive video on the **journey of a patient** and his carer, tying in with the existing **Embracing Carers** initiative. The September campaign built on the campaign in July, continuing to work with The Swallows and featuring video footage of the same patient, focusing on the transition from treatment to survivorship.

World Cancer Day

On February 4, we again marked World Cancer Day, an annual initiative led by the Union for International Cancer Control (UICC). Building on the UICC's theme "I Am and I Will", we created a compelling campaign to communicate our ongoing drive to transform cancer care. Our campaign, "I Am. I Will #TransformCancerCare." focused on how personal contributions make a collective impact on the evolution of oncology care. It was supported by 250 images from 13 countries generating over 33,000 impressions on social media.

Colorectal Cancer Awareness Month

In 2019, we stepped up our efforts to raise awareness of colorectal cancer (CRC). We worked closely with **DiCE**, a representative body for digestive cancer patients in Europe, to redefine the CRC Awareness Month campaign. We pooled resources, extending the collective reach of the campaign far beyond what would have been possible individually. We maintained a consistent, unifying theme throughout the campaign, encouraging our employees and external audiences to take part. In addition, we developed a suite of materials to maximize CRC Awareness Month activities,

including a video on the CRC screening journey and an infographic banner on the importance of such screenings.

Cancer Immunotherapy Month

June 2019 marked the seventh annual Cancer Immunotherapy Month, which aims to raise awareness of the **life-saving potential** of immunotherapies. On June 14, supporters were encouraged by leading cancer groups to wear white to promote a future without cancer and to promote their activities in social media via #WearWhiteDay. White represents the immune system's white blood cells (lymphocytes) that fight cancer. It also symbolizes the laboratory coats worn by the scientists and clinicians working to find a cure for cancer and it represents the color of all cancer awareness ribbons combined, which is significant as immunotherapy has the potential to treat all types of cancer.

World Multiple Sclerosis Day

We participated in the annual **World Multiple Sclerosis Day** on May 30, 2019. This year's official theme was #MyInvisibleMS, focusing on all the invisible symptoms of the disease. A total of 37 Group companies participated in this MS International Federation (**MSIF**) initiative by showcasing their activities in support of the MS community under the umbrella of our #MSInsideOut campaign.

As part of our World MS Day activities, we created the My Invisible MS art gallery. It was based on pieces of art created by people living with MS who illustrated their invisible MS symptoms. We displayed the art gallery in 17 different countries around the world.

We remain focused on bringing our commitment to fight MS to life in a meaningful way, addressing patients' evolving needs and improving the lives of carers. We also recognize the **valuable impact** that community and grassroots initiatives have in contributing to this effort. As a result, we are working on an initiative through which these groups can apply for a grant to supplement work specifically aimed at improving the provision of support to carers.

World Malaria Day

Since 2015, our company has been championing World Malaria Day, which takes place every year on April 25. We conduct campaigns that raise awareness of the disease. In 2019, we marked the event with our partners in Ghana and conducted an internal awareness campaign to showcase our engagement in the **fight against malaria**. In particular, the campaign highlighted our company's Malaria program as our company-wide approach towards the control and elimination of the disease. This program leverages competencies from all of our business sectors to deliver integrated

and transformative health solutions, such as new diagnostics, therapies and preventive methods, together with approaches that strengthen local health systems in low- and middle-income countries.

More information on our company's Malaria program can be found in the **Focus Programs** chapter.

World Health Day

On April 7, 2019, we celebrated World Health Day as an opportunity to communicate about the importance of equity in quality health services for individuals, economies and society. The campaign, promoted by the World Health Organization (**WHO**), highlighted the need for universal health coverage to ensure that all people can obtain the care they need, when they need it.

Since the spread of infectious diseases remains a major global health threat, the World Health Day is an occasion for us to confirm our engagement in combating schistosomiasis and malaria through science and technology innovations.

World Diabetes Day

For World Diabetes Day 2019, on November 14, we launched a campaign that echoed the International Diabetes Federation's (**IDF**) theme, namely- "The Family and Diabetes". The campaign was an extension of the previous year's World Diabetes Day campaign "See it. Slow it. Stop it.", which aimed to identify risk factors among people who are likely to develop type 2 diabetes.

The campaign focused on sharing the message that having a supportive family contributes significantly to people's ability to lead a healthier lifestyle and fight type 2 diabetes.

Our company remains steadfast in its commitment to its partnership with the IDF, working on a range of educational activities that seek to raise awareness of prediabetes and type 2 diabetes management and prevention.

Fertility Awareness Week

European Fertility week provided an opportunity for our company to increase awareness of in vitro fertilization and the patient journey. We created a platform for an open dialogue around the **reality of fertility**. This helped people living with infertility in Europe to be heard. The platform was supported by our global social media campaign "We are in it together", which comprised opinion pieces by our senior management and an employee emphasizing the need for collaboration to support female fertility.

At the same time, we launched various country initiatives. For instance, in France we had a #Testyourfertility social media campaign, focusing on prevention and creating awareness of infertility issues among 18- to 24-year-olds.

Healthy Women, Healthy Economies initiative

To help empower women to overcome the challenges of communicable and non-communicable diseases and to rise to their economic potential, we are committed to the “Healthy Women, Healthy Economies” initiative. Under the auspices of the Asia-Pacific Economic Cooperation (APEC), we collaborate with representatives of several governments through this public-private partnership, which seeks to identify and implement policies that advance women’s health and well-being to support their economic participation.

In July 2019, we partnered with the “March of Dimes” initiative in a three-year collaboration, launching “Healthy Babies, Healthy Business”, a program that supports health benefits for mothers and promotes family-friendly work environments.

Embracing Carers initiative

Embracing Carers is a global initiative that we lead in collaboration with prominent caregiving organizations around the

world. Embracing Carers is designed to increase awareness, action and discussion around the often-overlooked needs of caregivers. We believe that the topic of caregiving is one of the most under-addressed public health issues of our time, with caregivers receiving little recognition and support despite providing vital services for others. We raise awareness of the issues faced by caregivers, prompt stakeholders to show deeper engagement, establish **global best practices** and advocacy resources and endorse the improved integration of carer support into the spectrum of care.

In 2019, Embracing Carers worked to transform awareness into action by launching a global “Time Counts” campaign, which encouraged people to find large or small ways to help a caregiver in their lives and pledge that time. Embracing Carers also provides support to more than 30 patient and carer groups globally, enabling them to create initiatives dedicated to behavioral change and peer-to-peer support programs to improve caregivers’ lives.

product safety and quality

chemical product safety

Part of the non-financial report

Since many of our chemicals are classified as hazardous substances and mixtures, we must ensure that they pose no risk to people or the environment. We therefore comply with all relevant national and international regulatory requirements, laws and guidelines, an approach that is crucial to our business success. At the same time, we aim to meet the expectations that stakeholders such as customers and employees have of a comprehensive hazard management program.

Our approach to safe chemical products

Product safety is one of our top priorities. Starting at the development stage, we investigate the potential adverse impacts chemical substances may have. Along the entire value chain of our chemicals – **during import, manufacture and commercialization** – we fulfill all regulatory requirements, often even exceeding them. We publish extensive information on the safe handling of our products (see emdmillipore.com and emdgroup.com) on our websites.

How we ensure chemical product safety

Our Healthcare, Life Science and Performance Materials business sectors each have their own organizational structures in place to provide support and guidance on product safety. The employees responsible for product safety from all three units work in close collaboration with each other as well as with our Group-wide governance function Corporate Regulatory Affairs Chemicals (EQ-R) to ensure the safety of our products. Their tasks include registering chemicals, classifying hazardous substances and communicating risks by means of safety data sheets and labels.

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

EQ-R ensures that our company complies with all regulatory requirements Group-wide. Because it is not subject to any operational commitments and reports directly to the head of our Group Environment, Health, Safety, Security, Quality function, EQ-R operates independently of our business sectors. Any necessary corrective or preventive actions are the responsibility of each business sector. EQ-R furthermore supports individual units in implementing and harmonizing efficient processes.

Integrating Versum Materials and Intermolecular

In the process of integrating Versum Materials and Intermolecular, we are verifying whether their product safety practices comply with the applicable regulatory requirements as well as our internal standards, adapting the underlying processes as needed.

Our commitment: Legal requirements and Group-wide guidelines

Through Group-wide guidelines, we guarantee continual compliance with national and international regulations and have also endorsed general voluntary commitments of the chemical industry, such as the [Responsible Care® Global Charter](#).

Our Regulatory Affairs Governance Policy details our Group-wide processes for managing and **implementing product safety** and sets out the necessary management structures. To meet the product safety regulations relevant to our company, in 2019 we revised our Regulatory Affairs Governance Policy to more clearly define the roles, rights, powers, and responsibilities within our Group.

The legal requirements applicable to our operations include the Globally Harmonized System of [Classification and Labeling of Chemicals](#) (GHS) and its implementation in regional and national legislation (such as the CLP regulation in the European Union and HazCom in the United States). Our Group Label Standard provides a consistent framework for labeling products according to GHS requirements. In addition to these, we also comply with the EU chemicals regulation [REACH](#), the amended U.S. Toxic Substances Control Act (TSCA), and the amended German Federal Banned Chemicals Ordinance (ChemVerbotsV).

No significant incidents of non-compliance with regulations or voluntary standards involving chemical product labeling were reported in 2019.

REACH registration

In 2018, upon completing the third registration phase of the EU chemicals regulation REACH, we committed ourselves to the following actions: We shall continuously review our own registration dossiers to verify quality and keep the information up-to-date, improving the dossiers as needed. In 2019, we developed and implemented the processes necessary to accomplishing this.

ICCA Product Safety Summaries

By mid-2019, we had made product safety summaries available on the website of the International Council of Chemical Associations (ICCA). Effective October 1, 2019, the website had been taken down by the ICCA because information on chemical substances is available on other web portals. We provide information on the safe handling and use of our chemicals on the websites of our **Life Science** and **Performance Materials** business sectors.

Safety analysis during product development

We believe that product safety starts with development. By conducting **hazard, exposure and risk assessments**, we work to ensure that our chemicals can be safely used later on. As stipulated by law, we analyze all products in terms of their impact on human health and the environment, complying with the relevant regulatory requirements. Before launching a new product, we evaluate all pertinent hazardous substance data and classify the product according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), along with locally applicable regulations such as **CLP** in Europe. In conducting these safety assessments, the employees in our Life Science and Performance Materials business sectors receive advice and guidance from their respective Regulatory Affairs unit.

Our approach to nanotechnology

Nanotechnology is a highly innovative field of development that researches and uses structures 50,000 times thinner than a human hair. This technology opens up many opportunities for our Group. In our Life Science and Performance Materials business sectors, we utilize nanomaterials to develop products with new functions and properties that can help **make resource and energy consumption more efficient**, for example. In our Healthcare business sector, we explore the use of nanomaterials in medical therapies.

Despite their promise, the unique structure of nanoparticles may harbor risks, which we assess in line with legal requirements such as REACH. Our Group-wide **Policy for Use and Handling of Nanomaterials** underpins our approach to this technology. In the manufacture and processing of our products, we adhere to all legal requirements along

with standards such as those of the German Federal Institute for Occupational Safety and Health (**BAuA**), as well as the German Chemical Industry Association (**VCI**). We furthermore provide our customers with safety data sheets containing information on the proper handling of nanomaterials during transport, processing, storage, and disposal.

In principle, we only utilize this new technology with the greatest care, abiding by the **precautionary principle** and taking nanomaterial safety very seriously. In doing so, we observe Group-wide requirements for safety, environmental stewardship and health impact mitigation, and leverage our existing processes and systems to ensure product safety.

Sharing nanotech knowledge

Beyond our internal safety efforts, we regularly engage other companies, associations and regulatory agencies in a dialogue on the **opportunities and risks of nanotechnology**. We take part in committees and working groups, including the Nano Panel of VCI's Technology and Environment committee, as well as Responsible Production and Use of Nanomaterials, a joint technology working group of the Society for Chemical Engineering and Biotechnology (**DECHEMA**) and the VCI. Within the VCI, we furthermore review the latest scientific literature in order to stay abreast of new advances in nanotechnology.

Product safety information

As part of our efforts to communicate the potential dangers of our products, we provide our customers with in-depth informational material on all our chemicals. These brochures contain instructions on **proper use and handling** to prevent them from posing a danger to people and the environment.

We provide all chemicals classified as hazardous with **safety data sheets**. These contain information on the physicochemical, toxicological and ecotoxicological properties of the agent and reflect the relevant regulatory requirements of the countries in which they are published. We therefore produce country-specific safety data sheets in 44 languages for our Performance Materials business sector and in 37 languages for our Life Science business sector. We also provide safety data sheets for the non-hazardous materials and finished medicinal products manufactured by our Healthcare business sector. Since all these documents must be kept up-to-date and consistent, we have automated and standardized the majority of our Group-wide hazard communication processes within our business sectors.

In 2019, we updated 12 million safety data sheets for our Life Science business sector.

26 M.

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

We offer an app that enables our Life Science customers to access the latest product safety information. Covering the whole life cycle of the product along its entire supply chain, the information is available worldwide in the respective national language and takes country-specific regulations into account. To access it, customers only need to scan the product's barcode or enter it manually.

Informing and educating customers

In 2019, we ran the Docs Online project within our Life Science business sector, which allowed us to verify that customer documents such as CoAs (Certificates of Analysis), CoOs (Certificate of Origin) and safety data sheets are up-to-date and available on the Sigma-Aldrich [website](#), which has belonged to Merck KGaA, Darmstadt, Germany since 2015. Additionally, it is now **easier to locate the documents**. For individual special product groups, we contact our customers directly if needed, for instance when legal requirements change. Through our [SciDeEx[®]](#) program, our customers can check whether they can use a chemical safely within the boundaries of the EU REACH exposure scenarios.

patient safety

Part of the non-financial report

The safety of patients who are treated with our medicines is our absolute priority. Our pharmaceutical products need to be effective in treating the respective disease, while also posing as little risk as possible to patients. That is why we consistently monitor risks and any adverse effects that may arise and take the necessary actions to minimize them.

Our approach to ensuring patient safety

Through rigorous benefit-risk management, we help to ensure that the benefits of our drugs always outweigh the risks for patients. Every new medicine passes a series of precisely defined development stages. Before any drug is given to humans, we conduct extensive preclinical testing both in vitro and in vivo. Through toxicological testing, we determine whether an active pharmaceutical ingredient is toxic to living organisms and, if so, at what dosage. This also helps us determine the dose that humans can safely tolerate. Only when this is complete do we perform **clinical studies** to investigate the safety and efficacy of the drug when used in humans. During clinical development, we diligently use all collected data to continuously evaluate the drug's **benefit-risk profile**. If we consider the drug's benefit-risk profile to be positive, we then submit an application for marketing authorization to the regulatory authorities.

Continual monitoring

Once a drug is launched, the number of patients being treated with it increases significantly. In certain circumstances, rare adverse and potentially serious effects that go undetected during clinical development may occur, which is why we continuously monitor and manage the positive benefit-risk profiles after market launch. Pharmacovigilance includes the process of monitoring a drug on an ongoing basis to detect and assess signals as part of signal management activities. The aim is to track any adverse effects in an effort to take appropriate action to minimize and communicate the risks in a transparent way. We always provide physicians and patients with the **latest information on the safety** of all our marketed drugs. The above applies to the entire life cycle of a product, ranging from development, market launch and commercialization to expiration of the marketing authorization.

Capabilities that we have developed and strengthened in this area include:

- Advanced benefit-risk management
- Big data analytics (using real-world data)
- Advanced signal detection technology
- Pilot processes in patient-centric adverse effects collection

Based on the conditions of regulatory approval, we regularly develop and publish **educational materials for patients and healthcare providers** to communicate any known and potential risks and ways to minimize them for newly approved products (such as Bavencio® and Mavenclad®).

We assess the effectiveness of these materials in close collaboration with our Benefit-Risk Action Team. If required, we adjust the content of the materials and their distribution, and describe the results from the effectiveness analysis in our periodic safety reports and risk management plans, which we submit to relevant health authorities for evaluation.

How we monitor patient safety

Our Global Patient Safety unit is responsible for pharmacovigilance. It continually collects **current safety data** from a wide variety of sources across the globe, including clinical studies, early-access programs, spontaneous reports on adverse effects, patient support programs and articles published in medical and scientific journals.

Our experts help to make sure all information on the risks and adverse effects of our medicines is properly documented, tracked and reported to the respective health authorities in accordance with regulatory requirements. The Global Patient Safety unit analyzes all data and reassesses the benefit-risk profile based on these data, where required. We, then, inform regulatory authorities, physicians and patients about new risks, additional risk mitigation measures and potential changes **in the benefit-risk balance**.

Our Global Patient Safety unit became part of our Global Development function at the end of 2018, enabling us to better integrate **sound knowledge of patient safety** into early decision-making, in particular through the advent of predictive safety. Our expertise, in close collaboration with Chemical & Preclinical Safety, Translational Medicine and other functions, will help ensure the seamless assessment of benefit-risk profiles throughout the product life cycle to deliver therapies that are truly differentiated and provide transformational value to patients. We restructured the Medical Safety function in 2019. It is now therapeutically aligned as a holistic end-to-end function, including a unified Safety Scientist group and a new function known as Medical Operations and Analytics. Investigational and marketed drugs were previously managed through two separate functions within Global Patient Safety. Overall, this newly consolidated department will help us to focus on scientific data and medical safety. Acknowledging the importance and magnitude of our journey, we launched a Transformation Office. To establish a robust and streamlined end-to-end process for Individual Case Safety Report (ICSR) management, the Medical Assessment group was integrated into the Safety Operations group. Thus, one team is now accountable for the entire ICSR process.

The **Healthcare Quality** (HCQ) unit of Merck KGaA, Darmstadt, Germany processes quality complaints relating to our products. When quality defects may have an impact on patient safety or lead to adverse effects, Global Patient Safety gets involved.

Our Medical Safety and Ethics Board

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

Within the Global Patient Safety unit, the Benefit Risk Action Team is responsible for signal management, benefit-risk assessment, risk management and all topics regarding product safety and the benefit-risk profile of our medicinal products. Recommendations from the Benefit Risk Action Team are endorsed by the Pharmacovigilance Advisory Board (PVAB), also chaired by Global Patient Safety unit.

Our commitment: Guidelines and statutory requirements

We follow international guidance and standard procedures, such as the International Conference for Harmonization (ICH) guidelines and the Good Pharmacovigilance Practices (GVP) established by the European Medicines Agency (EMA) and national health authorities. In addition, we adhere to all statutory pharmacovigilance regulations in those countries where we market our products, and we continuously work to incorporate all required changes in our Group-wide standards and processes. We began harmonizing the **processing of personal data** according to new European legislation on data privacy (**General Data Protection Regulation**) in 2018 and continued this effort globally in 2019.

Collecting information and checking processes

In 2017, the EMA implemented a new process to monitor the safety of medicines in EudraVigilance: This provides marketing authorization holders with access to data on suspected adverse effects and requires them to monitor the EudraVigilance data for safety signals and to report these to health authorities. In response to these new requirements and to the new data transmission format stipulated by ICH guideline E2B (R3), we upgraded our **Global Safety Database** to ensure the technical capabilities needed to support the coordinated exchange of individual case safety reports. In 2019, we started safety reporting in line with the enhanced E2B(R3) standard in China, Europe and Japan.

In 2019, we assessed new **country-specific regulatory requirements** and implemented necessary changes in order to meet them. Examples include new benefit-risk assessment and safety signal notification requirements in Canada, Denmark, Serbia, and the United States, and requirements for local pharmacovigilance responsible persons in Botswana, Kazakhstan and Kenya. Other

examples include: the EU Falsified Medicines Directive (FMD, 2011/62/EU), the MHRA Guidance on the Regulation of Medicines, Medical Devices and Clinical Trials, and regulatory changes in African countries with – among others – respect to clinical trial guidelines. We also compiled comments on drafted guidelines and provided them to health authorities, for example on "ICH – Draft Guidance E8(R1) General Considerations for Clinical Studies" and "ICH – Draft Guidance E19 Optimization of Safety Data Collection."

Monitoring drug safety

Regulatory authorities conduct periodic inspections to verify that we comply both with statutory requirements and with our own internal standards for drug safety. In Germany, these are handled on behalf of the European Medicines Agency (EMA) by the German Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI), the German Federal Institute for Vaccines and Biomedicines. We follow up on the findings of health authority inspections and take the necessary actions to ensure the proper functioning of our pharmacovigilance system. In 2019, three **pharmacovigilance inspections** were conducted (France, Germany and Serbia).

Furthermore, we perform audits to ensure that all our **units and subsidiaries involved in pharmacovigilance consistently** meet all requirements across the globe. In 2019, we conducted a total of 29 pharmacovigilance audits and found no significant deviations in our pharmacovigilance system from these requirements. We also audit vendors and licensing partners involved in pharmacovigilance, which helps us hone our pharmacovigilance processes so that they surpass statutory requirements.

In line with our goal to enhance patient safety, we implemented a patient-friendly interface in the mobile app agReporter. With this app, not only field nurses and our sales representatives, but also non-medically trained users can **report any side effects** or adverse events arising from the use of our products. This places patient feedback at the core of our efforts to consistently collect data on adverse effects. In 2019, we implemented further changes to the app to improve data quality for the adverse events reported. We also made the app available in a total of 14 languages, with an Arabic version currently in preparation.

Innovative signal detection

Through our tool for signal detection, called Empirica, we analyze and manage large amounts of global data, such as scientific studies and news about adverse effects. This helps us to comply with regulatory timelines for safety signals and other safety-related factors and will ensure that all signal data, documentation and decisions are captured in one place. It also allows easy access to and analysis of our data as well as cross-functional collaboration between the Global Patient Safety unit and other internal and external stakeholders. We use a key performance indicator (KPI) to track whether all signals, validated and not validated, detected from external or internal sources are managed and completed within the timeline defined by standard operating procedure, which is 60 days from the date of detection. The

KPI shows that the implementation of Empirica **improved the tracking of all safety**. Using diverse statistical tools and leveraging all available safety data from our internal and external databases also helped to improve our signal detection rate.

Up-to-date labeling and product information

Our product information explains to physicians and patients how to properly use the respective drug and allows for an informed decision on the treatment. In accordance with statutory regulations, the **package leaflet** contains all relevant information such as indication(s) and ingredients, as well as dosage, storage, mode of action, instructions for use, warnings, precautions and possible adverse effects. Should the medicine contain ingredients that could impact the environment, the package leaflet may also contain information on the proper disposal of the product.

We review and update all product information documents such as package leaflets, ensuring that our medicinal products contain the latest information on safety, efficacy and pharmaceutical formulation, as appropriate. In accordance with statutory requirements, all modifications to the leaflets are submitted to the respective regulatory authorities for approval. In 2019, there were no incidents of non-compliance with statutory regulations concerning labeling of drugs or pharmaceutical products.

Internal and external training

All employees involved in the safety and quality of pharmaceutical products take part in training in line with our global training standards. We verify compliance with these requirements by producing training compliance reports and by performing regular audits.

Our training is delivered via a global-learning platform. All of the approximately 24,000 biopharma employees receive **basic pharmacovigilance training** once a year that covers the procedure for reporting adverse effects from our products. Other training courses keep employees up to date on their professional expertise as well as internal standard operating procedures and other relevant requirements. This helps to ensure adherence to Good Pharmacovigilance Practice (GVP) requirements.

Sharing expertise with other countries

We endeavor to transfer our drug safety expertise around the world, especially into countries where health workers need to build their pharmacovigilance expertise. In 2019, we continued the **pharmacovigilance workshops** for medical school students in Guatemala, as reporting adverse effects is often not sufficiently covered by the curricula there.

We also assist Latin American health authorities in **implementing electronic reporting processes** for adverse effects. We support the implementation of electronic reporting in Argentina, El Salvador and Peru. Health authorities in Brazil, Mexico and Tunisia are also moving towards adopting this technology.

Additionally, we conducted pharmacovigilance training and shared pharmacovigilance expertise in the Eurasian Economic Union (EAEU). As members of the pharmacovi-

gillance working group within the Association of International Pharmaceutical Manufacturers (AIPM), we shared our expertise through conferences, provided training and seminars in the industry, presented to university school students and professors and liaised with the health authority in Russia.

The Medical Dictionary for Regulatory Activities (MedDRA) is a clinically validated medical terminology system used by health authorities and the industry worldwide. Following the release of the new MedDRA version 22.0, the MedDRA Maintenance and Support Services Organization (MSSO) presented the Russian version of MedDRA. We also collaborated with health authorities in Brazil and China to contribute to the creation of local language versions of MedDRA.

In Russia, we implemented a **new adverse effects database** for the health authority in September 2019. Information for marketing authorization holders is currently being developed in collaboration with the national industry association and health authorities.

In 2019, we also formulated a new strategy to increase the contribution made by our Access to Health Initiative (A2H) to pharmacovigilance. **Improving access to high-quality health solutions** for underserved populations and communities in low- and middle-income countries is the key objective of A2H Initiative. A key aspect of this new strategy is fostering pharmacovigilance initiatives in safety data-sharing with health authorities and building pharmacovigilance capacity with reputable partners in underserved countries in a sustainable way.

To this end, we selected low- and middle-income countries from the UN Human Development Index (HDI) and included these in our project scope. The primary focus in 2019 was on encouraging universities and ministries of education in these countries to establish **pharmacovigilance curricula** in schools of medicine, pharmacy and nursing, and to support health authorities in adopting pharmacovigilance systems through industry associations or partnerships.

Furthermore, for the selected countries we appointed ambassadors per region to systematically collect and report information on pharmacovigilance initiatives and activities in each region. The analysis of preliminary information already demonstrated that we actively contributed to the preparation of the Brazil health authority's new pharmacovigilance regulations and the creation of a Brazilian-Portuguese MedDRA. In Russia, we began a **joint educational initiative** with the **Sechenov University**, which took place between October and December 2019, targeting students in their fourth year at the School of Pharmacy. The topic of pharmacovigilance was also covered in this training course.

Through the A2H initiative, we also promoted patient centricity in low- and middle-income countries through a **pharmacovigilance awareness video** that we developed and distributed. For example, this included presentations at a Tunisian pharmacovigilance congress, information on company-sponsored disease awareness websites in India, pharmacovigilance workshops for medical school students in

Guatemala and over 2,300 pharmacists in China. We plan to expand this approach to other countries.

Stakeholder dialogues in 2019

Lecture for pharmacy students of Peoples' Friendship University of Russia

Being members of the pharmacovigilance working group of the Association of International Pharmaceutical Manufacturers (AIPM), both, the Eurasian Economic Union (EAEU) Qualified Person for Pharmacovigilance (QPPV) and the Local Patient Safety Officer (LPSO) in Russia took part in projects to increase pharmacovigilance (PV) awareness among local and international industry, healthcare professionals and university students. They presented PV-relevant topics at professional conferences and educational events. In April 2019, representatives of our company held a lecture for pharmacy students at the People's Friendship University of Russia. In this way, we increased the students' knowledge on PV and raised awareness of its importance.

Boosting patient-centricity in North Africa

At the Tunisian pharmacovigilance congress in April 2019, we presented a **video on educating patients** about

adverse drug reactions. Reaching more than 200 participants and speakers from Algeria, Europe, Morocco and Tunisia, our #AdverseEventAwareness video built confidence among our partners and stakeholders, and enhanced patient centricity and pharmacovigilance awareness. The initiative was met with approval from Tunisian and Moroccan health authority representatives, who proposed collaborating to assess opportunities for further development.

Towards a digital pharmacovigilance partnership in Tunisia

To ensure the smooth implementation of **accurate, electronic reporting on pharmacovigilance** in Tunisia by using the ICH E2B system, we liaised with the Tunisian Pharmacovigilance Department. In this way, we helped to ensure the system complemented the Tunisian pharmacovigilance center's existing connection to the World Health Organization database for safer use of medicines, called **Vigibase**. The Tunisian Pharmacovigilance Department tested the system and plans to make it mandatory for all pharmaceutical companies involved in electronic reporting.

product-related crime

Part of the non-financial report

According to the World Health Organization (WHO), a considerable proportion of the medicines in developing countries are illegal, counterfeit or substandard. In industrialized nations, however, such products are also becoming increasingly available on the market through unlicensed Internet pharmacies and dubious online platforms, posing a risk to public health. Moreover, chemical products can also be used for illegal purposes such as the manufacture of illicit drugs.

Our approach to product-related crime

Our company develops and manufactures products of the highest quality. In order to protect both customers and patients, we secure our products against counterfeiting and are resolutely committed to fighting product-related crime by, for instance, collaborating with health, regulatory and law enforcement agencies at the **regional, national and international level**. In taking preventive action, we cooperate with industry representatives, Interpol and the World Customs Organization. Our guidelines, standards and processes apply to all our business sectors and markets worldwide.

How we define product-related crime

1. Counterfeit products: In line with the relevant WHO standard, we define a counterfeit product as "a product that is deliberately and fraudulently produced and/or mislabeled with respect to its identity and/or source to make it appear to be a genuine product."

This includes products

- with incorrect active ingredients or concentrations thereof
- without any active ingredients
- with dangerous impurities
- with modified/alterd packaging and/or incorrect brand names
- with an authentic active ingredient, but not one produced under GxP conditions
- that have expired
- that were diverted from the legal supply chain

2. Illegal diversion of products: This term refers to the diversion of either pharmaceuticals or chemical substances from within the legitimate supply chain either to sell or export them through illegal channels to produce narcotics, weapons or explosives, or to use them for other illegitimate purposes.

3. Misappropriation of products: This refers to theft from production sites and warehouses, or while in transit.

How we are tackling product-related crime

Our Group Corporate Security function coordinates all our anti-counterfeiting activities, all of which are overseen by the Chief Security Officer and the head of Environment, Health, Safety, Security, Quality (EQ). Furthermore, all our sites have a product crime officer who is responsible for investigating potential cases of counterfeiting, acting as the interface between local regulatory and law enforcement authorities, national associations, our Group functions, and our sites. In 2019, conference calls with all product crime officers were held every two weeks to discuss strategic matters along with local issues and suspected cases of criminal activity.

Integration of Versum Materials and Intermolecular

As part of integrating Versum Materials and Intermolecular into our organization, we are examining the structures and processes in place to prevent and prosecute product-related crime, making changes as needed.

Group-wide anti-counterfeiting network

Our Anti-Counterfeiting Operational Network (MACON) is responsible for **globally monitoring and executing all anti-counterfeiting measures** for our products. Along with coordinating prevention and the development of security systems, this organization is also responsible for investigations. Comprising experts from various units such as Legal/Trademarks, Product Security, Export Control, Supply Chain, Patient Safety, and Quality Assurance, this network is coordinated by our Corporate Security unit.

To investigate suspected cases, MACON collaborates with the competent law enforcement agencies and regulatory authorities. In 2019, MACON investigated and pursued numerous incidents that primarily involved **counterfeits within the legitimate and illegitimate supply chains** as well as theft and illegal diversion.

Our commitment: Group-wide guidelines and standards

Our guideline entitled "Crime Relating to Products of Merck KGaA, Darmstadt, Germany" describes our goals and strategies for combating product-related crime. The Group-wide Product Crime Investigation standard sets out **mandatory requirements** and defines the procedures we follow within the Group. Moreover, it ensures that cases are processed efficiently and creates a clear legal framework for dealing with illicit products.

Enhanced monitoring and reporting systems

We analyze and document all counterfeit product incidents using a Group-wide reporting system. This approach provides us with a **complete picture of the security situation**, enabling us to identify possible links between different cases and effectively tackle them. Introduced in 2018, our standard operating procedure entitled Data and Documentation Quality Management details the corresponding process, making the risks more transparent and the processes more efficient.

Tracking system for chemical substances

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

In addition to fulfilling the duties stipulated by **statutory provisions on export control**, we also report suspicious orders, inquiries and requests to the competent authorities. Through these efforts, we are honoring a voluntary commitment of the German Chemical Industry Association (VCI) and meeting the terms of the Guideline for Operators published by the European Commission. In 2019, we reported 1,519 orders placed for relevant substances, which represents 1.8% of the overall order volume. In addition, we received six inquiries from the authorities regarding specific suspected cases that we helped to resolve.

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

Supporting customers and patients

To protect patients, the identity and authenticity of pharmaceuticals must be verifiable. We ensure this by rigorously

implementing the requirements of the EU Falsified Medicines Directive. In February 2019, we started applying a **unique serial number** to the packaging of all the prescription medicines we commercialize in the European Union (Track and Trace). We also use this system in Colombia, Russia, the United States, Turkey, Egypt, and other parts of the Middle East. In the coming years, we intend to roll out this system in all African countries as well as the rest of the Middle East. Plans are in place to implement it in Malaysia and Indonesia as well.

In addition, we also pursue our own initiatives:

- We apply the Security M label to some of our products, enabling users to **easily verify authenticity**. We take a risk-based approach to identifying the products to be labeled in this manner.
- In our **Mobile Anti-Counterfeiting System (MAS)** project in Nigeria, we are working closely with one of our suppliers on a text message-based identification system. Patients scratch off a barcode that is printed on the product packaging then text this code to a number that has been specifically set up for this purpose. They immediately receive a response telling them whether their code is authentic.
- We sponsor the non-profit Global Pharma Health Fund (GPHF), which supplies the **GPHF-Minilab[®]**, a compact laboratory used mainly in low- and middle-income countries to test the quality of 90 different active ingredients quickly and inexpensively. You can find more information on this project under [Pharmaceutical supply chain](#).
- We offer our customers in the pharmaceutical industry **Candurin[®] pearl effect pigments** with unique color properties. When used to coat tablets and capsules, these pigments make it more difficult to create counterfeit copies.

Industry-wide exchange

In an effort to fight product-related crime, we actively participate in various associations and **industry-wide initiatives**. For instance, we work in very close partnership with the Pharmaceutical Security Institute (PSI), a non-profit organization dedicated to protecting public health. It both promotes the exchange of information on counterfeit products and helps the authorities to implement sanctions against the counterfeiters. You can find more information on our efforts under [Stakeholder dialogue](#).

Raising awareness of product-related crime

We aim to raise awareness of product-related crime among our business partners and employees, educating and training our employees Group-wide on the subject.

All staff involved in security, such as product crime officers, participate in **appropriate training programs** aimed at building their capacities and promoting best-practice sharing. We are continuously evolving these programs and adapting them to new trends. In 2019, for instance, we held 35 training courses for our product crime officers covering incident reporting, case management, and cooperation with the authorities.

Security audits for contract manufacturers and distributors

We regularly check whether our distributors and contract manufacturers are complying with GMP and GDP (Good Manufacturing Practice/Good Distribution Practice). These

audits are based on the **EMA ICH Q10** pharmaceutical quality assurance standard. They also allow us to ascertain the extent to which our **security requirements** are being met by contract manufacturers and distributors. In addition, we conduct special security audits if a concrete need is identified. We also perform these audits as standard practice when we certify external service providers for our Security M label. This applies to both pharmaceutical contract manufacturers as well as companies that print packaging. Defects that we deem as critical must be rectified either before we enter into a contract, or a detailed corrective action plan must be submitted for our approval. In 2019, we conducted this type of security audit in Russia, which found two critical, eight significant and two minor defects. Corporate Security is monitoring the implementation of the necessary corrective actions. As soon as these have been completed, we can start the planned business endeavors.

Transport and warehouse safety

Part of the non-financial report

We transport and store numerous products and materials around the world, including commercial chemicals and pharmaceuticals, raw materials, intermediates, and waste, as well as technical materials and packaging, all of which could pose a hazard to health and the environment if handled incorrectly.

Our approach to safe transport and storage

It is our aim for all our shipments to reach our customers and sites safely, undamaged and with the required safety information. Several of the materials we store and transport are classified as hazardous. The storage of such hazardous goods and the transport thereof – whether by road, rail, plane, or ship – are governed by regulations applicable worldwide. To minimize risks to people and the environment, we apply **strict safety regulations across the Group** that of course also comply with applicable legislation. We conduct regular reviews to ensure that our own warehouses as well as those of third parties comply with these regulations. In addition, we train our employees accordingly.

How we achieve transport and warehouse safety

The overriding responsibility for transport and warehouse safety lies with our Group Environment, Health, Safety, Security, Quality (EQ) function (see Environmental stewardship), which defines the standards and guidelines applicable Group-wide. In addition, our individual sites are subject to various national and international regulations governing environmental stewardship and public safety, which **local site directors are responsible** for complying with.

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

Our EHS managers are also responsible for **monitoring our contract warehouses**. Before signing a contract with a third-party warehouse operator, we assess whether they properly adhere to national and international storage and transport regulations and whether they are able to meet our additional requirements. We summarize the findings from this audit in an EHS report.

Integrating Versum Materials and Intermolecular

In the process of integrating Versum Materials and Intermolecular, which we acquired in 2019, we are reviewing their existing structures and processes for transport and warehouse safety, making adjustments as necessary.

Our commitment: Internal standards and international rules

Our **Group-wide safety concepts and standards** govern the safe storage of hazardous substances. Our Warehouse Safety standard, for instance, sets out measures to prevent materials from leaking or igniting and requires us to specify the dangers posed by any stored substance. Moreover, special safety rules apply to all warehouse employees.

Contract warehouses must also adhere to our high safety requirements. Before we sign a contract, providers must submit a statement detailing how they plan to meet our stringent safety standards. We also perform audits to ensure compliance from both our own warehouses as well as third-party facilities, utilizing a standardized checklist of the key requirements to help us assess potential contract warehouse risks. Furthermore, our Group standard Warehouse Requirements for Third-party Warehouses defines specific **structural and organizational requirements** for such facilities.

In Germany, the Technical Rules for Hazardous Substances (TRGS 510 "Storage of hazardous substances in non-stationary containers") govern the **storage of packaged hazardous materials** and apply across all our warehouse and distribution centers worldwide. An updated version of the TRGS is due to take effect sometime in 2020, and we are currently working with the Committee on Hazardous Substances (AGS) to revise these rules. Moreover, all our existing sites comply with applicable requirements of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). As part of the integration process, we are examining whether the sites of the recently acquired companies Versum Materials and Intermolecular are GHS-compliant.

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

All standards are reviewed as necessary, at a minimum every three years, and updated to reflect current requirements. When needed, we support our site directors in implementing relevant changes at the local level.

Enhancing transport and warehouse safety

In addition to the inspections conducted by our EHS and dangerous goods managers, we regularly perform Group **risk-based audits** to ensure that our sites comply with warehouse and transport safety regulations. We generally conduct these every four years, performing them more

frequently at sites that pose a potentially higher risk. If major shortcomings are identified, we re-audit the respective site the following year. Conversely, we may decide to extend the period between audits at facilities where, based on the findings from previous audits, we deem the potential risk to be low. Our EHS managers are also responsible for monitoring contract warehouses.

In 2019, we audited nine of our warehouse facilities for compliance with our Warehouse Safety and Transport Safety standards. All audit observations were assessed to pinpoint the areas where we can improve. For instance, we subsequently **revised our criteria for recycling shipping cartons** in order to reuse as many original shipping boxes as many times as possible at our distribution centers. In 2019, we also audited four third-party warehouses and drew up the necessary corrective action plans. Beyond this, we started analyzing our current audit processes for contract warehouses at the end of the year.

We report transportation incidents and accidents in accordance with the Recommendations on the Transport of Dangerous Goods – Model Regulations (UN Orange Book, section 7.1.9) in conjunction with the criteria of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, section 1.8.5). There was one reportable incident during 2019.

Employee training and best practice sharing

Our employees undergo regular training in line with their tasks and responsibilities, which is conducted by either their respective supervisor or our EHS and dangerous goods managers. Topics include internal standards and procedures, changes to international requirements, and proper incident management, and many of the subjects have ready-made training materials available that can be modified to reflect the circumstances of the respective site or country. All truck drivers employed by our company hold a dangerous goods driver's license, provided that this qualification exists locally. In Germany, our truck drivers are subject to the requirements of the German Professional Driver Qualification Act (BKrFQG) and must therefore complete additional training on transporting hazardous goods and securing cargo.

Across the globe, we conduct around **1,000 internal and external seminars on transport and warehouse safety every year**. The e-learning program we developed for hazardous material transport and storage is mandatory for logistics, EHS and dangerous goods managers. It currently features eight courses that are mandatory for the assigned participants.

Our dangerous goods managers hold regular conference calls to share their experiences and discuss current changes. All new EHS managers must complete EHStart-up! a three-day orientation seminar on environmental stewardship, safety and safe logistics. In 2019, 26 EHS managers took part in this training in Darmstadt.

Ensuring proper transport

We primarily use logistics companies to deliver our products to customers. In Germany, we transport the majority of our hazardous waste ourselves. Furthermore, we participate in the **Transport Accident Reporting and Emergency Response System** (TUIS) operated by the German Chemical Industry Association (VCI). Within this system, we exchange expertise and best practices on chemical transport with experts from other chemical companies and also provide hands-on assistance in the event of a chemical transportation accident. Our site fire departments in Darmstadt and Gernsheim collaborated with the fire departments in the region to develop the TUIS Messkonzept Südhessen. When a transportation or warehouse accident occurs, this standardized assessment system for southern Hesse allows us to quickly determine whether and how fast hazardous substances are spilling and spreading. In emergencies, our fire departments also provide on-site assistance using their specialized equipment.

Making transport vehicles safer

The safe transportation of dangerous goods requires safe vehicles, another factor our company takes very seriously. In Germany, for instance, we have been constantly evolving our **SafeServer truck body technology**. Under this design, the aluminum panels integrated into the side walls of the truck render the walls extremely stable. In 2019, 18 of our trucks had already been equipped with this technology.