# products

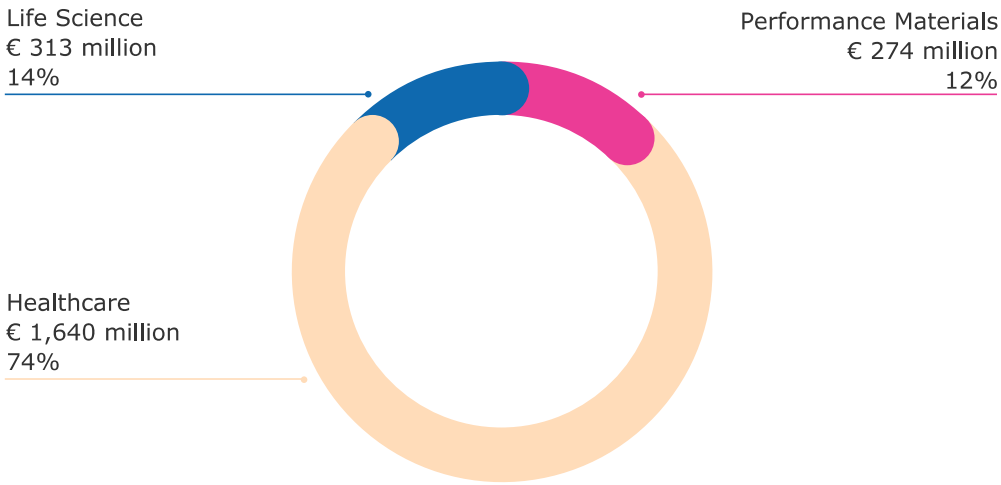
## Within this chapter:

# 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, enabling us to make many sustainable contributions. In 2020, we spent € 2.3 billion on R&D, corresponding to 13% of our net sales. Advances in digitalization are helping us to identify pioneering business models.

## Research and development costs by business sector[1] – 2020




[1] Not represented: research and development costs of € 62 million allocated to Corporate and Other.

## Our approach to creating innovation

Our business sectors use established strategies to drive new product developments for the benefit of patients and our customers. The diversity of the 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 our business sectors and beyond the current scope of our activities. Innovation fields in which we see potential for new business provide strategic direction. In our **end-to-end innovation process**, we endeavor to identify innovation projects that transcend our current portfolio and to develop them from the initial idea to market launch. This can succeed only if our business sectors work closely together and if we are open to external momentum.

We also create and **foster an innovation ecosystem** in order to bolster our overall innovative power in several areas. This ecosystem includes a presence in Darmstadt (Germany), in Guangzhou and in Shanghai (both China) as well as in Silicon Valley (California, USA) with internal and outreach programs. Additionally, we invest in innovative technologies and transformational ideas that have the potential to shape our core business areas and our sustainability pathway.

INFO

OUR INNOVATION FIELDS TO DRIVE INNOVATION BETWEEN AND BEYOND

**Clean meat**

This field concentrates on the biotechnology required to produce real meat grown in vitro. It 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.

**AI-enabled Health Solutions in China**

Our first innovation field targeted specifically to China focuses on Artificial Intelligence (AI)-enabled Health Solutions. It includes AI-related products and services that impact the medical and healthcare industries across their value chains, for example by increasing efficiency, saving costs or improving the customer experience.

We drive promising projects 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 stages. 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.

Digitalization is a major focus of our innovation efforts. We leverage digital opportunities to boost business performance, and we are increasingly forming new **strategic partnerships** with organizations that offer different perspectives. In this way, we expect to accelerate our research and development activities, better manage our supply chain and broaden our existing product portfolio to include new digital services, such as our PETRA health-screening robot.

You can find more information on research and development in our 2020 Annual Report.

## How we drive innovation

The organizational set-up 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 innovation strategies.

Our Group Strategy and Transformation function facilitates innovation between our individual business sectors and beyond our current business scope. It establishes an **innovation project portfolio** to generate 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 (Guangdong and Shanghai) and our Silicon Valley Innovation Hub in California.

Our Innovation Committee (IC) oversees the implementation of innovation projects between and beyond our business sectors. It reviews the progress of ongoing efforts and ensures 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.

## Investing in promising ideas

M Ventures is our strategic corporate venture capital arm. With a € 400 million evergreen fund, M Ventures invests in innovative technologies and transformational ideas with the potential to significantly impact our core business areas. M Ventures focuses on investing in **early-stage start-ups**, including the creation of spin-offs, to leverage our science and technology orientation.

## Leveraging data

We are in the process of rolling out a new Enterprise Data Strategy. Our focus is to increase the **data and analytics capabilities** across our company. To this end, we have established a consistent operating model that helps us make faster, better-informed decisions and take calculated risks based on past behaviors and future predictions. This will also help to drive innovation and research at a higher pace with strong business impact. The rollout of the strategy and the implementation of the associated organizational changes are scheduled for completion in 2021.

As a part of this data strategy, we are also investing in additional capacity for data management and data science. Linked via a global expert community, we employ several data science teams across the business sectors that drive projects in **advanced analytics and machine learning**. For example, these teams work with external and internal data to provide insights to sales teams in Life Science, use image recognition techniques to support the work of clinicians and researchers in Healthcare, and assist the research and innovation process in Performance Materials.

In the process of integrating Versum Materials and Intermolecular we have established a Chief Technology Office (CTO) to enable business innovation. The CTO will focus on identifying trends and vetting technologies that are beyond the time horizon or scope of our business units. We have also created a Technology Leadership Board to review and optimize technology investments across our Performance Materials business sector.

## Our commitment: Protecting innovative ideas

We are committed to ensuring the confidentiality of sensitive information, particularly of intellectual property in

digital 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 in the corresponding chapter.

## Innovation in the fight against Covid-19

To harness our company's innovation capabilities in the fight against the pandemic, we established a cross-business Covid-19 task force. The task force launched an internal idea-generating initiative and an **external idea call** for 2020 research grants. In addition, our task force implemented multiple projects. For example, it oversaw the selection process for medicines that could be used to treat Covid-19, including Rebif® and M5049, through to clinical development and it launched an antibody detection assay.

To learn more about our clinical development efforts to address Covid-19, please see the chapter on Clinical Studies.

## Easier employee testing with the help of software

We developed a software solution that digitalizes, streamlines and automates a significant proportion of the Covid-19 testing procedure for employees. The first version of the software, which is for internal use only, is focused on administration tasks associated with testing, e.g. automating e-mails, test invites and medical history. In addition, we document user consent, patient profiles, test cases, and sending out test results.

## Our Innovation Center: Growing ideas into business

Located in Darmstadt (Germany), our Innovation Center offers an ideal environment to cultivate ideas and scale them up into **viable new businesses**. In addition to propelling strategic growth fields, such as our innovation fields, the Innovation Center offers a platform for serendipity. It is open to anyone at our company who has an idea that is either cross-sectoral or beyond the current scope of our activities.

For example, this kind of lateral thinking has led to a collaboration to improve the manufacturing of tablets for oral administration in clinical trials. Producing tablets for such trials is typically time-consuming and costly using the traditional tablet manufacturing processes. Through a new partnership with AMCM, a sister company of 3D printing world-market leader EOS, we are developing a GMP-certified 3D printing solution to make tablet production simpler and more flexible, saving time and costs.

## Silicon Valley Innovation Hub: Accelerating the future of food

The Silicon Valley Innovation Hub is leading our Clean Meat innovation field, also referred to as cultured or cell-based meat. As a **technology enabler** for this emerging industry, we are leveraging our vast Life Science expertise in bioprocessing technologies. Apart from building strong connections and partnerships with start-ups, academia and leading organizations, such as the Good Food Institute, we are working on innovation projects to address specific technology challenges.

A major hurdle and cost driver in cultured meat production is cell culture media, which is estimated to account for 55% to 95% of production costs. For production at scale, the media needs to be cost-efficient, suitable for effective growth and differentiation into specific cell types and **free of any animal-derived material** such as fetal bovine serum. One of our innovation projects addresses exactly these challenges and aims to design and commercialize media formulations that are free from animal-derived products. Utilizing our cell culture media expertise, we partner with start-ups to enable the efficient production of various cultured seafood as well as avian and mammalian species. The project is led by the Silicon Valley Innovation Hub in collaboration with the Innovation Center and Process Solutions experts from our Life Science business sector.

## China Innovation Hub: Growing the global impact of our innovation ecosystem

Our China Innovation Hub expands our innovation ecosystem to China and strengthens our global innovation impact. The China Innovation Hub leads the China-specific innovation field **"AI-enabled health solutions"** to explore future business for our global innovation pipeline.

The local presence of two innovation hubs in Guangdong and Shanghai also accelerates our innovation and digitalization development by building up a nationwide innovation network and leveraging the vibrant innovation ecosystem in China. For example, we have formed partnerships with leading academic institutions, incubators and accelerators, cross-industry players, and local governments in Guangdong and Shanghai.

Since 2019, our Accelerator China program has connected us with 18 start-ups to support entrepreneurs' early-stage technologies and foster open innovation. In addition, we established a China Seed Fund of € 13 million in 2019, with the objective of strengthening our links with local entrepreneurs and investors. It **targets early innovation** generated within the Chinese innovation ecosystem. The first investment was made into SynSense, an AI-chip start-up, in May 2020.

In 2020, a series of cross-functional internal ideation programs, such as "Innovate to Fight Covid-19", inspired hundreds of employees to ideate and submit their creative ideas for new solutions. Our Innovator Academy and Innovation Salon provide training sessions on innovation approaches and idea exchanges for employees and external stakeholders, helping to empower them to transform ideas into business projects.

## Synergizing external ideas

Our **Accelerator** program supports select enterprises in their development through programs at our global headquarters in Darmstadt as well as 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.

**M Ventures** has a mandate to invest in the areas of Healthcare, Life Sciences, Performance Materials, and Frontier Tech & Sustainability and takes an active role in its portfolio companies. One such investment example is Akili. In June 2020, Akili announced that the U.S. Food and Drug Administration (FDA) had approved EndeavorRx™ (AKL-T01) as a prescription treatment for children with attention-deficit/hyperactivity disorder (ADHD). This is the first digital, video game-based therapeutic device prescription treatment to receive FDA approval. Delivered through a video game experience, EndeavorRx™ can help to improve attention span among children aged 8-12 with primarily inattentive or combined-type ADHD.

## Fruitful strategic partnership

Syntropy is a joint venture formed by our company and Palantir Technologies. The partnership's imperative is to unlock the power of data in the fight to cure cancer and several other diseases. Through its secure, trust-based environment, Syntropy enables data curation, collaboration and the generation of new insights while ensuring that data ownership remains with the provider. The partnership offers the scientific community a new model for collaboration, supporting our collective purpose to achieve breakthrough cancer research.

By simplifying and accelerating collaboration-driven insights, Syntropy will help to usher in a **new era of scientific discovery**, enabling researchers, their institutions and the scientific community to make further advances.

## Promoting visionary research

At the 2020 Future Insight Virtual Event, which we sponsored, the Future Insight Prize in the Multidrug Resistance category was awarded to a team from the Technical University of Munich led by Stefan Sieber for its activities to identify new antibacterial compounds with the potential to make the multi-drug resistance breaker product a reality.

In 2020, we also offered additional **research grants** to the scientific community, focusing on four topics: drug discovery oncology and autoimmune disease, pandemic preparedness including the fight against Covid-19, bioreactor design for cultured meat, and neuromorphic computing. In total, we received more than 1,200 research proposals from around the world.

# 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 theirs. 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 any adverse 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, asking ourselves right at the start of product development how to best reconcile these requirements.

Our Performance Materials business sector develops and produces numerous smart 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 highly hazardous materials where possible is a principle that is embedded in our product development process. Working with our customers, we support their efforts to continue advancing technology innovation while at the same time employing products with minimum environmental impact.

### How we include sustainability in product design

The Life Science business sector works across its business units to drive product-related sustainability. This includes our Design for Sustainability (DfS) program for environmentally sound Life Science products as well as DOZN™, a web-based tool for assessing more sustainable alternatives.

In 2020, we started the process of restructuring the **sustainability governance** of our Performance Materials business. We will provide information on the new structure in future reports.

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

### Integration of Versum Materials

We achieved several implementation milestones with respect to the integration of Versum Materials in 2020. On June 1, we announced the completion of the integration of the Human Resources processes. The next phase will focus on the structural integration of business processes and systems. This is due to be completed by the end of 2021.

### 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 **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 increasing 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: Consulting** pillar focuses on working with our customers to solve specific sustainability and/or Green Chemistry challenges they face.
- Our **DfS: Re-Engineering** pillar focuses on our established portfolio of products and on looking at how we can improve the environmental footprint of these products by applying 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 expanded the use of this 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).

### Ensuring business continuity during the pandemic

During the Covid-19 pandemic, our sites were fully committed to ensuring business continuity while protecting the health and safety of our employees.

The Performance Materials site in Suzhou was our first factory in China to restart operations after the Covid-19 outbreak. It resumed production on January 29, 2020. The

Suzhou site provides essential photoresist products to display panel manufacturers.

Our liquid crystal technology is widely used in the displays of vital medical devices needed during the pandemic. Globally, our Performance Materials teams work to ensure a continuous supply of high-end liquid crystal materials to support the increased demand for medical equipment.

## Putting the Convention on Biological Diversity into practice

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, 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.

We employ 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 conduct comprehensive training on this standard across relevant units. In 2020, we established an additional internal exchange within the Group to ensure continued cross-business alignment and to develop and deliver ongoing training. This keeps the relevant units informed of changes to access and benefit sharing.

Where appropriate, we seek to obtain genetic resources and traditional knowledge with the prior informed consent of the relevant Nagoya Protocol member state. Their use is governed by **mutually agreed terms**. If applicable, for instance when launching a new product, 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 our Group-wide standard are met.

## Sustainable product design in the Life Science business sector

Through our Design for Sustainability (DfS) program, we have developed a comprehensive approach to increasing the sustainability of our Life Science products. The "DfS: Development" program provides our product developers with a **range of tools** that enable them to analyze product impacts in terms of materials used, energy and emissions, water, packaging, usability and innovation, circular economy, as well as supplier- and manufacturing-related issues. 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.

In 2020, we launched the **new version** of our "DfS: Development" program. It comprises additional criteria and a new scoring system that helps our development teams to better address and minimize negative product- and supply chain-related factors and enables us to improve our communication of product sustainability credentials to our customers. We will progressively deploy these new elements across our organization.

## Green Chemistry assessment tool

Through our "DfS: Re-Engineering" initiative, our Life Science researchers are developing innovative solutions in line with the 12 Principles of Green Chemistry developed by chemistry professors 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 of "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 50 products.

The customer-facing version of DOZN™ 2.0 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. Since its introduction in 2019, approximately 500 users worldwide have registered to utilize it.

In 2020, we established partnerships with universities in the United States aimed at applying the DOZN™ tool in both virtual and in-lab chemistry curricula. Using DOZN™ in an academic setting yields many benefits. Firstly, it increases the overall accessibility and tangibility of Green Chemistry and its principles. Secondly, it provides a practical opportunity to calculate scores for chemical products and processes and further reinforce learning while highlighting the importance of sustainability in the minds of future scientists.

As of December 2020, more than 1,100 greener alternatives had been made available across our platform of solutions.

## 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 use **non-food, renewable resources**, making them more environmentally sustainable. 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. We were awarded € 12 million towards building a new Cyrene™ production facility in Europe by the EU research and innovation program Horizon 2020. As part of the project, we are committed to developing new applications for Cyrene™.

Beyond this initiative, we also continue to partner with leading academic institutions in order to develop innovative products that enable us to expand our green solvents portfolio.

## Sustainable laboratory 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 with previous systems, this system and its purification cartridges are 25% and 33% smaller, respectively, helping to cut down on the amount of plastic used.

## Less plastic in cell culture creation

Our eco-friendlier alternative to our Stericup® sterile filtration system, the Stericup® E, allows our customers to connect the bottle containing the sample being filtered directly to the Stericup® E filtration unit, thus avoiding the use of a plastic funnel. Depending on the product version, the Stericup® E can **reduce the amount of plastic** used by up to 48% and 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 $CO_2$ emissions during transportation. It also takes less space to store the product at our distribution centers or at customers' facilities, while furthermore reducing the volume and cost of waste disposal (including biohazardous waste) for our customers. Taking the entire life cycle into consideration, this approach can reduce the global warming potential of the product by up to 46%. Stericup® E was recognized as "New Product of the Year" at the 2020 BIG Awards for Business.

## Innovative single spin purification kits

Traditional DNA and RNA purification uses silica membrane columns to isolate nucleic acid from cell, tissue, blood, and other sample types. DNA or RNA are bound to silica using high concentrations of chaotropic salts. These bind-wash-elute methods usually require multiple wash and spin steps. In 2020, we launched our GenElute™-E kits, which do not contain any chaotropic salts, organic solvents or EDTA, resulting in improved performance in downstream applications. Also, the kits align with both the "Prevention" and "Designing Safer Chemicals" principles of the 12 Principles of Green Chemistry. They offer several **sustainability benefits**, such as a 55% reduction of plastic consumables (tubes, pipets, tips) and the avoidance of hazardous liquid waste compared to silica-based kits. These kits also adhere to the principles of SMASH Packaging, our global strategy to reduce the environmental impact of our packaging.

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

## Colloidal silica

Over the past decade, our semiconductor materials customers have been increasing their efforts to use more environmentally sustainable materials in their chip manufacturing, while simultaneously improving the performance of their computer chips at lower costs. We have responded to this challenge by developing **next-generation colloidal silica products** using at least 30% less colloidal silica. This reduces the volume of product needed, which in turn shrinks our environmental footprint.

We successfully launched a next-generation product that meets our customers' technical and commercial targets, thereby reducing the number of shipping containers used for this product line by approximately 180 units annually. We also optimized our own production process, lowering process water consumption by over 53 million liters compared to our standard products. The availability of these next-generation colloidal silica products in concentrated form means that our customers are able to reduce their process waste treatment and have a smaller number of product containers requiring disposal.

## 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 is classified as an SVHC (Substance of Very High Concern) under the European Union's REACH regulation. We are continuously working on developing **new cleaning chemistries** and launched several new products in 2020. By designing custom solvent systems for our customers' cleaning applications, we help avoid hazardous chemistries while also reducing the volume of material used and waste generated.

## Switchable windows

Windows that can be darkened within a matter of seconds are possible, enabled by eyrise®, our liquid crystal window (LCW) technology. These darkened windows regulate the heat generated by direct sunlight. 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. In addition, the people behind these

windows feel more comfortable and work more efficiently thanks to the positive effects of natural daylight. To assess societal impacts, we have developed the Sustainable Business Value method. More information can be found here.

## Shifting to more natural-based 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. At the end of 2020, 78 of our cosmetic pigments and active ingredients had been certified to Ecocert's COSMOS standard for organic and natural cosmetics. We had also obtained **halal certificates** for over 90% of our cosmetic products, including a significant proportion of the pigments we produce in Gernsheim (Germany) and Savannah (Georgia, USA) by the end of 2020.

## Alternatives to microplastics in cosmetics

Functional fillers play a crucial role when it comes to the look, feel and quality of cosmetics. 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. We are working to reduce the amount of material we use while also employing more eco-friendly materials. Furthermore, we help our customers take a more sustainable approach to recycling or disposing of 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 work to make it as sustainable as possible. With more than 300,000 products in our Life Science portfolio – ranging from biochemicals to lab chemicals, 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 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

Based on these goals, we have defined targets for the years up to 2022. They address the development of new product packaging and the improvement of existing product and distribution packaging.

New product packaging is where we can achieve the greatest impact. Our approach consists of implementing **new standards and guidelines** that development teams can apply to create more sustainable packaging. Going forward, we will assess the sustainability characteristics of new product packaging based on our Design for Sustainability scorecard, which was redesigned in 2020.

Our specialty gas and thin films businesses in Performance Materials focus on product packaging that performs well in terms of transportation and handling safety. When introducing new packaging, we use a process that includes a safety review, evaluating package specifications and sizes, shipment frequency, route, carriers, emergency response capabilities, and elements of safety in the supply chain. All product containers undergo a review for chemical compatibility, purity, leak-tightness, and regulatory compliance. The presence of specific hazards and specific container sizes can necessitate a more detailed risk assessment.

## Making product packaging more sustainable: Life Science

Within the scope of our SMASH Packaging sustainable packaging strategy, we are pursuing a number of projects for the Life Science business sector:

### How product design affects packaging: ZooMAb®

Most traditional antibody products need to be shipped at temperatures between 2°C and 8°C, using specific insulated shipping containers with wet ice bricks. This results in high packaging material consumption and transport emissions. Our ZooMAb® antibodies were developed as a freeze-dried product, giving them improved ambient shipping capabilities and storage stability. This makes it possible to eliminate the use of polystyrene coolers and ice bricks, resulting in significant packaging weight reductions for product shipments. Based on current projections, this will allow us to avoid the emission of 75 metric tons of $CO_2$eq per year by 2025.

### Shrink: How we minimize the amount of packaging

We seek **eco-friendly alternatives** to ship our products safely, which is why we partnered with a biotech company and jointly developed 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 in the corrugated cardboard used, which translates to a 17% decrease in greenhouse gas (GHG) emissions throughout the life cycle of the packaging materials. In 2020, we saved around 12 metric tons of corrugated cardboard. Moreover, our customers require 70% less time to open and then dispose of the packaging.

Our distribution teams in Germany and India continue to benefit from optimization projects that we conducted in 2019. At our distribution center in Darmstadt (Germany), we reduced the grammage of kraft paper used as packing material from 100g/m$^2$ to 80g/m$^2$. This initiative allows us to save 14 metric tons of paper annually while maintaining the **same level of performance** in protecting our products.

## Secure: How we are moving towards zero deforestation

A large proportion of our packaging consists of fiber derived from wood. As part of our SMASH Packaging strategy, we have set a goal that none of our wood or fiber-based packaging materials contribute to deforestation.

We assess the practices of our suppliers and the characteristics of our packaging annually in order to measure our progress towards our zero deforestation ambitions. This also enables us to identify opportunities to increase the volume of recycled material and the percentage of packaging we use with **sustainable forestry certifications,** which are awarded in line with sustainability standards developed by the Forest Stewardship Council (FSC), the Programme for the Endorsement of Forest Certification Schemes (PEFC) and the Sustainable Forestry Initiative (SFI).

In 2020, we collected information from our strategic suppliers who represent 85% of our fiber-based packaging materials spending. Overall, by volume, around 80% 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. We have also initiated several projects to obtain sustainable forestry certification for a further 1,000 metric tons of our corrugated and paperboard packaging.

## Switch: How we substitute plastics

In the past, we used insulated containers made of expanded polystyrene (EPS) for the shipment of our chemicals in glass bottles and 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. Our goal is to **reduce our use of EPS by 20% by 2022**.

We are replacing EPS wherever possible with molded components made of cellulose and recycled paper pulp. Our molded pulp components can be easily recycled with other paper materials and **compacted together** for storage and transport. 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.

In 2020, we began implementing an alternative cooler at one of our distribution centers in the United States. This cooler is made from renewable resources and is certified as recyclable with corrugated materials. We use it to ship products with wet ice at temperatures of 2°C to 8°C. We plan to progressively deploy these new coolers in our key North American distribution centers.

Aqueous solutions are usually supplied in plastic bottles. We use Titripac® because it offers an eco-friendlier alternative. The cardboard carton and plastic liner with an integrated withdrawal tap have made the packaging lighter and more recyclable. Since the withdrawal tap protects the product against contamination, contents can be used to the very last drop. This helps reduce chemical waste. In 2020, our products sold in Titripac® 10L packaging configuration allowed to avoid 16 tons of non-renewable packaging materials, resulting in a reduction of 75 tons $CO_2$eq emissions across the life cycle of the packaging compared to 1L plastic bottles.

## Save: How we maximize recycling of packaging

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 2020, this amounted to approximately 8,000 boxes that were reused at least once, making it possible to save 1.8 metric tons of EPS.

## Expanding product recycling

In cooperation with a waste management company based in Massachusetts (USA), we offer a comprehensive recycling program to our Life Science customers in the United States. Product waste from research labs and biopharmaceutical manufacturing operations is collected, sanitized and **recycled into plastic lumber**. This material can be used in many industries, such as landscaping, transportation and marine construction.

We continue to expand this program throughout the United States while exploring new options and recycling technologies in other regions such as Europe and Asia. It now serves 14 major biopharma manufacturing customers. Our goal was to recycle 5,000 metric tons of single use plastic through the program by 2020. Since launching the program in 2015, we have recycled more than 5,200 metric tons, exceeding our goal and avoiding the emission of approximately 3,385 metric tons of $CO_2$eq.

## Making product packaging more sustainable: Performance Materials

Our Performance Materials business sector uses a variety of packaging types, each tailored to the specific needs of the individual business fields and with its own unique sustainability characteristics.

### Reusable packaging

Packaging for our specialty gas and thin films products is designed to be reused. Reusable packaging types include various sizes of cylinders and tube trailers for bulk specialty gases, along with smaller stainless steel and quartz containers for thin films. Once our customers have used the product within the container, the spent containers are returned to our production facility for cleaning, refurbishment and refilling. This cycle greatly reduces the number of containers to be disposed of. It diminishes the demand for construction of new containers and the subsequent resource needs, thus moving us **closer to a circular economy**.

### Recyclable packaging

For large quantities of products in our planarization business, we use totes for packaging. Totes are typically constructed of high-density polyethylene. One of our main tote suppliers has a recycling program in place that our customers can also use. Each tote from this supplier has a return ticket attached to it, and the supplier picks up the used tote so that its parts may be reused or recycled.

# Health for all

## Global strategy

At least half of the world's population still does not have adequate access to health. We are striving to make health solutions affordable and accessible, 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 overarching aim is to create a healthier future for all. We use innovation in science and technology to also 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** focuses on the elimination of schistosomiasis and malaria as public health problems, and the prevention and control of non-communicable diseases, such as diabetes and hypertension in low- and middle-income countries.

The strategy is designed to overcome access barriers for underserved populations and communities in those countries in an economically viable and sustainable way, thereby creating shared value. For us, this means developing business models that increase the value and competitiveness of our company by **solving unmet health needs** and strengthening local health systems.

We follow three core operating principles:

- **Developing innovative solutions:** We play a leading role in the elimination of schistosomiasis and we create new, integrated drugs, diagnostics, technology, and vector control solutions for schistosomiasis and malaria.
- **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 opportunities based locally.
- **Creating business opportunities via a shared value approach:** We help to sustainably improve the health of underserved populations using our portfolio from across all three of our business sectors.

Using focus programs to address our priority areas, we aim to play a key role in improving health as a leading and reliable partner. In particular, by building capacity across the value chain, we intend to strengthen healthcare systems, making them more resilient to health crises.

Our **Access to Health strategy** comprises four 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 our R&D portfolio of projects by developing and providing access to innovative products and technologies 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 assistance also includes addressing challenges regarding pricing and intellectual property. Furthermore, we are working on innovative and sustainable access paths for health solutions to fight NTDs. For instance, we aim to ensure the affordability of our new pediatric drug to treat schistosomiasis in children under six years old.
- **Awareness**: We empower healthcare professionals, communities and patients to make informed decisions and 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 enable localized health solutions. We also strive to strengthen our supply chains to 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 leads the implementation of our strategy regarding innovative solutions for infectious diseases and for global access to 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. By **delivering high quality health solutions**, we seek to create long-term value for the business, our stakeholders and society.

Our Schistosomiasis Elimination Program guides our efforts to eliminate schistosomiasis in **close collaboration with external partners**, such as the World Health Organization (WHO). Since 2007, we provided more than one billion tablets to WHO for the treatment of schistosomiasis. The donation is a major part of the integrated and coordinated approach we adopt towards treating and eliminating schistosomiasis.

Our Global Health Institute translates science, technology and digital approaches into integrated solutions to strengthen health systems. This means we develop and implement a portfolio of projects for transformative treatments, diagnostics, technologies, and preventive measures against infectious diseases, especially schistosomiasis and malaria. The institute also engages in science and technology activities with local experts. It operates as a social business enterprise to deliver new solutions for the most vulnerable members of society.

Our Access to Health strategy aims to address the health system gaps that prevent underserved populations from receiving healthcare. We coordinate with multiple partners to identify and develop solutions, such as sustainable access business models. This approach applies to neglected and non-communicable diseases in low- and middle-income countries.

## Our commitment: Providing a solid basis for access to healthcare

Our commitment to expanding access to healthcare is summarized in our Access to Health Charter. It sets out the following guidelines on:

- Our approach
- Pharmaceutical product donations
- Fake medicines
- R&D for infectious diseases
- Pharmaceutical product pricing
- Intellectual property rights

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 in low- and middle-income countries, ranging from Research & Development and Intellectual Property sharing, to capacity building and donations. We use the ranking to inform and guide our access to health strategy and approach.

The Foundation revised the Access to Medicine Index methodology in 2020. The latest Index was published in January 2021. We came in eighth place (previously fourth place). Our position among the top ten confirms our continuous commitment to improving sustainable access to high-quality solutions for all. The ATM Index for 2021 **recognized us for our performance in Research & Development**, where we ranked fifth. Our leading role in Intellectual Property sharing also received accolades.

We remain committed to the objectives of the London Declaration on Neglected Tropical Diseases (NTDs), through which participating companies, governments and private organizations promise to help control and ultimately eliminate the top ten most prevalent NTDs. We are engaged in the fight against schistosomiasis.

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.

## Fighting the global Covid-19 pandemic

The Covid-19 pandemic is having a substantial impact on low- and middle-income countries. The health systems in several of these countries are already struggling with the dual burden of infectious diseases such as schistosomiasis and malaria, and the rising incidence of non-communicable diseases such as diabetes and hypertension.

Our Global Health unit spearheads a considerable variety of initiatives to combat the virus and its effects on the world's most vulnerable countries. These efforts include direct measures, such as the donation of masks and protective equipment to Cameroon, Ethiopia and Tanzania, as well as more sustainable initiatives, e.g. in Ghana and Senegal, that **strengthen the overall resilience of health systems** against the current and future health crises. Read more about our contribution to this global challenge here.

## Partnering to build the resilience of health systems

The private sector is a critical partner in responding to global health threats, such as the current Covid-19 pandemic. Beyond developing novel health solutions, we must ensure that health systems are prepared to address emergencies effectively and deliver care to people in need. We aim to sustainably strengthen prevention, preparedness and resilience of health systems in low- and middle-income countries. Our efforts entail the following aspects:

- **Employing innovative technology** targeted to prevent schistosomiasis and malaria and to improve local health-related capabilities
- **Increasing country crisis preparedness** by creating scientific and healthcare workforce competencies and capacity through a network of experts
- **Optimizing the monitoring and evaluation** of health initiatives at country level through data-processing and digitalization

We apply this approach in our R&D collaborative programs that build local expertise and capacity, as well as in our health educational initiatives with our local partners, primarily in and for several African countries.

Learn more about our focus programs here.

## Engaging stakeholders

Partnerships and dialogue are vital to improving access to healthcare. 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

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 and the Swiss Alliance against Neglected Tropical Diseases.

The Access Dialogue Series organized by our company is a multi-stakeholder platform for sharing information and **exchanging best practices** on broadening access to healthcare. The shared ideas inform and drive our access strategy, plan of action and engagements.

## Discussions at a global level

In 2020, we continued to engage with key stakeholders to advance global health discussions and address shared challenges such as infectious diseases. We also deepened **collaborations with the scientific community** through publications and patents as well as by taking on active roles at international, largely virtual, events.

For example, we were panelists in a series of World Health Organization webinars on neglected tropical diseases that flanked the publication of the new NTD roadmap. The webinars were devoted to the topics of innovation and the power of partnerships. We also engaged into the annual meeting of the Coalition for Operational Research on Neglected Tropical Diseases (COR-NTD), fulfilling our role as a leading and reliable partner in the fight against NTDs by providing scientific contribution to the discussions. We were on stage at the Geneva Health Forum to talk, together with our partners, about open innovation to combat infectious diseases.

# Focus programs

Neglected tropical diseases occur almost exclusively in impoverished populations in low- and middle-income countries. Hardly known in industrialized nations, they attract little public attention or research funding. One example is schistosomiasis. Our aim is to eliminate this neglected disease as well as other, more familiar infectious diseases such as malaria.

## Strategy for preventing and treating infectious diseases

Our strategy focuses on the elimination of schistosomiasis and malaria. To implement our strategy, we develop and provide medicines, improve diagnostics, counter disease transmission, increase disease control, expand access to healthcare, conduct awareness programs, and strengthen local health systems.

## Our fight against schistosomiasis

Schistosomiasis, also known as bilharzia, is a tropical disease caused by parasitic worms and one of the most prevalent parasitic infections in Africa, placing a significant burden on public health and the local economies. The disease affects almost 240 million people worldwide, with more than 90% of cases occurring in Africa. An estimated **200,000 people** die every year from long-term effects of schistosomiasis, such as liver and kidney infections, bladder cancer, genital schistosomiasis, and anemia. School-aged children are particularly vulnerable to the disease and often suffer from the long-term consequences and complications, including anemia, stunted growth, and learning difficulties.

Our ultimate aim in all our schistosomiasis-related work is to eliminate the disease as a public health problem. To achieve this goal, we adopted an integrated schistosomiasis strategy that we are implementing in close collaboration with multiple partners worldwide. The approach focuses on five pillars to ensure progress:

- **Treatment:** We donate up to 250 million tablets of praziquantel per year to endemic countries in partnership with WHO. Nearly 50 years after its development, praziquantel still remains the standard of care for the effective treatment of schistosomiasis around the world.
- **Research and Development (R&D):** We advance R&D to support the global fight against schistosomiasis. In particular, we drive collaborative R&D programs for innovative treatments, including a new, pediatric formulation of praziquantel for children under the age of six, more sensitive diagnostics, and vector control methods. We also strengthen research expertise and capacity through collaborations with local institutions in endemic countries.
- **WASH** (Water, sanitation and hygiene)**:** Since schistosomiasis is transmitted through contaminated water sources, we also support WASH projects that aim to prevent transmission of the disease through the provision of sanitary infrastructure and new access-to-water technologies.
- **Health education:** We invest in education and behavior change initiatives that raise awareness of the causes and dangers of schistosomiasis and teach people how to prevent it.
- **Advocacy and Partnerships:** Collaborating with partner organizations for our programs and initiatives, as well as with the wider stakeholder community through the Global Schistosomiasis Alliance (GSA), we are accelerating the progress towards schistosomiasis elimination.

## 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 almost 70% occurring in children under the age of five. Over 90% of cases and of deaths occur in Africa. Every two minutes, a child dies from the disease.

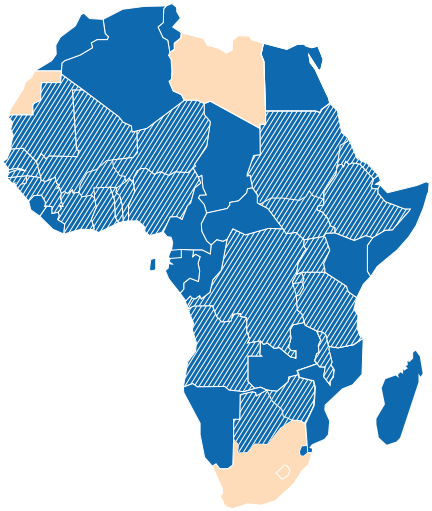
There is a need for new products to overcome the problem of increasing drug resistance and to achieve our goal of elimination. Through our "As One against Malaria" program, we are helping to deliver integrated and sustainable health solutions entailing treatments, diagnostics and prevention methods to fight malaria in endemic countries.

## Schistosomiasis: Over one billion tablets donated

As part of our long-standing partnership with WHO, we are committed to donating praziquantel tablets annually. To date, our tablets have been distributed in 47 endemic African countries to treat school-aged children. In 2020, we donated around **226 million tablets** for distribution in 30 countries, 27 of which are in sub-Saharan Africa. Moreover, we maintain our commitment by ensuring that we have sufficient production capacity to manufacture up to 250 million tablets a year.

## Countries that have received donations of praziquantel tablets

Since 2007, we have donated over **1.3 billion** tablets of praziquantel, which is enough to treat around 520 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 2020.
- Countries that have received no donated tablets to date.

* Launch of our Praziquantel Donation Program.

### Schistosomiasis health education project

In 2020, we extended our partnership with the NALA Foundation for another three years. This joint health education project focuses on southwestern Ethiopia and is aimed at promoting long-term behavioral change in the drive to **eliminate schistosomiasis** and other neglected tropical diseases. WASH measures play a crucial role in these efforts. Our local partners conduct training sessions in schools and among local communities. The majority of participating schools have established hand-washing stations: Safe water and latrines are now available in these stations throughout the school year, and teachers also report major improvements in students' personal hygiene and general levels of cleanliness in the schools.

### The GSA: A central platform in the battle against schistosomiasis

The Global Schistosomiasis Alliance (GSA) is a coordinated, multi-sectoral effort to combat the complex disease schistosomiasis. The GSA continues to help eliminate the disease through its working groups and to raise awareness through coordinated campaigns. In November 2020, the World Health Assembly endorsed a new WHO road map that "sets global targets and milestones to prevent, control, eliminate and eradicate 20 neglected tropical diseases and disease groups" for the time period from 2021-2030. The GSA contributed to WHO consultations during the roadmap conception phase.

### Partners in schistosomiasis research

Over time, we have developed a portfolio of R&D projects on schistosomiasis. These include making a new child-friendly pediatric formulation of praziquantel available 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 new technologies for safe water access and approaches for vector control.

If left untreated in children of **preschool age**, schistosomiasis can have long-term effects such as anemia, stunted growth and impaired learning. It can seriously affect their lives and potentially cause chronic diseases, including bladder cancer or female genital schistosomiasis. Together with the Pediatric Praziquantel Consortium, we develop, register and provide access to the pediatric formulation of praziquantel. Consortium partners include both public and private sector representatives from developed and endemic countries to ensure that the strategy and implementation meets local requirements and needs.

The program is currently in Phase III clinical development. The pivotal trial is designed to evaluate the efficacy and safety of the new **pediatric praziquantel ODT (orodispersible tablet) formulation** in children three months to six years of age who are infected with schistosomes. The trial is taking place in Côte d'Ivoire and Kenya, 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 and is designed to support registration and market authorization for this important new treatment for very young children. Due to the Covid-19 pandemic, the study needed to be paused in line with national restrictions.

Meanwhile, together with international key stakeholders, we are defining an innovative procurement access path, including local manufacturing, to ensure the future affordability, availability and adoption of the new medicine.

Praziquantel is an effective and well-tolerated drug, but it is not effective in all developmental stages of the parasite. We continue to collaborate on research activities with many partners. 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 and Tropical Medicine. We have since worked to identify potential new candidates for preventing infection and curing patients affected by schistosomiasis. In 2020, we identified a lead molecule for further

development to potentially serve as an alternative to praziquantel.

The need for **more sensitive diagnostics** is crucial in the fight against schistosomiasis. Since early 2019, we have been collaborating with the Foundation for Innovative New Diagnostics (FIND) to develop a sensitive rapid diagnostic test (RDT) to improve mapping and case detection for schistosomiasis. Building on the prototype, a consortium of partners was formed in 2020 to accelerate the development.

In 2020, we entered into a strategic alliance with Janssen Pharmaceuticals Inc. to develop an artificial intelligence-based diagnostic tool to improve the diagnosis of neglected tropical diseases, schistosomiasis and soil-transmitted helminthiasis (STH).

Beyond these efforts, we continue 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 an access-to-water program in Senegal. In partnership with the Access to Water Foundation, we intend to provide innovative safe-water platforms to local communities and health centers, in order to improve sanitation and reduce exposure to parasites. Details can be found under Community Engagement.

We also continue to implement research and advocacy 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 supported a clinical trial to **optimize therapeutic treatment for women** suffering from FGS in Madagascar, with results expected in 2021.

## Malaria: Developing new therapeutic solutions

As part of our "As One against Malaria" program, we are developing a new drug (M5717) for the prevention and treatment of malaria. In 2020, we initiated a Phase Ib clinical trial (for prevention) to test efficacy of the compound in the liver/first stage of infection in healthy volunteers.

The World Health Organization (WHO) recommends that new drug therapies against malaria should include a combination of two active principles with different mechanisms of action, in order to **prevent the emergence of resistance**. We have therefore initiated the discussions with other partners to evaluate drug candidates that can be combined to initiate the next clinical development phase for treatment and/or prevention.

Our strategic collaboration with the University of Cape Town in South Africa and the Medicines for Malaria Venture continues its drug discovery activities with the aim of identifying new therapeutic solutions for malaria and building research capacity in and for Africa. Together with our partners, we have identified promising drug candidates that are progressing into preclinical stage.

## Preventing and controlling malaria transmission

Preventive methods, such as the use of insect repellents, form part of our strategic toolkit to combat malaria. We are testing our insect repellent IR3535®, which is already used for protection against the bites of insects and ticks that can transmit diseases such as Lyme, Zika, Dengue, and Chikungunya.

In a three-phase program defined in 2020 and implemented in Ghana, we are evaluating a **new formulation technology** for long-lasting efficacy of IR3535® – through laboratory tests and in a community-based study. Positive results would enable IR3535® to serve not only as a preventive method for personal use, but also, on a larger scale, as a vector control method to support population-based National Malaria Control programs.

In partnership with local institutions in Africa, we are improving health worker capacity in Ghana in using microscopy to detect cases of malaria and other diseases that can be diagnosed via blood samples even faster. In addition, we have established PAVON (Pan-African *Vivax* and *Ovale* Network), an African network of centers of excellence for the epidemiological surveillance and scientific research on malaria. We involved over ten African countries in the PAVON project in 2020.

# open innovation sharing

We consider it our responsibility to improve global access to healthcare through our technological advances. We support a reliable and transparent legal framework for intellectual property that allows sustainable investment in research and development.

## Our approach to sharing and protecting intellectual property

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 indicate that between 90% and 95% of the pharmaceutical products on the WHO Model List of Essential Medicines are off-patent.

We support a sustainable approach to intellectual property that drives innovation and enables access to health. We have made a commitment to refrain from enforcing patents in a majority of 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 the publicly accessible database Pat-INFORMED. 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, and 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.

We provide access to patent information through our initiatives and partnerships. Through our open innovation research projects, we give access to parts of our chemical compound libraries. We aim to accelerate collaborative research programs that develop novel R&D platforms in search of new active substances.

## How we organize access to our intellectual property

The Open Innovation initiative of our company is a collaborative and cross-functional effort. We aim to accelerate early discovery in diseases with high unmet needs and outside of our expertise through intellectual property sharing. 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 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. This agreement extends the deadline for least developed 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 acts as a global gateway to medicine patent information. It offers tools and resources that help determine the existence of patents relevant to products sought by national and international drug procurement agencies, making it easier for them 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 on small-molecule drugs for cardiovascular diseases, diabetes, hepatitis C, HIV, cancer, and respiratory disorders, as well as any products on the WHO Model List of Essential Medicines that are not within these therapeutic areas.

## Open innovation collaboration through WIPO Re:Search

We continue to take part in the WIPO Re:Search Consortium co-led by Bio Ventures for Global Health and WIPO, whose mission is to accelerate the discovery and development of medicines, vaccines and diagnostics. In 2020, we renewed our commitment and contribution until 2022. The initiative aims to create **new solutions** for people affected by neglected tropical diseases, malaria and tuberculosis.

In 2020, we began implementing a collaboration agreement with Griffith Institute for Drug Discovery, Griffith University, Australia. For this collaboration, we have shared our chemical library for screening against leishmaniasis, Chagas disease and African sleeping sickness.

## Creating research opportunities

In 2020, we launched the Open Global Health Library. It publicly shares 250 compounds from our proprietary chemical library that may be used for infectious diseases research, including antimicrobial resistance, with the not-for-profit R&D organization GARDP.

Additionally, our "Open Lab" initiative allows academic guest scientists to bring their own research and work side-by-side with our researchers in our laboratories, gaining access to our state-of-the art science and technology.

## Drugs for Neglected Diseases initiative

Under the leadership of the Drugs for Neglected Diseases initiative (DNDi), along with other pharmaceutical companies, we are involved in the Drug Discovery Booster project to discover novel medicines against neglected tropical diseases.

More information on our collaborations regarding open innovation for global heath can be found on our website.

# 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. Efficient supply chain management and local manufacturing are crucial in order to achieve this goal.

## 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 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 strengthen supply chains in low- and middle-income countries and 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 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 enable us to track our inventories and current deliveries as well as predict expected demand for medicines.

## How we organize our supply chains

Our Global Planning unit is responsible for our medicine supply chains and is part of Biopharma Supply Network Operations within our Healthcare business sector. Global Planning collaborates with supply chain representatives from the markets 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. In addition to our RFT concept, 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 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.

## Ensuring supply during the Covid-19 pandemic

We ensured that all our manufacturing sites could continue operations during the Covid-19 pandemic. No business interruptions occurred at our facilities. They were able to carry on with medicine production thanks to sufficient stocks of active pharmaceutical ingredients. We were in constant dialogue with our distribution partners to make sure that we could deliver our goods despite severe transportation constraints.

## Working with partners to achieve more

We store supplier information within a centralized platform, enabling us to exchange information Group-wide and use it for our collaborations and partnerships. This further supports our efforts to organize shared supply chains more efficiently.

## Shared data platform for medicine donations

NTDeliver is a digital information tool for improving transparency in medicine donation supply chains created through public-private partnerships. Deliveries sent by companies that are running donation programs are clearly displayed – from purchase orders made by the World Health Organization (WHO) 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. The tool also features an alarm that informs key stakeholders about upcoming expiry dates of medicines that may still be in their inventory. We deploy the NTDeliver tool to monitor the volumes of schistosomiasis **medicines**.

## Access delivery mentorship

Our partners and stakeholders require support when addressing the critical "last mile" challenge: ensuring that medicines are delivered to the patient. We help build the supply chain capacity of our partners through our access delivery **mentorship** initiative. It comprises a volunteer pool of supply chain experts who share their knowledge and experience. We also collaborate with Business for Health Solutions (BHS) to work with local distributors in Tanzania in order to address their supply and logistics challenges.

Two examples of this successful program can be seen in Tanzania: Bahari, a Tanzanian distributor, recorded a 96% order fulfillment rate (compared with an average of 82% before the project), a 75% faster purchasing time

and a **50% faster delivery time**. Mansoor Daya, a local Tanzanian manufacturer of essential medicines, recorded a 90% reduction in customs processing time, a 100% quality improvement of raw materials, and a 40% improvement in supplier quality and ceased business with predominantly high-risk suppliers due to increased documentation requirements.

## Coalition for better medicine access

We are a member of **CAMP-N**, a coalition of government agencies, private-sector entities, non-governmental organizations, philanthropic foundations, and academic institutions. Together, we are dedicated to increasing access to medicines and health products for non-communicable diseases (NCDs) and reducing the impact of conditions such as diabetes, hypertension, and cardiovascular disease.

In 2020, we joined a technical working group to help develop a demand forecasting tool for medicines and health products used to treat non-communicable diseases in sub-Saharan Africa. We are the only private sector company representative in the cross-sectoral working group. As a next step, we will share the prototype NCD demand forecasting model with country stakeholders for feedback, and test it in Kenya and Uganda, followed by Tanzania.

## Promoting local production

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

## CURAFA™

In 2018, our company established the CURAFA™ initiative to develop a sustainable business model for primary healthcare services. In August 2020, the social enterprise Access Afya took over CURAFA™ and its associated facilities, thus supporting its goal to provide quality-assured, **low-cost microclinics** in underdeveloped areas.

# Prices of Medicines

**Part of the non-financial report**

In OECD countries, pharmaceuticals accounted for between 6% and 35% of total healthcare spending in 2019. 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, fair and sustainable 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 as well as 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. In line with our fair pricing commitment, we also make our products affordable to patients in low- and middle-income countries by participating in government tenders, establishing high-quality affordable brands or branded generics, implementing early access programs and operating patient access programs.

Moreover, we support innovative 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 evaluates market launch prices in coordination with the respective franchises. The team reports directly to a member of our Healthcare Executive Committee. Our local affiliates 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 affordable prices.

## Understanding the effects of Covid-19 on medicine pricing

The pandemic has put a major strain on health systems and treatment payers around the world. In December 2020, we organized a virtual expert roundtable with former payers from Brazil, Germany, Italy, Japan, Saudi Arabia, and the United Kingdom. The objective was to understand the impact of Covid-19 on payer priority, affordability, budget shifting, and resource allocation, in order to identify effective approaches to work in partnership with payers from different markets. Due to the budget constraints caused by the Covid-19 crisis, those payers perceived higher needs in pricing approaches including patient access programs, direct discounts, public-private partnerships and value add services. This is in line with our key pricing initiatives and will help us further reinforce these measures going forward.

## Customer-centric contracting models

We are dedicated to advancing value-based healthcare through pricing and contracting mechanisms that fully comply with all applicable local laws and regulations. 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, Ireland and Germany, we continued with innovative risk-sharing agreements that provide immediate access to Mavenclad® for patients with multiple sclerosis (MS).

We have also established innovative contracting models for our oncology drug Erbitux®, our MS drug Rebif® and our growth hormone Saizen®, to make it easier for patients to obtain access to 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. In addition, we supply products at affordable prices to certain countries in Africa, Asia, Latin America, and the Middle East. In India, we continued to cooperate with public sector representatives, such as Bharat Heavy Electricals Limited (BHEL) and the Oil and Natural Gas Corporation (ONGC), National Thermal Power Corporation (NTPC) and Indian Railways (IR) to offer **discounted prices** for certain general medicine and endocrinology products to patients with a limited ability to pay out of pocket.

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.

## High-quality affordable second brands

For some of our existing brands, we have created high-quality second brands at affordable prices, particularly in countries with a large percentage of patients with very low incomes. In Brazil, 11 of our high-quality products are available at these affordable prices and in South Africa, we also offer Betacor™, a second brand for bisoprolol (Concor®), with a price reduction on all payer formularies to increase access for low-income patients. We have also established new affordable second brands in countries, such as Mexico, the Philippines and Poland.

## Branded generics

We offer branded generics particularly in low- to middle-income countries. We do this together with selected reliable partners with whom we enjoy trusted collaborations. These partners generally have **track records in quality control** and are able to provide products that comply with our high standards. In this way we can better meet the urgent need for affordable, high-quality medicines required to treat endemic diseases. We already have six such products available to patients in low- to middle-income markets, including in Brazil, Chile, Mexico, and the Philippines, and we are currently registering further branded generics to expand this effort to more countries.

## Patient access programs

We operate patient access programs that allow us to offer certain products at affordable prices in several countries. We run patient access programs in countries, such as India, where we offer a patient access program for Erbitux®, providing financial assistance to qualified patients of low financial means for their treatment – in line with applicable local laws and regulations. Every year, we reach over 500 patients through this program. In addition to our oncology initiatives, we also offer such programs for our medicines in other therapeutic areas, such as Rebif®.

## Patient support programs

We provide digital health and "beyond-the-pill" solutions as part of our holistic approach to supporting patients, caregivers and physicians. This approach enables health professionals to **manage conditions more effectively**, thus helping to generate improved patient outcomes. We offer a customized medication and adherence program for cardiometabolic patients in Brazil and Russia, registering significant improvements in the rates of adherence to the treatment. We also support prediabetic patients with digitally enabled, tailored and evidence-based lifestyle intervention programs, such as GlycoLeap in the Asian-Pacific region and Virgin Pulse (previously Blue Mesa Health) in Latin America.

# Health awareness

Many people have health conditions but do not realize it. This results in individuals either not receiving treatment or not receiving it in time, even though effective medicines and therapies are available. Therefore, we conduct global campaigns to raise awareness and improve knowledge of diseases in accordance with our expertise. Ultimately, healthcare professionals and patients can make informed decisions only if they have proper knowledge and the right information about symptoms and treatment options.

## Our approach to raising health awareness

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

For example, we 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 business units. Our various business units plan and implement our awareness projects either on a global level or through our 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. 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 are aligned with **our core competencies**, expertise and experience along the health value chain. These include cancer (specifically colorectal as well as head and neck cancer), thyroid disorders, diabetes and multiple sclerosis in particular. We also conduct awareness campaigns in low- and middle-income countries, mainly focusing on the neglected tropical disease schistosomiasis as well as other, more familiar infectious diseases, such as malaria.

## Awareness and knowledge transfer for thyroid disorders

In May, we supported International Thyroid Awareness Week (ITAW) for the 12th consecutive year. The 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.

This year's ITAW was dedicated to the theme "mother and baby", with a focus on mothers learning how to protect themselves and their babies from any potential complications related to thyroid disorders. The campaign reached people in many countries via virtual events and press articles. On social media, we generated over 5.7 million views and 34,000 likes. In addition, our symptoms checker received almost 300,000 views and over 166,000 tests were carried out.

## World Cancer Day

February 4 marks World Cancer Day, an annual initiative led by the Union for International Cancer Control (UICC). Building on the theme "I Am and I Will", we created a compelling campaign to communicate our ongoing commitment to transform cancer care. Our campaign focused on how personal contributions make a collective impact on the evolution of oncology care. It was supported by more than 240 images from 20 countries, receiving over 400,000 views on social media.

## World Multiple Sclerosis Day

We participated in World Multiple Sclerosis Day on May 30 – an annual awareness day by the MS International Federation (MSIF). This year's official theme was #MSConnections and it focused on building community connection, self-connection and connections to quality care while **challenging the social barriers** that leave people affected by MS feeling lonely and socially isolated.

For World MS Day, we collaborated with Twitch, the world's leading service and community platform for multiplayer entertainment. Through an eight-hour livestream with Twitch influencers and special guests, we virtually connected people affected by the disease and raised awareness among young gamers. The livestream was also used to raise money for MSIF's "Informed Decision Making" program, which helps create digital resources so that people with MS have access to the best possible information on the disease for free.

## World Diabetes Day

The theme of this year's World Diabetes Day was "The Nurse and Diabetes": As the name suggests, the goal was to highlight the incredible work carried out by nurses. We also extended our awareness-raising activities to prediabetes, the lesser-known precursor to type 2 diabetes. We partnered with social media influencers to launch our social campaign **#AreYouReadingTheSigns**. The aim of this campaign was to highlight the importance of individual responsibility when it comes to health as well as the significance of lifestyle changes in diabetes and prediabetes management. We launched our prediabetes initiative one day before World Diabetes Day in order to raise awareness of prediabetes and inform the public of the risk factors for developing the condition. Ultimately, we wanted to encourage people to use our prediabetes symptom checker to understand their level of risk and take appropriate action if necessary.

## Fertility awareness week

European Fertility Week (EFW) in November 2020 provided an opportunity for our company to increase awareness of in vitro fertilization and the patient journey. Using our social media channels, we drew attention to the importance of providing equal access to infertility treatment across Europe and relying on medical guidance to provide safe, efficient and non-discriminatory treatment to all who need it.

## Awareness campaigns focusing on low- and middle-income countries

We use global health-related campaigns to foster awareness of diseases, such as schistosomiasis and malaria as well as non-communicable diseases with high prevalence in low- and middle-income countries. The campaigns are part of our commitment to improve health in those countries.

Global health-related awareness campaigns in 2020 included:

- World NTD (Neglected Tropical Diseases) Day (January 30)
- World Water Day (March 22)
- World Health Day (April 7)
- World Malaria Day (April 25)
- World Mosquito Day (August 20)
- World Water Week (August 23-28)
- World Science Day (November 10)
- Universal Health Coverage Day (December 12).

## Purpose-driven initiatives

Healthy Women, Healthy Economies and Embracing Carers™ are two initiatives that we are using to promote awareness of issues that go beyond the patient. The interconnectedness of both initiatives is rooted in shared themes and goals. In particular, the Covid-19 pandemic demonstrates the **critical importance of caregiving** as a part of the healthcare ecosystem and the significant role that women play as caregivers: 70% of caregiving hours globally are provided by women and girls. Effective caregiving is intrinsically linked to the health, well-being and prosperity of women. Through these initiatives, we aim to both promote women's empowerment and expand access to healthcare.

## Healthy Women, Healthy Economies

To empower women to overcome the challenges of communicable and non-communicable diseases and rise to their economic potential, we are committed to the Healthy Women, Healthy Economies initiative. Within the scope 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, thereby supporting their participation in the economy.

In 2020, we continued our partnership with the "March of Dimes" initiative in a three-year collaboration supporting "Healthy Babies, Healthy Business", a program that provides health benefits for mothers and promotes family-friendly work environments. As part of this partnership, we support the Center for Social Science Research. In 2020, we helped fund two U.S.-focused studies on issues such as access to healthcare and birth inequities.

Through our partnership with the Wilson Center, we highlighted the disproportionate **economic impact of Covid-19** on women. This included a podcast on the pandemic, caregiving and women's leadership, featuring Belén Garijo, Vice Chair of the Executive Board and Deputy CEO of Merck KGaA, Darmstadt, Germany, and a webinar with expert panelists.

## Embracing Carers

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 frequently 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 challenges faced by caregivers, prompt stakeholders to show deeper engagement, establish **global best practices** and advocacy resources, and endorse the improved integration of carer support.

In 2020, we launched a survey involving 12 countries to explore the unmet physical, economic and emotional challenges carers face amid the Covid-19 crisis. We want to determine how these challenges differ by gender, socio-economic status, length of time as a carer, the types of conditions under which carers are working, and the level of care needed. We aim to use the results from this survey, in conjunction with other secondary research, to increase media attention, raise awareness of these issues and inform calls to action for policy advancements.

# product safety and quality

## chemical product safety

**Part of the non-financial report**

Many of our chemical products have intrinsic hazardous properties. We are working to minimize the risk to human health and the environment resulting from their use. National and international regulatory requirements such as laws and guidelines form the basis of our data and documents. Beyond this, we strive to improve our product safety and reduce the environmental impact of our business through innovative solutions and digital communication tools.

### Our approach to safe chemical products

Product safety is one of our top priorities. Starting at the product launch stage, we investigate the potential adverse impacts chemical substances may have.

Along the entire value chain of our products – **from raw materials to manufacture and commercialization** – we provide relevant information on the hazardous properties and related use instructions to allow the safe handling and use of our products, in line with regulatory requirements. We communicate this information mostly through relevant digital channels (Internet, e-mail, mobile apps). Paper safety data sheets are still common in some countries and can also be provided on demand through customer service.

We support developments related to the European Green Deal and are preparing to translate the pertinent elements into a dedicated chemicals sustainability strategy for our company.

### How we ensure chemical product safety

Our Healthcare, Life Science and Performance Materials business sectors have organizational structures in place to implement our product safety strategy for their businesses and customers. This includes registering chemicals, classifying hazardous substances and highlighting risks by means of safety data sheets, labels and digital communications.

Our Corporate Governance function issues **Group policies and standards** as a framework to govern the setup of effective operational processes for product safety, hazard communication and chemicals regulations compliance throughout our various business sectors. Our Group Product Safety Committee monitors relevant regulatory developments.

This approach also applies to innovative fields of development such as nanomaterials, which we utilize with the greatest care in line with the precautionary principle. Furthermore, our Group-wide Policy for Use and Handling of Nanomaterials provides the necessary guidance on the utilization of this technology.

### Legal requirements and internal guidelines

Through internal guidelines, we define the roles and responsibilities and basic processes required to **comply with national and international regulations**. We have endorsed general voluntary commitments of the chemical industry, such as the Responsible Care® Global Charter.

The legal requirements relevant to compliance with chemicals regulations are mainly related to hazard communication as well as local and regional chemical registration activities. These requirements are expanding globally, with a growing number of countries adapting local rules to existing regulatory frameworks such as REACH. We are well-placed to comply with emerging regulations of this kind in important markets such as China, India, Japan, South Korea, and Taiwan. Using the Globally Harmonized System (GHS) for hazard communication allows us to streamline our internal processes and provide consistent, harmonized and high-quality information to our customers.

Our **worldwide network of regulatory experts** in all three business sectors continuously monitors changes in legal requirements and scientific developments to stay ahead of trends and best practices.

In 2020, there were two minor incidents of non-compliance with regulations, specifically concerning potential health and safety impacts and the labeling of our chemical products. Neither human health nor the environment were negatively impacted.

### REACH registration

In July 2020, our company signed the Cefic REACH Dossier Improvement Action Plan to review and improve the quality of our registration dossiers. This way, we also keep the information up-to-date and adapt to increasing regulatory requirements.

### Safety analysis during product launch

We believe that product safety starts with development. At an early stage in the product launch process, we analyze innovations in terms of their impact on human health and the environment. In doing so, we can quickly identify any undesirable properties. In line with the applicable rules, we

evaluate the intrinsic hazards of our existing as well as new products to create the relevant product safety information.

## Product safety information

Chemical product safety is all about protecting human health and the environment from negative impacts resulting from the use of chemical products throughout a product's life cycle. To achieve this, we **provide all relevant information to our customers and the public**, raising awareness of the hazards and building understanding of how to mitigate risks and use the products safely.

To obtain all the relevant information on hazard profiles, we utilize **industry standard digital tools** that gather all information available for the substances we use. We then cross-reference this data with local and regional rules to establish the relevant hazard classifications. We publish this information digitally on **country-specific safety data sheets** in multiple languages and on the labels of our products. The data sheets are maintained electronically and updated if there are relevant changes, or during a 3-5 year review cycle. We have automated and standardized the majority of our hazard communication processes.

For products with little information available, we are investigating the feasibility of using alternative predictive, **non-animal testing methods** such as read-across and (Q)SAR. For third-party products, we expect robust product safety documentation from our suppliers, which we feed into our processes or share directly with our customers.

## Helping customers access safety information

To share information with our product users, we employ the latest digital tools and continuously explore new technologies.

Our Life Science customers can access product safety information in their respective language and according to country-specific regulations through a dedicated **mobile app called "My M Safety"** (Android and iOS). The information is retrieved by scanning a bar code on the product label or entering a material number.

Through our ScIDeEx™ web tool, anyone can check whether using a particular chemical is safe within the boundaries of EU REACH exposure scenarios. ScIDeEx™ is based on a full implementation of the ECETOC TRA 3 model for human exposure assessments in industrial and professional settings.

# patient safety

**Part of the non-financial report**

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

## Our approach to ensuring patient safety

Through a rigorous benefit-risk management process, we help to ensure that the benefits of our drugs always outweigh the risks for patients. Every new medicine goes through a series of precisely defined development stages. Before any drug is administered to human subjects, 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 relevant 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 were not detected during clinical development may occur, which is why we continuously monitor and manage the 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 adverse effects in an effort to take appropriate action to minimize and communicate the risks in a transparent way. We always provide healthcare professionals 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 develop and update **educational materials for patients and healthcare providers** to communicate any known and potential risks and ways to minimize them for newly approved products. We assess the effectiveness of these materials in close collaboration with our Benefit-Risk Action team. If required, we adjust the contents of the materials and their distribution and describe the results from the effectiveness analysis in our periodic safety reports and risk management plans. We then submit these to the 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. Our Global Patient Safety unit analyzes all data and reassesses the benefit-risk profile based on these data, where required. We then inform regulatory authorities, healthcare professionals and patients about new risks, additional risk mitigation measures and potential changes **in the benefit-risk profile**.

In order to implement our R&D Strategy 2023, our Global Patient Safety unit in on a journey of transformation. Our vision is to integrate deep knowledge of safety into early decision-making as we evolve to practice predictive safety. As part of our transformation, in 2020 we refined our approach to benefit-risk assessments. We now apply a scoring system based on safety aspects and are using it to prioritize product management; in addition, we are redesigning our pharmacovigilance processes.

Our **Healthcare Quality** unit 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 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 human-related 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, also chaired by Global Patient Safety unit. Important issues may be submitted to the MSEB for final assessment.

## Effects of the divestment of Allergopharma on patient safety

On March 31, 2020, we completed the divestment of our allergy business Allergopharma to Dermapharm Holding SE. We entered into a transitional service agreement with Allergopharma/Dermapharm that defines certain services from us for an interim period after the closing date. One of these transitional services was a Pharmacovigilance Statement of Work (PV SOW), defining the transitional pharmacovigilance services provided by our company until all affected pharmacovigilance activities had been migrated to Allergopharma/Dermapharm on November 30, 2020. This step was achieved one month prior to the scheduled date.

## 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.

In 2020, our Global Patient Safety unit formed a Pharmacovigilance Intelligence Council that focuses on changes in pharmacovigilance legislation and their impacts on our global and local pharmacovigilance systems. This enables us to make strategic decisions and to govern changes in pharmacovigilance requirements.

## Collecting information and checking processes

In response to new requirements 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 (ICSR). In 2019, we started safety reporting in line with the enhanced E2B(R3) standard in China, Europe and Japan, and further rolled out the reporting to Russia and Taiwan in 2020.

We are following up on changes to the European GVP guidelines and preparing for the introduction of the new clinical trial regulation. In addition, we are implementing the new pharmacovigilance requirements in the United Kingdom associated with Brexit and introducing changes according to the timeline proposed by the Medicines and Healthcare products Regulatory Agency (MHRA).

In 2020, we assessed new **country-specific regulatory requirements** and implemented necessary changes in order to meet them.

## 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 2020 we did not receive any requests for **pharmacovigilance inspections**.

Furthermore, we **perform audits** to ensure that all our units and subsidiaries involved in pharmacovigilance consistently meet all requirements across the globe. In 2020, we conducted a total of 19 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 improve our pharmacovigilance processes so that they surpass statutory requirements. In light of the Covid-19 situation, we adjusted our audit plan and methods. Several audits were postponed and others were conducted remotely.

## Responding to the Covid-19 pandemic

In light of the Covid-19 outbreak in 2020, various health authorities across the world issued guidance clarifying the expectations for manufacturers, importers and marketing authorization holders on the implementation of clinical trials, reporting of adverse events from clinical trials and post-marketing sources, and the management of other safety aspects during a pandemic.

Based on this we changed several of our standard reporting procedures. For example, adverse event reports associated with Covid-19 were identified as a priority and submitted as required to the respective national health authorities.

Furthermore, some national health authorities adapted their requirements regarding the electronic submission of adverse events and additional **risk minimization** information, and we did so accordingly. Industry representatives and health authorities discussed the need for more regulatory flexibility to account for the potential increased reporting of adverse events related to widespread use of medical products to help treat or prevent Covid-19.

Our Global Patient Safety unit's Business Continuity Team (BCP) routinely monitored the impact of Covid-19 on pharmacovigilance operations. No disturbances to our own operations at a local or global level were detected, and the impacts on business partners were minimal.

As in many other areas of our business, we made use of a remote working model due to physical distancing requirements. We introduced electronic signature processes for safety data exchange agreements with business partners as well as for internal documents to safeguard business continuity.

## Redefining our approach to benefit-risk assessments

We have developed a benefit-risk blueprint strategy in order to help us transform from a reactive and compliance-driven organization into a proactive and benefit-risk-focused organization. By truly understanding the benefit-risk profiles of our products, we can enable early decision-making within the organization. Ultimately, the aim is to be able to provide **the right medicine to the right patient at the right time**.

As part of this initiative, we have also developed the concepts and principles for conducting benefit-risk assessments at each stage of product development and post-marketing.

We have completed the design phase of this benefit-risk blueprint strategy, created guidance and developed a change management plan. We are now in the implementation phase and are conducting several pilots to better understand the model's impacts and adjust it accordingly.

## Assessing the safety of our products

We employ a product prioritization tool as a means to score the safety of our products in an objective, proven way, based on several critical safety and relevant cross-functional parameters. The output scores provide a categorization of products into high, medium or low priority. These categories have a major impact on the subsequent methodology used for all safety activities, allowing us to define working models for safety surveillance and benefit-risk assessment activities for low- and medium-priority products, allowing us to focus on high-priority assets. The tool is helping us to further develop an integrated, proactive safety approach. Additionally, it provides us with a reference to ensure regulatory compliance.

We are in the process of redesigning all pharmacovigilance processes (ICSR management, signal management, benefit-risk blueprint strategy and aggregate safety reporting) to account for product priority category in the component process steps.

In particular, we are successfully incorporating the product prioritization tool into the development of our risk-based operating model within the Global Patient Safety unit. We published the initial version of the product prioritization tool in January 2020. A planned annual update ensures that the tool accurately reflects the current safety status of all products.

## Innovative safety signal detection

Through our tool for safety 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 helps to 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. The implementation of Empirica has **improved the tracking and oversight of all safety signals**. Using diverse statistical tools and leveraging all available safety data from our internal and external databases makes it possible to identify new signals and their assessment of risk for the patients.

## Up-to-date labeling and product information

Our product information explains to health care professionals and patients how to properly use the respective drug and allows for an informed decision on 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 2020, 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 of our Healthcare 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.

## Enhancing patient safety and sharing expertise with other countries

### Reporting side effects with the agReporter app

In line with our goal to enhance patient safety, we have created and published a patient-friendly app called agReporter. In 2020, we continued with the rollout in several markets and developed it further. With this app, not only field nurses and our sales representatives, but also non-medically trained users can **report any suspected 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 2020 we initiated the collaboration with local professional associations in Kenya, Nigeria and potentially other countries to deliver training to healthcare professionals on identifying adverse events and how to report them. We will roll out the agReporter app in these countries with instructions on how to report suspected adverse events associated with our medicinal products. The app is available in a total of 14 languages and additional language versions are in preparation.

### Pharmacovigilance in Access to Health

We endeavor to transfer our drug safety expertise around the world, especially to countries where healthcare workers need to build their pharmacovigilance expertise.

We want to increase the contribution of pharmacovigilance in our Access to Health strategy (A2H). Fostering pharmacovigilance initiatives in safety data-sharing with health authorities and building pharmacovigilance capacity with reputable partners in underserved countries in a sustainable way are key aspects of this strategy. This is why we selected low- and middle-income countries from the UN Human Development Index (HDI) and included these in our project scope. For the selected countries we employ ambassadors in each region to systematically collect and report information on pharmacovigilance initiatives and activities, as further detailed below:

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 and we contributed to the review of the Russian translation. We also collaborated with health authorities in Brazil to support the creation of a local language version, which was released in March 2020.

Through the A2H initiative, we also promote patient centricity in low- and middle-income countries through **pharmacovigilance awareness** communication measures that we develop and distribute. In 2020, we conducted an adverse event campaign in Kenya and Nigeria. The campaign was aimed at sensitizing the public to unexpected symptoms that individuals may experience after taking a medicine and the actions they can take – such as seeking medical advice and reporting the incident to the relevant health authority or market authorization holder. We also plan to roll out a non-promotional video and audio messages through local media agencies, explaining how to identify adverse events as well as recommended steps in both English and Swahili.

The Kenyan health authority, the Pharmacy and Poisons Board, has approved the project for the awareness-raising campaign, the training of healthcare professionals and the use of our agReporter app. The project is scheduled for rollout in the first quarter of 2021. The lessons learned from this campaign will be incorporated within a similar campaign and initiative that is being planned in Nigeria.

## Off-label use

We endeavor to **drive scientific and medical progress**, often doing so in close collaboration with medical professionals.

We receive inquiries about the therapeutic use of our products beyond the marketing authorization (also referred to as off-label use). For example, while each medicine is authorized for use in specific indications, a physician may wish to administer a product to a patient suffering from a disease for which it is not approved.

We market our medicines only within the scope of their specific marketing approval. Any medical-scientific information about the use of our products beyond the existing marketing authorization is provided by qualified medical personnel only in the case of unsolicited inquiries. The information shared must be backed by scientific evidence and factually balanced clearly stating that it applies to unapproved use. Also, employees of our company are not permitted to give any sort of treatment recommendation on individual patient care or treatment.

Our principles for providing information about the unapproved use of our products have recently been updated in a standard document which became effective in 2020.

# product-related crime

**Part of the non-financial report**

According to the World Health Organization (WHO), a considerable proportion of the medicines in low- and middle-income 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 criminal 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 customers and patients, we secure our products against counterfeiting. We are also resolute in our fight against product-related crime by, for instance, collaborating closely with health, regulatory and law enforcement agencies at the **regional, national and international level**. In taking preventive action, we cooperate with 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."
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, warehouses or while in transit.

## How we are tackling product-related crime

Our Group Corporate Security function coordinates all our activities for fighting product-related crime. All measures are overseen by the Chief Security Officer and head of "Environment, Health, Safety, Security, Quality" (EQ). Furthermore, all our sites have a product crime officer, who is responsible for responding to potential cases of counterfeiting, acting as the interface between local regulatory and law enforcement authorities, national associations, our Group functions, and our sites.

### 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. As well as coordinating preventative measures and the development of security systems, this organization also oversees 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 2020, our Anti-Counterfeiting Operational Network (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 "Illicit Trade & Product Crime Prevention" describes our goals and strategies for combating product-related crime. The Group-wide Product Crime Incident Management standard sets out **mandatory requirements** and defines the procedures we follow within the Group, thereby ensuring cases are managed efficiently. Moreover, it creates a clear 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 **comprehensive picture of the security situation**, enabling us to identify possible links between different cases and effectively tackle them. Our standard operating procedure entitled "Data and Documentation Quality Management" describes the corresponding process, making the risks more transparent and the processes more efficient.

## Tracking system for chemical substances

We monitor chemical substances 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 released only 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 2020, we reported 1,148 orders placed for relevant substances. In addition, we received 15 inquiries from authorities regarding

specific suspected cases that we helped to resolve. We evaluate the effectiveness of our measures for avoiding product misuse based on, among other things, the number of incidents suggested to us by the authorities and solved.

## 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. We apply a **unique serial number** to the packaging of all the prescription medicines we commercialize in the European Union (Track and Trace). We also comply with similar government-stipulated systems in other countries around the world.

**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 the **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.
- According to a WHO report, more than 10% of all medicines in low- or middle-income countries and emerging countries are counterfeit or substandard. That is why we sponsor the non-profit Global Pharma Health Fund (GPHF), which supplies the **GPHF-Minilab®**, a compact laboratory used mainly in countries with inadequate access to health solutions to test the quality of up to 100 different active ingredients quickly and inexpensively. The test methods are described in a manual, which has also been available in French and Spanish since 2020. More than 890 Minilabs are currently in use. In 2020, 29 Minilabs were delivered: 21 went to Africa, particularly to countries in the Economic Community of West African States (ECOWAS), and seven went to Asia (Afghanistan and Bangladesh). One remained in Germany for future training sessions as part of the "Global Health Protection Program" run by the Germany Federal Ministry of Health.
- Since 2018, we have been collaborating with Boston University. Together, we are testing, investigating and optimizing a new **user-friendly instrument (PharmaChk)**, which identifies and quantifies active ingredients and helps us to detect counterfeit and substandard medicines. We are planning to use the portable instrument primarily for antimicrobial and anti-malarial compounds in low- and middle-income countries.
- We offer our customers in the pharmaceutical industry **Candurin® pearl effect pigments** with unique color properties. When used to coat of tablets and capsules, these pigments make it more difficult to create counterfeit copies.

## Raising awareness of product-related crime

We aim to continuously 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.

## Security audits for contract manufacturers and distributors

We regularly check whether our distributors and contract manufacturers are complying with GMP- and GDP-Standards (Good Manufacturing Practice/Good Distribution Practice). These audits are based on the "EMA ICH Q10" pharmaceutical quality assurance standard and 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. This applies to both pharmaceutical contract manufacturers and 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 2020, we conducted this type of security audit in China, which found four critical, two significant and three minor defects. No contract was entered into.

# Transport and warehouse safety

**Part of the non-financial report**

Around the world, we transport and store numerous products and materials. These include 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

All our shipments are 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 dangerous 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 requirements across the Group** that of course also comply with all applicable laws. 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 on warehouse and transport safety requirements.

## How we achieve transport and warehouse safety

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 national and international regulations governing environmental stewardship and public safety. At the local level, the **respective site directors** are responsible for ensuring compliance with all safety requirements.

Each of our sites around the world with logistics activities has an EHS manager and a **dangerous goods manager**, a position that equates to the Dangerous Goods Safety Advisor required by EU regulations. Both individuals 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 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 can meet our additional requirements. We summarize the findings from this audit in an EHS report, which contains additional warehouse and storage requirements.

## Our commitment: Internal standards and international rules

We have Group-wide standards in place that govern the safety levels for the storage of hazardous substances at our sites. Accompanied by standard operating procedures and best practices, these standards describe the technology and organizational infrastructure needed to achieve the appropriate safety levels.

Contract warehouses must also adhere to our strict safety requirements. Before we sign a contract with an operator, they must submit a statement detailing how they meet our prerequisites. Our Group-wide standards also define the **technical and organizational requirements** for such warehouses.

In Germany, the **storage of packaged hazardous materials** is governed by the Technical Rules for Hazardous Substances ("Storage of hazardous substances in non-stationary containers", TRGS 510), which apply across all our warehouse and distribution centers Group-wide. A completely revised version of the TRGS was published at the beginning of 2021; the update was handled by the Committee on Hazardous Substances (AGS) with input from our company's own experts.

Our Group Transport Safety Standard is based on the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations. This guideline is especially important for sites in those countries with no local regulations covering the **conveyance of hazardous materials**.

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

During the process of integrating Versum Materials and Intermolecular, we reviewed all relevant standards and made adjustments as necessary. We adopted the vast majority of the special requirements of Versum Materials and Intermolecular. Specifically, these pertained to the storage of gases and the evaluation of highly hazardous materials for transport.

## Enhancing transport and warehouse safety

In addition to the inspections conducted by our EHS and dangerous goods managers, we regularly perform internal **risk-based Group audits** to ensure that our sites comply with warehouse and transport safety regulations. We generally conduct these audits 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. Using a standardized checklist, our EHS managers verify whether contract warehouses meet our requirements. This inventory also helps us assess risks before entering into a business relationship with a third-party warehouse.

Due to the Covid-19 pandemic, we were unable to perform all the audits we had planned for 2020. We audited two of our warehouse facilities to verify their compliance with Group-wide standards and also audited one contract warehouse.

We report transportation incidents and accidents in accordance with the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations (7.1.9) in conjunction with the criteria of the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, 1.8.5.). There was no reportable incident during 2020.

## Employee training and best-practice sharing

In line with their specific tasks and responsibilities, our employees undergo regular training that 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.

Across the globe, we conduct around **1,000 internal and external seminars on transport and warehouse safety every year.** Due to the Covid-19 pandemic, only 60% of our seminars could took place. Many of these were rescheduled as webinars. The **e-learning program we developed** for hazardous material transport and storage is compulsory for logistics, EHS and dangerous goods managers. It features ten courses that we assign to the participants to complete.

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 onboarding seminar on environmental stewardship, safety and safe logistics. In 2020, we held this training online program through a series of webinars.

## 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 German Transport Accident Reporting and **Emergency Response System** (TUIS) operated by the German Chemical Industry Association (VCI). Within this system, we share chemical transport expertise and best practices with experts from other chemical companies and also render hands-on assistance in the event of a chemical transportation accident. Our site fire departments in Darmstadt and Gernsheim collaborate closely with the fire departments in the region and provide specialized equipment to help in emergency situations.