PRODUCTS

Sustainable innovation & technology

We are committed to creating solutions that positively impact people and the environment. To this end, we are determined to make discoveries that change the landscape of entire industries and drive technological as well as scientific innovation to solve the most critical issues of today and tomorrow. Customers, investors and regulators across our markets are increasingly seeking sustainable product solutions.

Our approach to creating sustainable innovation and technology

The sustainable innovation that we envision or drive forward must align with and support the **three goals** of our sustainability strategy. We define sustainable innovation as new or improved products, services, technologies, or processes that generate economic benefits and have positive environmental and social impacts. Therefore, we develop **long-term solutions** for our innovation and research activities that consider the entire value chain and evaluate each product's impact over its lifecycle.

Today, our products already have a positive impact on human progress and global health, namely our medicines and our biological and chemical innovations that utilize the latest technologies. We want to continuously improve the way we measure our progress by adapting and integrating sustainability criteria into our product development processes across the business sectors.

In 2022, we continued our partnership with the well-established patent information platform LexisNexis® PatentSight®. In this context, we created a framework to evaluate the sustainability impact of our intellectual property. For 2022, we evaluated the baseline for the first time and identified that 27% of our patent families published that year have a positive sustainability impact based on LexisNexis® PatentSight®.

To develop pioneering solutions that have a **positive impact on society** and support organic growth, we are exploring transformative technologies beyond our core products and markets. At the same time, we maintain strategic proximity to our business sectors to leverage our existing assets and capabilities. Business model innovation, including digital business models, is one approach we use to generate value for our business and stakeholders.

We fuel transformative technologies through internal incubation, partnerships or strategic investments and collaboration with academia. In addition, we continually seek to foster and encourage **open innovation**.

Roles and responsibilities

The organizational set-up of our R&D activities reflects the overall structure of our company. All three of our business sectors operate independent R&D units that pursue their own innovation strategies. **Group Corporate Sustainability** supports our business sectors and Group functions to advance and integrate sustainability within the R&D and innovation processes in line with our shared goals. We developed a methodology for creating a Group-wide overview of the potential contribution of our R&D portfolio towards sustainable solutions that went live in December 2022.

Our **Group Science & Technology Office** leads the implementation of our combined strategy for innovation, data and digital, enabling innovation across our business sectors while harnessing the power of advanced data and digital capacities. It aims to identify and integrate transformative, strategically relevant technology trends into our business sectors while maintaining a Group-wide view of our tech roadmap and innovation portfolio. Fostering data and digital capacities is key to accelerating sustainable innovation and enabling rapid action and personalized offerings. Innovation projects are incubated either through our corporate innovation teams or in the business sectors.

Our venture capital fund, M Ventures, prioritizes sustainable innovations through equity investments. The fund's mandate is to invest in innovative technologies and products that have the potential to significantly impact our core business areas. In addition, the fund focuses on investments in two areas of high strategic relevance to our company: digital technology and sustainability.

M Ventures' sustainability investment strategy follows two fundamental approaches. First, it invests in sustainable solutions relevant to our three business sectors, such as novel solutions for reducing emissions and waste, green life science technologies and green electronics technologies. These solutions may be more energy- or resource-efficient or may create products designed for circularity or with a lower carbon footprint. As many of these technologies are still in their early stages, M Ventures is partnering with **SEMI.org** along with the leading corporate venture capital funds to help accelerate the innovation and adoption of potential sustainable semiconductor solutions.

The second approach involves making investments that leverage our core competencies to drive sustainability in other markets. These may include start-ups addressing sustainable foods, bio-manufacturing, or carbon capture and utilization.

Our commitment: Aiming for circularity

Within our R&D processes, we are committed to continuously improving and integrating sustainability and circular economy criteria to assess the **sustainability performance of our products and portfolio**. For example, our Life Science business sector developed Design for Sustainability (**DfS**) and the **DOZN**™ tool to create more sustainable products for our customers. In 2022, we tailored and rolled out the DfS concept to our two other business sectors and integrated an overarching company dashboard. In 2023, we aim to generate an understanding of our R&D portfolio and use the insights to steer future R&D activities. Therefore, we have developed an indicator to track our progress.

Furthermore, the Electronics business sector launched a web-based application to automatically extract process and reaction data from research, development and manufacturing databases to calculate and evaluate carbon footprint of our operations. This allows sustainable decision making to reduce resource consumption as well as direct and indirect CO_2 emissions from chemical processes. The app has been launched in September of 2022.

In addition, we have dedicated corporate resources for our **circular economy strategy** and we are driving several circular economy pilots and initiatives throughout the organization.

More information on sustainable product design can be found in the **Sustainable products & packaging** chapter.

Accelerating the future of food: Cultured meat

Our Cultured Meat Innovation Field focuses on the biotechnology required to grow real meat in vitro. These research and commercial efforts aim to enable animal protein production that is healthier, more ethical and environmentally sustainable. As a **technology enabler**, we are leveraging our vast life science expertise to realize our vision of providing fit-for-purpose bioprocessing products and services for cultured meat production. In addition to building strong connections and partnerships with start-ups, academia and leading organizations, we are working on innovation projects to address specific technology challenges, such as cell culture media and bioreactor designs that are cost-effective and suitable for this emerging field.

To achieve production at scale, the cell culture media must be cost-efficient, produced from a robust food-grade raw material supply chain, suitable for effective growth and differentiation into specific cell types, and free of any animal-derived material such as fetal bovine serum. Our flagship project **MeatDia** aims to build a food-grade raw material supply chain via performance testing in research labs and qualification in one of our production facilities to manufacture the required media formulations. In addition, we have established multiple **partnerships with leading start-ups** that are building pilot-scale manufacturing facilities. We are supplying dry powdered cell culture media, to these customers, who are bringing the first cultured meat products to market.

Another technological challenge is the need for suitable bioreactor designs to efficiently produce structured cuts of meat rather than lesser-value ground meat. CraftRidge is our flagship bioreactor project focused on delivering an edible hollow fiber bioreactor system that can produce entire cuts of meat cost-effectively. In parallel, we are collaborating with **two leading academic labs**. Together with a team at Tufts University in Massachusetts, USA, we aim to enable the production of whole-muscle cultured meat through textile bioengineering. At the same time, we will apply industrial rapid printing technology to **create complex meat structures** in collaboration with a team at the Technical University of Darmstadt (TU Darmstadt) in Germany.

Our M Ventures portfolio includes Mosa Meat, a pioneer in cultured meat, and Formo, a company focused on making cultured cheeses using recombinant protein synthesis.

Fruitful strategic partnership

Our long-term commitment to academic research partnerships reflects our strong ambition to find sustainable solutions to pressing problems. In the framework of the **Sustainability Hub**, which was established in 2021, we continued our strategic collaboration with the TU Darmstadt in multidisciplinary fundamental research projects. The projects cover basic challenges of life cycle modelling, 3D liver tissue model, biodegradation of plastics and the simulation of neuromorphic computing architectures. The ongoing research continues to increase our understanding of product sustainability assessment, toxicological testing of drugs, circular material flows and energy efficient computing, respectively.

Promoting visionary research

The **2022 Future Insight Prize** recognized achievements in energy technologies that help reverse the effects of climate change. The € 1 million prize was awarded to Professor Tobias Erb, Director at the Max Planck Institute for Terrestrial Microbiology in Marburg, Germany. His research enables solutions that make it possible to **convert CO_2** into valuable chemical products, which can then be used as feedstock for fuel.

In 2022, we again offered sustainability research grants to the scientific community to stimulate innovative research and sponsored two research grants: Sustainability in Healthcare R&D and Innovation within Green Chemistry. In total, we received more than 200 research proposals from around the world. Selected projects will receive funding in 2023.

We also entered into a cooperation agreement with Esy-Labs GmbH, the winner of one of our research grants in 2021. In addition to funding research activities through the grant, we initiated long-term collaboration by hosting the research activities of this company at the emerging GreenTech Park FLUXUM in Gernsheim, Germany.

Sustainable products & packaging

We believe it is our duty to consider the sustainability performance of our products throughout their life cycle, starting with the development stage. This also allows us to help our customers to improve the sustainability of their products. To this end, we are in the process of aligning our approaches across our business sectors.

Our approach to sustainable product design

Life Science

In our Life Science business sector, we work to reduce the adverse impacts of our products on health and the environment. This applies to **the entire life cycle**, from manufacture and use to end of life. At the same time, we seek to make our products more efficient and user-friendly, asking ourselves from the start of product development how to best reconcile these requirements.

Through our Design for Sustainability (DfS) framework, we follow a comprehensive approach to increasing the sustainability of our Life Science products. The DfS: Development pillar provides our product developers with a **systematic approach** that enables them to analyze product impacts in terms of materials used, energy and emissions, water, packaging, usability, innovation, and 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 help us to improve our products and are incorporated into subsequent development stages. Experts from Research and Development (R&D), Product Management, Quality, Procurement, and other departments collaborate along every step of the process.

In 2022, we implemented a **new version** of our DfS: Development pillar within our enterprise product development processes. The new framework introduces data-driven deliverables at each phase of our product development process to ensure we consider sustainability factors in all newly developed products. It also comprises a new scorecard system that helps our development teams address and minimize negative product- and supply chain-related factors and improves our communication of product sustainability credentials to our customers.

Healthcare

In our Healthcare business sector, we aim to reduce any adverse impacts our medicines may have on the environment during their development, manufacture, transportation, use, and disposal. We are developing an **overarching strategy** to make our medicines, our medical devices and their packaging more ecologically sustainable and user-friendly.

At the same time, we are working on advancing environmental compatibility in different phases of the healthcare value chain. In the area of pharmaceutical development, we have defined an ecotoxicological testing strategy that involves identifying environmental properties of drug candidates early in development. Ideally, we would then be able to use this knowledge to avoid emissions into the air and water.

In 2022, we started to implement the Design for Sustainability framework in our Healthcare R&D approach. We will also establish a governance framework to integrate sustainability and define **sustainability criteria** for qualitative and quantitative scorecards that can be used to measure sustainability impacts.

Our newly launched Green Biotech program helps to integrate sustainable innovation and state-of-the-art technology into our development processes and products along the clinical manufacturing value chain. This program is aligned with our Healthcare sustainability strategy to drive progress for more than one billion people through sustainable science and technology and is linked to other sustainability projects aimed at helping us achieve climate neutrality by 2040.

Electronics

In our Electronics business sector, we aim to reduce any potential adverse environmental impacts caused by the manufacture, packaging, transportation, use, and disposal of our products.

We view sustainability as a competitive advantage, and we proactively engage in partnerships with our customers to collectively drive more sustainable value creation.

According to our new principle, highly hazardous materials are to be avoided in our product development process wherever possible. Therefore, we have also prioritized new green and innovative materials that deliver sustainable value to our customers. We are committed to a holistic approach comprising:

- **Sourced responsibly**: We use our membership in the **Responsible Minerals Initiative** to support the responsible sourcing of minerals, such as tantalum, tin, tungsten, gold, and cobalt, so that their supply chains make positive contributions to global, social and economic development.
- **R&D**: In 2022, we developed and launched a scorecard focusing on sustainable criteria in the development of new products and solutions. The scorecard is a tool for fostering a sustainability culture in our R&D by identifying opportunities and risks at early stages and acting accordingly. The tool also makes the R&D team’s contribution to our global sustainability goals more transparent.
- **Process development**: We started a project to automatically calculate key sustainability performance indicators, such as process mass intensity, solvent and water intensity, as well as an estimate of the carbon footprint to improve the sustainability of chemicals and related manufacturing processes.
- **Assessment of the current product portfolio:** In 2022, we started to review our current product portfolio in order to understand the current sustainability profile and determine whether greener and equally effective chemistry alternatives are available. A multi-functional team is working to establish a process that puts greater emphasis on the sustainability and green chemistry aspects of our product portfolios. In addition, a Product Sustainability Committee was established in 2022 to oversee the portfolio sustainability assessment process and results.
- **Contributing to the sustainability goals of our customers:** We seek to establish partnerships with our customers to optimally understand how our products and activities can contribute to their sustainability goals. In 2022, we established a partnership with one of our customers to develop and eventually produce gas solutions with a low global warming potential; these are currently in a practical testing phase.

Our approaches to sustainable packaging

We work to deliver our products in packaging that is safe and easy for customers to handle, while also working to improve the sustainability characteristics of our material choices.

Life Science

With more than 300,000 products in our Life Science portfolio – ranging from antibodies and lab chemicals to filtration materials, systems and instruments – we face a variety of packaging challenges. We work to improve the sustainability characteristics of this packaging to reduce its environmental impact. Our **SMASH Packaging** strategy for Life Science is built upon 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 the amount of packaging
- **Secure**: achieve zero deforestation
- **Switch**: improve plastic sustainability characteristics
- **Save**: maximize recycling

In our efforts to achieve our 2022 targets, we also worked to define the future priorities and goals for our SMASH Packaging strategy as we want to continue to improve the sustainability characteristics of our new product packaging as well as our 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 upgraded Design for Sustainability scorecard.

Healthcare

In 2022, our Healthcare business sector launched a sustainable packaging initiative called MPact, which pursues the same four pillars as the Life Science SMASH program: Shrink, Secure, Switch, and Save. This initiative investigates product packaging solutions to reduce the overall environmental impact.

We are in the process of aligning the goals of all three pillars. Meanwhile, we are continuing to implementing various initiatives to reduce our product packaging, switch to more sustainable materials and promote recycling and circularity. We also intend to adjust packaging requirements for intermediate materials where feasible.

Electronics

Our process for introducing new packaging includes a safety review that evaluates 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. Furthermore, in our specialty gas and thin films businesses, for example, we focus on product packaging that performs well in terms of transportation and handling safety.

Roles and responsibilities

Life Science

The Life Science business sector works across its business units to drive holistic sustainability of operations, products and culture. Our structure helps us to implement an ambitious and coordinated sustainability strategy to formalize our processes, governance and goals – helping to embed the strategy into our business and becoming a sustainability multiplier for our customers.

Our sustainability governance structures are as follows:

The Sustainability and Social Business Innovation team within Life Science drives the setting of KPI and targets as well as the planning and execution of our strategy as well as monitoring and reporting activities.

Healthcare

Our Healthcare business sector has integrated sustainability across its R&D and operating units. The implementation of its sustainability strategy is steered by the Healthcare Executive Committee. Any decisions made regarding sustainability objectives are cascaded to the corresponding units, which are responsible for implementing measures to achieve these objectives.

Electronics

We have implemented a process to structure the sustainability governance of our Electronics business sector. This structure helps us to implement a coordinated sustainability strategy across the business units, manage goals and processes, strengthen our customer relations, and ensure overall accountability within our ESG approaches.

Our sustainability governance structures are as follows: In 2022, a new organizational structure within Electronics was introduced to ensure that our sustainability strategy is implemented across all business units. The Electronics Sustainability Council acts as a cross-functional executive committee that oversees and signs off on relevant initiatives within Electronics sustainability programs. In addition, a dedicated team coordinates business-related sustainability activities.

In 2022, we assessed the core responsibilities and defined key activities to improve the structure of our sustainability commitments. New responsibilities include a monitoring role as well as driving initiatives that contribute to the scope and targets of our **sustainability strategy**. Furthermore, dedicated working groups within the business units are responsible for developing individual targets for their business units and implementing corresponding projects.

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.

Life Science

Within our Life Science business sector, our strategic platform is founded on a **data-driven approach to** help our experts drive sustainability improvement during the development of products and packaging. Our Design for Sustainability (**DfS**) framework is a comprehensive approach aimed at increasing the sustainability of our products, focusing 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 evaluating how we can quantify and improve the environmental footprint of these products by applying the 12 Principles of Green Chemistry in our process.

As of December 2022, about 1,860 greener alternative products had been made available on our platform.

Healthcare

Within our Healthcare business sector, chemical product safety is a key sustainability aspect when developing, producing and distributing products. We strive to comply with all relevant legal requirements regarding chemicals regulations, hazard communication and local and regional chemical registration activities.

Our Group-wide policy also incorporates legal norms concerning the transport of hazardous chemicals, biocides, cosmetic ingredients, and products used in food and animal feed. Our Group Label Standard provides a consistent framework for labeling products according to GHS requirements.

More information can be found under **Chemical product safety**.

Electronics

Product safety is one of our highest priorities. Starting at the development stage, we investigate the potential adverse impacts chemical substances may have. We intend to meet all statutory requirements along the entire value chain for our chemicals, with our Regulatory Affairs organization ensuring regulatory compliance.

Within our Surface Solutions business unit, we aim to meet the strict standards of the EU Cosmetics Regulation for all our raw materials intended for the cosmetics industry. In addition, these raw materials should be produced in line with Good Manufacturing Practices for Cosmetic Ingredients (**EFfCI** GMP).

Adhering to the Convention on Biological Diversity

We support the general principles laid out in the Convention on Biological Diversity, especially the third objective: the fair and equitable sharing of benefits arising from the use of genetic resources and traditional knowledge in accordance with the terms and conditions of the Nagoya Protocol. This is an international supplementary agreement to the CBD. A key element of this principle is access and benefit-sharing, which ensures that countries providing genetic resources and traditional knowledge also benefit from their use.

We apply a Group-wide standard entitled “Access to Genetic Resources”, the objective of which is to define **requirements, roles and responsibilities** to ensure compliance with the Nagoya Protocol, even in countries that are not party to the Protocol. In addition, each business sector defines specific procedures to help ensure they meet the requirements of our Group-wide standard.

We have established an internal exchange across our business sectors for aligning and sharing information on initiatives related to access and benefit sharing. In 2022, we successfully filed a due diligence declaration for two product developments with a genetic resource to the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) in accordance with current EU regulations. This achievement was also mentioned in the BfN’s “Newsletter zum Nagoya-Protokoll” in February 2022.

Wide range of solutions

Life Science: Green chemistry assessment tool

Our proprietary, web-based tool, **DOZN™**, enables us to evaluate various products and/or processes to identify opportunities for sustainability improvements and provide transparency to our customers. DOZN™ industrializes the 12 Principles of Green Chemistry, a previously theoretical framework, and **rates products** in three stewardship categories of “Improved resource use”, “Increased energy efficiency”, and “Reduced human and environmental hazards”. DOZN™ 2.0 is the tool’s external interface, allowing our customers and other scientists to make **more ecologically sustainable choices** in their development processes. In 2022, we counted approximately 1,500 users of DOZN™ from 60 countries.

In 2022, we worked to establish new partnerships with universities in the United Kingdom and Germany in addition to our existing partnerships with universities in Canada, France, India, Switzerland, and the United States. These partnerships apply 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 reinforces learning while highlighting the importance of sustainability to future scientists.

Life Science: Greener solvents

Switching to bio-based solvents, such as our alternative, more environmentally compatible solvent **Cyrene™**, helps our customers reduce their carbon footprint. We are a member of the EU Horizon 2020 project, ReSolute, which started the construction of a new Cyrene™ production facility in 2021. Located in France, the site is scheduled to open in the second half of 2023 and will produce 1,000 metric tons of Cyrene per year to help us meet the growing demand for greener solvents.

In 2022, we also launched Cyrene™ blends, a greener solvent system that extends applications for organic synthesis. We published our results in **The Royal Society of Chemistry’s** Green Chemistry journal.

In 2022, we worked to expand our selection of bio-based laboratory chemicals included in the BioPreferred® program of the U.S. Department of Agriculture (**USDA**) program. These chemicals are certified by the USDA to be derived from plants and other renewable agricultural, marine and forestry materials and provide an alternative to conventional petroleum-derived products. These chemicals include sustainable solvents such as bio-renewable acetone.

Life Science: Sustainable laboratory water use

Our most recent Milli-Q® IQ and IX series ultrapure and pure water purification systems use innovative, mercury-free UV oxidation and/or bactericidal lamps. Their optimized components, processes and hibernation modes reduce electricity consumption by 18% to 41% compared with previous systems while preserving system water quality. The systems also reduce water consumption by between 2% and 13%.

Life Science: Less plastic in cell culture creation

Our greener 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 volume and weight of packaging by up to 69%. 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 further 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 sterile filtration unit by up to 46%. Across all product versions since their launch, we have prevented 3,2 metric tons of plastic and corrugated cardboard from entering our customers' laboratories across all product versions.

Life Science: Expanding product recycling

We have continued expanding the biopharma recycling program that we kicked off in 2015, in which single-use plastic product waste is collected from biopharmaceutical manufacturing operations and **recycled into plastic lumber**. This material can be used in many industries, such as landscaping, transportation and marine construction. The program now serves 23 major biopharma manufacturing customers. Since its launch in 2015, it has recycled more than 8,700 metric tons of plastic waste.

This program continues to expand throughout the United States as we simultaneously explore new options and recycling technologies in other regions, such as Europe and Asia. By assessing advanced recycling technologies and collaborating across multiple industries, we will develop innovative **circular economy** programs.

Electronics: Sustainable product design

In 2021, we started to systematically incorporate sustainability into our portfolio management process. In 2022, for example, one project defined and incorporated sustainability criteria focusing on product design into the product development process. This initiative enables us to understand the sustainability impact of our new products across the entire value chain and create improvements early in the R&D phase. In addition, we perform sustainability assessments for every R&D program within Electronics, giving us a baseline to create a more sustainable product portfolio and sustainable innovations for our customers.

Electronics: Colloidal silica

Over the past decade, our semiconductor materials customers have increased their efforts to use more environmentally sustainable materials in their chip manufacturing and improve the performance of their computer chips while lowering costs. We have responded to this challenge in 2017 by developing **next-generation colloidal silica products** using at least 30% less colloidal silica. This advancement reduces the volume of product needed, which in turn shrinks our environmental footprint. Customer feedback on the products is promising. Together, we are working to improve production efficiencies and reduce the use of colloidal silica even further.

Electronics: NMP-free removers

The production process for semiconductor devices requires numerous cleaning steps to remove the photoresists used to pattern the circuit design. These cleaning methods require complex solvent chemistries that selectively remove these photoresists without damaging the sensitive electronic components.

However, the most effective solvents pose a significant environmental hazard. For example, 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. Therefore, we are continuously working to develop new cleaning chemistries. In 2022, we began launching a series of **green cleaning solvents** that are TMAH- and DMSO-free while still being effective in removing thick photoresist (both liquid and dry) film, for example AZ® Remover 910 and Dynastrip 5008, Dynastrip 8889, and Dynastrip 8070T.

Electronics: PFAS replacement program

PFAS (per- and polyfluoroalkyl substances) have unique chemical properties and are widely used in our daily lives. However, there is strong evidence that exposure to PFAS can lead to adverse health outcomes in humans. Therefore, over the last decade, international regulations have started focusing on PFAS as chemicals of concern. They have become known as "forever chemicals" due to their extremely long lifespans.

Chemical products containing PFAS are essential in today's electronics manufacturing processes. Therefore, PFAS pose a serious dilemma for the electronics industry as emerging global regulations trend towards restricting the use of PFAS in the future.

We are committed to intensifying our R&D efforts to actively drive a PFAS-related substance replacement program. As a trusted partner in the electronics industry, we are working closely with our customers and providing information throughout this process.

Electronics: Dynamic liquid crystal glazing

Liquid crystal dynamic window glazing adjusts its tint level within seconds according to the weather conditions. The self-darkening glazing effectively regulates glare and solar heat gain without blocking the view. As a result, it increases the occupants' visual and thermal comfort while simultaneously lowering air conditioning and lighting energy consumption by up to 10% compared with conventional shading. We offer these products under the **eyrise®** brand. Many real estate investors regard eyrise® as an important building feature for delivering on their ESG targets. One company installed 3,000 m^2 of our product in its new flagship building in Zurich, Switzerland.

Electronics: Shifting to more natural cosmetic ingredients

We are working closely with our partners in the cosmetics industry to find solutions for more naturally based cosmetic ingredients. The resulting cosmetic formulations comply with strict criteria. At the end of 2022, 84 of our cosmetic pigments and active ingredients had been confirmed as being compliant with Ecocert's COSMOS standard for organic and natural cosmetics. We have also obtained **halal certificates** for all our cosmetic ingredients.

Electronics: Vegan cosmetic products

A growing number of consumers view the use of non-animal and non-animal derived ingredients, i.e. vegan and plant-based raw materials, as a critical product attribute. Therefore, the majority of our cosmetic raw materials, including our special effect pigments and functional fillers, contain no components of animal origin, by-products or derivatives and are thus suitable for vegan cosmetics.

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 storage stability and allowing them to be shipped at ambient temperatures. This makes it possible to eliminate the use of expanded polystyrene (EPS) coolers and ice bricks, resulting in significant packaging weight reductions for product shipments. In 2022, it allowed us to avoid the emissions of around 12 metric tons of CO_2eq.

Shrink: How we minimize the amount of packaging

We seek **eco-friendly alternatives** for shipping our products safely, which is why we partnered with a biotech company a few years ago and jointly developed a more sustainable bulk packaging design for transporting our Millistak+® Pod Disposable Depth Filters. We also expanded this approach to a subset of our Durapore® and Millipore Express® filter cartridges. These products are dedicated to high-volume clients and deliver both environmental and economic benefits to our customers compared with traditional individual or multipack packaging.

For example, changing from a three-pack to the new bulk packaging for our ten-inch filter cartridges reduces the amount of corrugated cardboard required by 55%. This corresponds to a 49% decrease in greenhouse gas (GHG) emissions throughout the life cycle of these packaging materials. In addition, our customers spend approximately 50% less time unpacking, reducing labor costs. In 2022, these bulk packaging solutions allowed us to save around 19 metric tons of corrugated cardboard and we continued working on developing similar solutions for additional products.

Shrink: Packaging for Smalls

In 2022, we developed and implemented new packaging solutions that significantly reduced the air space and material consumption associated with the shipment of small products from some of our U.S. and European distribution centers. Through these measures, we will be able to achieve around 50% air space reduction for 1,150+ shipments daily, leading to a reduction of 65 metric tons of packaging materials annually.

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 ourselves the objective of ensuring 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 Program for the Endorsement of Forest Certification Schemes (**PEFC**) and the Sustainable Forestry Initiative (**SFI**).

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 sent to landfill.

Wherever possible, we are replacing EPS 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.

In 2022, we completed the validation and pilot implementation of our new greener coolers at one of our U.S. distribution centers to replace EPS in our cold-chain shipment. The greener cooler is made from renewable resources and is certified recyclable with corrugated materials. We will roll out these **greener coolers** at our major U.S. distribution centers in early 2023 for wet ice shipments. At the same time, we continued investigating solutions to expand the use of greener coolers for dry ice shipments. We also initiated a project to develop a greener cooler solution that meets the requirements of our European market.

Aqueous solutions are usually supplied in plastic bottles. We use Titripac® because it offers an **ecologically sustainable 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, customers can now use the entire contents and reduce chemical waste. In 2022, our products sold in Titripac® 10L packaging configurations avoided non-renewable packaging materials by 14 metric tons, resulting in a reduction of 66 metric tons of CO_2eq emissions across the life cycle of the packaging compared with 1L plastic bottles.

Save: Reusing wooden pallets

At our site in Darmstadt, Germany, we implemented a new process for reusing wooden pallets employed in the delivery of raw materials. Instead of recycling the pallets after one use, we now reuse them for an expected average of three cycles until they show signs of damage. This initiative eliminates around 1,000 metric tons of wood pallets sourced annually, leading to a reduction of about 330 metric tons of CO_2eq.

Making product packaging more sustainable: Healthcare

We launched our MPact sustainable packaging initiative in 2022. Our solutions will ensure the safe and secure delivery of products to our customers while decreasing the environmental footprint of our packaging.

Slim packaging solutions

Our new packaging for Pergoveris®, Gonal-f® and Ovidrel® fertility pens is **decreasing the adverse impact** on sustainability by reducing the pack size by 40% and eliminating plastic pollution by replacing plastic inserts with paper-based materials.

It is estimated that the new pack will also reduce our carbon emissions in the supply chain, as it requires less cold storage space, thereby allowing more products to be transported in each shipment.

Making product packaging more sustainable: Electronics

Our Electronics 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.

Efficient packaging

In 2022, we launched a **new packaging solution** for cosmetics and skincare products in collaboration with five other companies. This packaging consists of new lightweight tubes that require 37% less material. It is produced with mono-materials for easy recycling and is designed for easy waste separation. We provide Colorstream® effect pigments for packaging, Iriotec® laser-sensitive pigments for durable laser marking and Ronastar® pigments that veil shower gel in liquid shimmer.

Reusable packaging

The packaging for our specialty gas, thin films and some patterning products – manufactured in semiconductor technology – is designed to be reused. Our reusable packaging types include various sizes of cylinders and tube trailers for bulk specialty gases, smaller stainless steel and quartz containers for thin films and totes and drums made of high-density polyethylene for patterning.

Once our customers have used the product within the container, the used 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 reduces the demand for construction of new containers and the associated resource requirements, thus moving us **closer to a circular economy**.

Recyclable packaging

For large quantities of products in our patterning and planarization business, we use totes for packaging. Totes are typically made 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 can be reused or recycled.

Redesign packaging labeling approach

Plastic packaging generates almost half of the world’s plastic waste. With Iriotec® 8000 pigments, we enable inkless printing with contact-free and durable laser marking technology, making it possible to label plastics, which in turn, can be traced and **recycled more easily** afterwards, thus restoring value to the used plastic packaging.

The laser marking provides a unique identifier and, as a digital product passport, serves as the link between the product and the database. It can replace ink and labels, thus further increasing recyclability. Laser marking is a unique, sustainable, reliable, durable, and economic way to achieve an individual mark for any plastic product and can be used for plastic packaging, automotive components, cables, and electronic devices.

Health for all

Global Health

Half of the world's population lacks access to essential health services. Therefore, we are striving to innovate, make health solutions affordable and accessible, raise awareness about diseases, and help people learn how to manage them. We work with partners to tackle these complex challenges.

Our approach to improving health for all

Our overarching aim is to create a healthier future for all. We are committed to advancing global health and to using our scientific and technological innovation to improve the health of underserved populations in low- and middle-income countries.

Our **Global Health strategy** aims to develop and provide access to health solutions in low-and middle-income countries by creating equitable and **sustainable access mechanisms** for patients and society. Besides enabling access to our healthcare portfolio, our strategy focuses on diseases that disproportionally impact underserved populations. These include the **neglected tropical disease** (NTD) **schistosomiasis**, which is largely unknown in industrialized nations and attracts little attention or funding, and **malaria**. Specifically, the goals of this strategy are:

- To expand access to our healthcare portfolio of products and technologies to patients in low- and middle-income countries.
- To eliminate **schistosomiasis** as a public health problem.
- To catalyze innovative solutions for global health challenges, primarily targeting schistosomiasis and malaria. We strive to particularly reach those who are most vulnerable: **women** and **children**.

Three core operating principles drive the execution of our Global Health strategy:

- **Creating sustainable business models and opportunities:** We strive to increase our company's value and competitiveness by solving unmet health needs of underserved populations with our products and technologies.
- **Engaging with cross-sector partners:** We participate in multi-stakeholder global health platforms to help achieve our goals and support the United Nations (UN) Sustainable Development Goals. We use access alliances and create partnerships to implement treatment programs on the ground and for research and development projects.
- **Developing innovative solutions:** We develop new medicines, diagnostics and vector control solutions for schistosomiasis and malaria through our integrated science and technology approach.

We also engage in **building capacity and expertise** across the value chain to strengthen health systems and make them more resilient to health crises.

Our Access to Medicine approach

Our access strategy for low- and middle-income countries is a core part of our broader sustainability strategy. In these countries, we aim to accelerate and expand access to our portfolio of products, for example for cancer indications and neurological as well as immunological disorders.

Our strategy is also designed to help reduce launch delays by taking low- and middle-income countries into special consideration in our integrated development plans. With this approach, we also aim

- to ensure wider availability by registering our products across a greater number of countries, particularly those with a high disease burden;
- to improve affordability (further details can be found under **Prices of Medicines**);
- to extend faster accessibility of our medicines through global health partnerships and shared value initiatives that address health system barriers to access.

Eliminating schistosomiasis as a public health problem

Schistosomiasis, also known as bilharzia, is a tropical disease caused by parasitic worms. The disease affects **almost 240 million people** worldwide and **kills an estimated 200,000 people** every year. More than 90% of cases are in sub-Saharan Africa, significantly burdening public health systems and local economies.

The ultimate aim of our schistosomiasis-related work is to eliminate the disease as a public health problem in line with the World Health Organization (WHO) **NTD Roadmap 2021-2030**. We are committed to the objectives of the **Kigali Declaration** on NTDs, in which participating companies, governments and private organizations commit to helping control and ultimately eliminating the 20 most prevalent NTDs, including schistosomiasis.

To achieve the elimination of schistosomiasis, we have adopted an integrated strategy, which we are implementing in close collaboration with multiple partners worldwide. The approach focuses on four pillars:

- **Treatment:** We donate up to 250 million tablets of praziquantel to endemic countries every year in partnership with **WHO**. Nearly 50 years after its development, praziquantel 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 programs for a next generation of drugs, for the development of arpraziquantel, a potential new treatment option for children aged six and under, and for new and more sensitive diagnostics. We are also building **research expertise and capacity** through our collaborations with institutions in endemic countries.
- **Health education & WASH** (water, sanitation and hygiene): We believe prevention is the most effective health intervention. Therefore, we invest in behavior change initiatives to raise awareness of the causes and dangers of schistosomiasis and teach people how to prevent it. Since the disease is transmitted through contaminated water, we also support WASH projects that aim to prevent transmission of the disease by providing sanitary infrastructures and access to clean water.
- **Advocacy and partnerships:** We are accelerating the progress towards schistosomiasis elimination through partnerships as well as through the dialogue with the wider stakeholder community, for example via the Global Schistosomiasis Alliance (**GSA**).

Preventing and fighting malaria to support elimination

According to WHO's estimates, nearly half of the world's population is at risk of contracting malaria. In 2020, more than **200 million cases of malaria** and over 600,000 related deaths were recorded, with about 80% occurring in children under the age of five. 95% of cases and 96% of deaths occur in Africa. The numbers continue to increase as the focus in many endemic countries has shifted to controlling the Covid-19 pandemic.

There is a need for new products to overcome the problem of increasing drug resistance and to achieve the goal of elimination. Through our **As One Against Malaria program**, we help to deliver integrated and sustainable health solutions involving treatments, diagnostics and preventive measures to fight malaria.

Roles and responsibilities

Our Global Health organization is responsible for Group-wide initiatives, programs and sponsorships. It embeds initiatives to strengthen capacity in low- and middle-income countries. Our experts collaborate closely with the Life Science, Healthcare and Electronics business sectors to leverage our common strengths and competencies. Our Global Health organization also facilitates access to health in underserved populations and leads the implementation of our strategy to eliminate schistosomiasis as well as the development of innovative solutions for infectious diseases including malaria.

Our Access to Health unit enables access to our company's healthcare portfolio in low- and middle-income countries through a strategic access approach and shared value initiatives that we implement in collaboration with our global and country teams.

Our **Schistosomiasis Elimination Program** implements our efforts to eliminate schistosomiasis in **close collaboration with external partners,** such as WHO.

Our **Global Health Institute** catalyzes innovations for global health challenges by translating science, technology and digital approaches into transformative, integrated health solutions (treatments, diagnostics, technologies, preventive measures) to support control and elimination programs related to infectious diseases – mainly schistosomiasis and malaria.

Our commitment: Providing a solid basis for access to health

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

- **Our approach**
- **Pharmaceutical product donations and philanthropic activities**
- **Falsified medicines**
- **R&D for infectious diseases**
- **Equitable pricing in low- and middle-income countries**
- **Intellectual property rights**
- **Sustainable supply chains**

Every two years, the **Access to Medicine Foundation** publishes the **Access to Medicine Index**. The Index 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. These initiatives

range from research & development and intellectual property sharing to capacity building and donations. We use the results of this benchmarking to inform and guide our access to health strategy.

The latest Index was published in November 2022. We **ranked fifth**, moving up from the eighth position in the 2020/2021 ranking. Our ranking is mainly attributable to our strong performance in the areas of research and development, intellectual property and capacity building.

Sustainable access to medicines in low- and middle-income countries

We apply access models in global health, which include donations (e.g. praziquantel), and work with partners to explore new models such as at cost procurement mechanisms for upcoming innovations for NTDs (e.g. arpraziquantel, rapid diagnostic tests).

To prevent and control high-burden, non-communicable diseases (NCDs), we significantly invest in access initiatives that address health system gaps in low- and middle-income countries. We adopt a partnership approach to maximize our impact in this complex and challenging environment.

This includes our shared value program, which supports our teams in low- and middle-income countries in implementing initiatives to address health systems barriers to patient access through capacity building and training for healthcare professionals. For example, in the context of the shared value program, the team in Argentina carried out a series of activities to raise awareness about the importance of early detection of head and neck cancer, reaching 4.6 million people across the country. To date, our shared value initiatives have reached 28 million patients via screening and awareness and trained around 15,000 healthcare professionals.

Our **collaborations in Africa** to establish robust and sustainable supply chains are also crucial for ensuring safe, effective and continuous healthcare delivery. Our Access Mentorship program, where expert volunteers from our Global Supply Network Organization share knowledge with local African distributors, demonstrates our commitment to improving supply chain operations and increasing access to healthcare.

In 2022, we also initiated the Access to Health pitch competition to engage with start-ups in Indonesia, Vietnam and the Philippines. This initiative aims to identify innovative solutions that address health system gaps and make our products more accessible to underserved populations.

We have also developed an evaluation tool to track the impact of our access programs on patients, healthcare providers and health systems. This tool will enable us to monitor our progress over time and to continue integrating recommendations from the Access to Medicine Index into our strategy.

Eliminating schistosomiasis: Four pillars

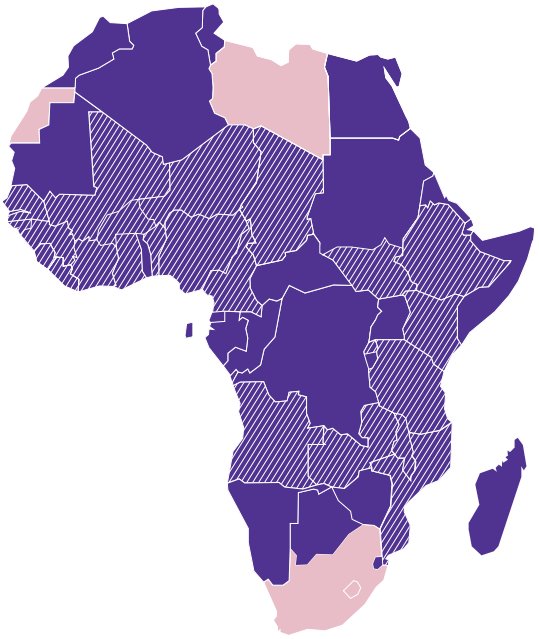
To support the elimination of schistosomiasis, we have adopted an integrated approach based on four pillars: treatment, research & development, health education & WASH, and advocacy & partnerships.

Treatment

As part of our long-standing partnership with WHO, we are committed to producing and donating up to 250 million praziquantel tablets every year. This initiative is a major part of our integrated and coordinated approach to treating and eliminating schistosomiasis as a public health problem. Since 2007, we have donated **1.7 billion tablets** to WHO to combat this disease. They have been **distributed in 47 endemic African countries**, primarily to treat school-aged children. In 2022, we donated more than 200 milliontablets for distribution in 27 countries, 24 of which are in sub-Saharan Africa. Due to Covid-19, demand and implementation at country level was severely impacted.

Countries that have received donations of praziquantel tablets

Since 2007, we have donated over **1.7 billion** tablets of praziquantel, which is enough to treat around 680 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 2022.

Countries that have received no donated tablets to date.

* Launch of our Praziquantel Donation Program.

To improve transparency of the supply chain for NTD medicine donations, including praziquantel, we use NTDeliver, a digital tool. We work with multiple partners to optimize efficiencies and timelines from the manufacturing site to the national warehouse, and from there to the delivery of treatments. In Kenya, a tailored tracking system has been implemented to capture real-time data up to the distribution level, reporting the number of tablets used and any remaining stock. In 2022, this digital last-mile tracking system was rolled out in six Kenyan counties.

Research and development

In partnership with the **Pediatric Praziquantel Consortium**, we have developed a **potential new treatment** option, arpraziquantel, for preschool children aged six and below who are infected with schistosomiasis. The clinical development program was completed with positive results from the pivotal **Phase III trial** performed in Côte d'Ivoire and Kenya. In November 2022, we submitted the regulatory application to the European Medicines Agency (EMA), which started its review process. A scientific opinion from EMA is expected in late 2023. This will facilitate WHO pre-qualification and local registrations in African countries. We plan to start the launch phase in 2024 and to provide the drug through a new procurement mechanism currently under development to ensure equitable and affordable access to this new treatment option. Furthermore, the ongoing ADOPT implementation research program is collecting data and best practices that will pave the way for future large-scale delivery in endemic countries.

In 2022, we also progressed with the development of new drugs to prevent and cure schistosomiasis. A promising candidate is currently in pre-clinical development.

To support drug discovery, we have introduced innovative artificial intelligence and epidemiology modeling for targeted treatments and started to develop new medical device technologies to diagnose schistosomiasis, including **female genital schistosomiasis**.

In this context, there is still a critical need for more **sensitive diagnostics** to detect cases in low-endemicity settings for the effective management and surveillance of schistosomiasis and as tools to eliminate the disease. Therefore, we continued our collaboration with the Foundation for Innovative New Diagnostics (**FIND**) and a consortium of partners to develop a sensitive rapid diagnostic test to improve schistosomiasis mapping and case detection.

All our research & development programs integrate and invest in scientific, educational and training initiatives to enhance expertise and capacity in low- and middle-income countries. More information can be found under **Building health capacity and awareness**.

Health education and WASH

Our health education project with the **NALA** (Neglected Tropical Disease Advocacy, Learning, Action) Foundation focuses on southwestern Ethiopia. It includes WASH activities and aims to promote **long-term sustainable behavioral change** via a community-based approach to eliminate schistosomiasis and other neglected tropical diseases. In 2022, we launched two research projects to serve as proof of concept: community-based schistosomiasis snail mapping, and operational research. This research compares two districts to evaluate the effectiveness of behavioral change in combination with mass drug administration versus mass drug administration alone. Results are expected in 2023.

Despite the challenges, including the Covid-19 pandemic, security issues and political instability, the NALA Foundation was able to continue the implementation of school-, community- and WASH-based interventions. An impact evaluation in two of the target districts showed a meaningful decrease in the prevalence of schistosomiasis since the start of the program in 2017.

In Ghana, we implemented our collaborative access to water program to improve WASH in communities, including schools and healthcare facilities, to combat waterborne infectious diseases such as schistosomiasis. We also trained health workers in schistosomiasis case management. Performed in partnership with World Vision, the program includes an implementation research study that analyzes WASH in healthcare facilities and water quality in selected districts. The results show that only 17% of the healthcare facilities have access to improved water supply within the premises; to address this challenge, we are partnering to provide WASH to 15 institutions by July 2023, with an estimated outreach of about 24,000 people.

More information can be found under **Building health capacity and awareness**.

Advocacy and partnerships

We work with international and local partners to advance schistosomiasis control and elimination. We continue to support the Global Schistosomiasis Alliance (**GSA**), a coordinated, multi-sectoral effort to combat the complex disease. The role of the GSA as central platform in all matters concerning schistosomiasis has been considerably strengthened over the past few years. In 2022, the GSA developed a new four-year strategy, which lays out the agenda for the global schistosomiasis community on the road to elimination.

Malaria: Treatment and prevention

Developing new therapeutic solutions

As part of our "**As One Against Malaria" program**, we are developing a new drug (M5717) with the potential to be a promising treatment and preventive option for malaria due to its activity in several **different stages** of the parasite's life cycle. The drug has successfully completed two clinical Phase I studies as a single agent for cure and prevention, and we published the results in peer-reviewed scientific journals (e.g. **The Lancet Infectious Diseases**). In 2022, we joined the PAMAfrica Consortium and are preparing for the start of the

clinical Phase II study as a combination therapy for cure in 2023. In addition, a clinical Phase II trial for prevention is being prepared through a new partnership. Preclinical research and new technologies, including a **new 3D culture-based hepatic platform** used to investigate the activity of our drug candidate, have supported the clinical development program.

Preventing and controlling malaria transmission

Preventive methods such as insect repellents are part of the strategic toolkit to combat malaria. We are testing our insect repellent IR3535® for potential use in malaria. IR3535® is already used for protection against insect and tick bites that can transmit diseases such as **Lyme disease**, **Zika**, **dengue fever**, and **chikungunya**.

The laboratory tests conducted in Ghana evaluated the efficacy of a **new formulation of IR3535®** for longer-lasting protection. Based on the positive results, an additional test is being carried out in communities to determine how IR3535® performs in real-life settings. The study aims to confirm that this insect repellent is a safe and efficacious solution to prevent malaria in all populations, including pregnant women and babies.

In partnership with local institutions in Africa, we have established PAVON (Pan-African Vivax and Ovale Network), a network of centers of excellence for the epidemiological surveillance and scientific research on malaria. Across more than ten African countries, PAVON supports policy making and offers training to African scientists.

Engaging stakeholders

Partnerships and dialogue are critical to addressing global health challenges and improving access to healthcare. Our partners include multinational organizations, government agencies and NGOs, as well as academic institutions, health industry associations, private companies, and independent global health experts.

In 2022, we continued to engage with our partners and key stakeholders, including **WHO**, to advance global health discussions and address shared challenges, including neglected tropical diseases. We collaborate with partners such as the **END Fund**, **WIPO** and **DNDi**, as well as with academia in African countries. We engage in consortia of partners, such as the **Pediatric Praziquantel Consortium**, alliances, like the **Swiss Malaria Group**, and advocacy groups, including the **Uniting to Combat NTDs** and **GSA**. In addition, we work closely with foundations that support scientific research and health access, including the **Bill & Melinda Gates Foundation** and the **Access to Medicine Foundation**. We have also joined forces with funders, including the Global Health Innovative Technology Fund (**GHIT**) and the European and Developing Countries Clinical Trials Partnership (**EDCTP**).

We also strengthen our **collaborations with the scientific community** through publications, patent sharing and by taking active roles at international events. For example, in 2022, we organized a panel discussion with experts on schistosomiasis at the Geneva Health Forum (**GHF**). In 2022, our CEO Healthcare represented our company at the Gates CEO Roundtable that discussed the strategy to expand access to medicines in low- and middle-income countries. On several occasions, we presented the progress of the Pediatric Praziquantel Consortium program that we lead, including at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), the Global Health EDCTP3 Launch Event, and the International Symposium on schistosomiasis. We also attended the Annual NTD NGO Network and the Coalition for Operational Research on Neglected Tropical Diseases (**COR-NTD**) to address the spread of misinformation about NTDs.

Open innovation sharing

We have a responsibility to improve global access to health through our technological advances. We support a reliable and transparent legal framework for intellectual property that enables sustainable investment in research and development.

Our approach to sharing and protecting intellectual property

The responsible treatment of intellectual property is not a barrier to health, but rather ensures the **safety and high quality** of medicines for patients worldwide. Almost none of the medicines that address the highest burden of disease in low- and middle-income countries are 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 **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, including non-exclusive voluntary licenses, legally binding non-assertion covenants and clauses that aim to widen access to health.

We also support the concept of patent pools and believe that these should be structured to improve access to medicines, prevent anti-competitive behavior and overcome geographic limitations. We consider joining **patent pools** that are relevant to our portfolio and meet all our efficacy, quality and safety requirements.

Through our **open innovation research projects** for global health, we grant access to small sections of our chemical compound libraries. In doing so, we aim to accelerate collaborative research programs that develop novel R&D platforms in search of new active ingredients for infectious diseases.

Roles and responsibilities

Our Open Innovation initiatives are collaborative and cross-functional efforts that facilitate the exchange of intellectual property. We aim to accelerate early discovery in diseases with high unmet needs through intellectual property sharing. We hope to foster the discovery of new generations of health solutions that will address the needs of the most vulnerable populations, with a primary focus on the neglected tropical disease schistosomiasis and on malaria.

Our commitment: supporting transparent and reliable frameworks

We support **TRIPS**, an international agreement administered by the World Trade Organization (WTO), which addresses trade-related aspects of intellectual property rights, as well as TRIPS addenda, such as the Special Declaration on the TRIPS Agreement and Public Health. This agreement extends the deadline for the 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**), a global gateway to medicine patent information. 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.

Creating research opportunities

Our **Open Global Health Library** publicly shares 250 compounds from our proprietary chemical library that may be used for infectious diseases research. Since its launch in 2020, the library has been accessed 28 times for screening in 18 indications.

We were a member of the WIPO Re:Search Consortium until the initiative was terminated at the end of 2022. Our contributions supported screening and drug discovery activities at institutions in low- and middle-income countries to identify potential investigational candidates to treat neglected tropical diseases, such as schistosomiasis. This initiative also enabled the transfer of knowledge and expertise for research, mainly in and for Africa.

Schistosomiasis research grants

We are dedicated to accelerating innovation and advancing science for the benefit of the most neglected populations. That is why we catalyze research in an open innovation spirit and with the intention of reducing financial hurdles. For example, through our **Schistosomiasis Research Grant Initiative**, established in 2021, we awarded 15 research projects with € 30,000 each. In 2022, all projects were launched, and interim reports on their progress have been shared.

Drugs for Neglected Diseases initiative

We are collaborating with the Drugs for Neglected Diseases initiative (DNDi) and, through the memorandum of understanding with DNDi and the Swiss Tropical and Public Health Institute, we are continuing our dialogue for research in the field of **schistosomiasis**. In 2022, DNDi held several expert meetings seeking to establish a target product profile for antischistosomal drugs.

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

Prices of medicines

In 2021, pharmaceutical spending accounted for **between 6% and 32%** of total health spending by OECD countries. At the same time, 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

To help ensure that all patients have access to the most effective medicines for their needs, we are working to prevent cost from becoming a barrier to treatment. Therefore, we adapt our medicine prices according to people's ability to pay in different geographic and socioeconomic segments.

We are committed to **fair, flexible and sustainable pricing** – both within and across countries. We therefore adapt our prices based on local market considerations, such as unmet medical and treatment needs, health system capacity, infrastructure and socioeconomic standards. This approach involves working closely with governments and other stakeholders. In addition, 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 conduct price analyses annually to validate price thresholds and provide guidance on local pricing to our subsidiaries for the following year. The aim is to ensure they meet patient access needs, taking a **consistent, data-driven approach**. We also make our products affordable to patients in low- and middle-income countries with an equitable value and access strategy that includes participating in government tenders, providing flexible pricing, establishing high-quality affordable brands or branded generics and operating patient access programs.

Furthermore, 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.

Roles and responsibilities

Our Global Market Access and Pricing (GMAP) unit evaluates market launch prices in coordination with the respective franchises. The team reports directly to a member of our Healthcare Executive Committee. The GMAP unit systematically evaluates our medicine portfolios and applies equal access initiatives to them. Our local affiliates are responsible for managing prices and adapting them to evolving local conditions in compliance with our pricing governance and the defined price approval process.

Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition. Our medicine pricing adheres to the stipulations of our overarching **Access to Health Charter** and is defined in detail in an internal guideline. Additionally, our Patient Access Programs Policy sets out standards for offering medicines at affordable prices.

Value-based contracting models

We are committed 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 have developed various product- and market-specific reimbursement and contracting models. These help to provide patients with prompt **access to our innovations**.

In Germany and Ireland, we continued in 2022 with innovative risk-sharing agreements that provide immediate access to Mavenclad® for patients with multiple sclerosis. In addition, the value-based contracting model for Mavenclad® has also been implemented in four more countries in Europe, Latin America, and the Middle East with more countries under assessment for further implementation. Besides that, we facilitated a roundtable with payers in Argentina, Brazil, Colombia, Germany, Italy, and Spain to discuss the current and future landscape of the value-based contracting model for Mavenclad®.

Equitable value and access approaches to serve low- and middle-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.

Strategic tender activities

Our pharmaceutical tender excellence initiative offers a strategic tender framework. This includes a web-based system that helps country teams increase **quality and agility** in tender decisions, while improving performance tracking and collaboration. We regularly participate in government tenders for products 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 high-quality products, we have created second brands at affordable prices, particularly in countries with a large percentage of patients with very low incomes. For example, second brands for the betablocker bisoprolol (Concor®) are available at affordable prices in Brazil, Chile, Poland, and South Africa.

Patient access programs

We operate patient access programs that enable us to offer certain products at affordable prices in several countries. In India, we offer a program for our oncology drug Erbitux®, for example, to provide financial assistance to eligible underprivileged patients – in line with local laws and regulations. Since the initiation of the program in 2017, it has been made available to over 5,000 patients in the country. In 2022 alone, more than 1,500 patients benefited from the program.

In 2022, we continued to collaborate with national pharmacy chains in Mexico to provide patients with adherence support, discounts on blood tests and education on prediabetes and diabetes, thyroid, cardiovascular and obesity disorders. To improve adherence, in Central America (Costa Rica, the Dominican Republic, Guatemala, Honduras, Nicaragua, and Panama), we offer a digital loyalty program for the aforementioned conditions. To strengthen health systems and raise patient awareness in China, we sponsored the Hypertension Center Program in 2022, which is organized by the China Cardiovascular Association. The program aims to elevate awareness of standard diagnosis and treatment for patients with hypertension and increase blood pressure target achievement.

Building health capacity & awareness

We believe that in order to achieve health for all, it is imperative to help health professionals and patients make informed decisions about treatment paths. This support includes building health capacity as well as awareness. As a prerequisite, health systems need to be strong and benefit from solid collaborations to build resilience against crises and emergencies.

Our approach to building health capacity and awareness

Capacity-building and awareness-building play key roles in our approach to improving **access to health**. We empower patients, communities, scientists, and healthcare professionals by providing appropriate tools, skills and information so that they can make **informed decisions** about prevention, diagnosis, treatment, care, and disease management.

The private sector is a crucial partner in responding to global health threats. Beyond developing innovative health solutions and applying adapted mechanisms for access to medicines, we support countries in building up infrastructure and expertise for preparedness of local health systems to deliver care to all patients in need and address emergencies effectively. That is why we invest to sustainably strengthen the prevention, preparedness and resilience capabilities of health systems in low- and middle-income countries. Our efforts include the following aspects:

- **Increasing country preparedness** by enhancing scientific and healthcare workforce competencies and capacities through a network of experts.
- **Forming partnerships** to extend disease awareness and address the challenge of enabling consistent access to medicines for all patients in need.
- **Optimizing the monitoring and evaluation** of health initiatives at country level through data processing and digitalization.

We operationalize these elements along the entire value chain in our collaborative programs and through our health education initiatives with our local partners.

We also collaborate with committed global partners to conduct educational campaigns for prevention, early diagnosis and awareness. We focus primarily on the diseases for which we have the greatest expertise. Our activities include specific initiatives that promote awareness for **carers** as well as **women's health and economic empowerment** to expand their access to health.

Roles and responsibilities

Our Global Health organization leads collaborative capacity strengthening and awareness initiatives in low- and middle-income countries to support our mission of improving the health of the most vulnerable populations.

Our awareness initiatives are aligned with our Group strategic direction and planned by the various businesses. They are implemented either on global and/or local levels, with projects organized according to the **specific needs of the relevant community**. Our subsidiaries are also responsible for mobilizing our global campaigns locally.

Our commitment: access to health through awareness and education

Our strategy for addressing access to health incorporates the topic of awareness and education as detailed in our **Access to Health Charter**. Our campaigns and initiatives 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 that guide our **interactions with health systems** and by communication material review processes that ensure we comply with global, regional and national rules and regulations.

Working with partners to achieve more

Our Global Health portfolio consists of collaborative initiatives that aim to strengthen the capacity and effectiveness of health systems in low- and middle-income countries. We support work in these four key areas:

Local research and development

We build scientific capacity through our **R&D programs** and focus primarily on schistosomiasis and malaria. Some examples include:

- Clinical trials in African health centers to investigate arpraziquantel as a potential new treatment option for pre-school children infected with schistosomiasis. These trials have enabled local healthcare professionals to acquire valuable experience in Good Clinical Practice, which they can apply in future studies.
- Our partnership with the **University of Cape Town for malaria drug discovery** activities that transfers scientific expertise and supports the employment and training of talented local young scientists.
- **PAVON** (Pan-African Vivax and Ovale Network), a network of centers for excellence on malaria surveillance and pandemic preparedness implemented in more than ten African countries. The project offers training to African scientists in a collective effort to strengthen local health systems to treat all forms of malaria.

Manufacturing and supply chains

We manufacture some of our products directly in the regions where they are needed. We also strengthen local manufacturing and supply chain capacities through **technology and best practice transfers**. Our aim is to increase service quality while ensuring safe, effective and reliable access to quality medicines where they are needed most.

- We produce praziquantel, the standard-of-care treatment for schistosomiasis, in our production facility in Mexico, to enable the provision of up to 250 million tablets per year to treat the disease, mainly in school-age children.
- We apply a local production approach in our work with the **Pediatric Praziquantel Consortium** to help countries become self-sufficient and serve local populations in need. Following our 2021 manufacturing agreement with Universal, a contract manufacturer in Kenya, we are preparing for the large-scale production of arpraziquantel upon its registration, in addition to production by Farmaguinhos in Brazil.
- We partner with Business for Health Solutions (**BHS**) to build sustainable supply chains of local distributors in Africa through our **Access Delivery Mentorship program**. In 2022, we started three collaborations with distributors, thus a total of six distributors in five different countries.

Education and awareness raising

We invest in **education and behavioral change initiatives** that raise disease awareness. Examples of those initiatives include:

- In Ethiopia, we operate a joint health education and WASH project in partnership with the **NALA Foundation** and the Ethiopian Ministry of Health. We are aiming to reach 50,000 community members in 8,000 households and more than 170,000 school-age children in districts with the highest prevalence of schistosomiasis.
- In partnership with the Cardiological Society of India (**CSI**), the country's largest professional cardiology association, we implemented an initiative that raises awareness in populations with a high risk of cardiovascular diseases.
- To support behavioral change for schistosomiasis elimination, we have introduced the **Bilharzia Storytelling Lab**. The lab brings together storytellers, health experts and community leaders from one country to develop creative communication products that provide accessible and tailored disease information to risk groups. We award the most promising solution with a € 10,000 prize. We intend to apply the concept in several endemic countries in sub-Saharan Africa. The first lab took place in Kenya in 2021, the second in November 2022 in Rwanda.

Health infrastructure and training

We **build infrastructure and support training** with a strong focus on African countries. In 2022, we

- supported the management of **integrated mobile health units in Cameroon** to diagnose and treat female genital schistosomiasis, **HIV**, **HPV, and cervical cancer** for women aged 14 to 30. This initiative includes training to enhance the skills and experience of local health professionals;
- set up **microscopy stations in Ghana, Burkina Faso and Botswana** and provided training sessions to improve local health workers' ability to detect malaria and other diseases that can be diagnosed via blood samples;
- implemented our collaborative **access to water program in Ghana** to improve healthcare infrastructure through safe water services in health centers as well as training to health workers on schistosomiasis case management;
- partnered with the H3D Foundation at the University of Cape Town to co-create a Massive Open Online Course on research and **development for young African scientists**. Participants earn a certification after taking the course and can also join a Mentorship Program delivered by R&D employees of our company.

More information can be found under **Global Health**.

Global awareness campaigns

We regularly conduct campaigns to raise awareness of various diseases across the globe, often in collaboration with patient advocacy and carer groups. We focus on diseases that are aligned with **our core competencies**, expertise and experience along the health value chain. These diseases include cancer (specifically colorectal cancer, head and neck cancer and bladder cancer), thyroid disorders, diabetes, infertility, and multiple sclerosis. Throughout the year, we also conduct awareness campaigns that focus on tropical diseases, such as schistosomiasis and malaria.

We actively participated in several awareness days:

January 30: World NTD Day

World NTD Day brings together civil society advocates, community leaders, global health experts, and policymakers, who collaborate across disciplines to control and eliminate neglected tropical diseases.

February 4: World Cancer Day

February 4 marks **World Cancer Day**, an annual initiative led by the Union for International Cancer Control (UICC). It aims to raise cancer awareness and improve its prevention, detection and treatment. In 2022, the theme was “Close The Care Gap”.

March 22: World Water Day

Held on 22 March every year since 1993, it celebrates water and raises awareness of the 2 billion people living without access to safe water.

April 7: World Health Day

World Health Day raises awareness about a specific health theme each year to highlight a priority area of concern for the World Health Organization. In 2022, the theme was “Our Planet, Our Health”.

April 25: World Malaria Day

World Malaria Day highlights the need for continued investment in and sustained political commitment to malaria prevention and control.

May 25-31: Thyroid Awareness Week

In collaboration with the Thyroid Federation International (**TFI**), the annual awareness campaign, which used the slogan “Do You Speak Thyroid?” in 2022, focused on preventing information from being lost in translation between thyroid patients and their caregiver teams.

May 30: World Multiple Sclerosis Day

World Multiple Sclerosis Day is an annual awareness day by the MS International Federation (**MSIF**). It brings the global MS community together to share stories, raise awareness and campaign with everyone affected by multiple sclerosis. In 2022, it focused on supporting the community to create meaningful connections.

July 27: World Head And Neck Cancer Day

World Head and Neck Cancer Day is an opportunity to inform the general public about head and neck cancer and recognize the impact it has on those affected in the community.

August 1: World Lung Cancer Day

The Forum of International Respiratory Societies has observed World Lung Cancer Day every year since 2012 to raise awareness about the risk factors of the disease.

September 29: World Heart Day

World Heart Day was established by the World Heart Federation and increases awareness about cardiovascular diseases and how to control them to negate their global impact.

November 1-7: European Fertility Week

European Fertility Week raises awareness about infertility and conveys the issues faced by people with infertility. It also aims to remove the stigma around infertility and amplify the issue of unequal access to treatment in Europe.

November 10: World Science Day

World Science Day for Peace and Development highlights the vital role of science in society and the need to engage the broader public in debates on emerging scientific issues. By linking science more closely with society, World Science Day for Peace and Development aims to ensure that citizens are kept informed about important scientific developments.

November 14: World Diabetes Day

World Diabetes Day was created in response to growing concerns about the escalating health threat posed by diabetes. The 2022 campaign, the theme of which was “Education to Protect Tomorrow“, aimed to keep diabetes in both the public and political spotlight.

Purpose-driven initiatives

Healthy Women, Healthy Economies and **Embracing Carers®** are two initiatives we are using to promote awareness of public health issues extending beyond patients. The interconnectedness of both initiatives is rooted in shared themes and goals. The majority of unpaid and underpaid caregiving hours globally are provided by women and girls. Through these initiatives, we aim to both promote and support women’s health and economic empowerment and expand access to health.

Healthy Women, Healthy Economies

To empower women to overcome the challenges of communicable and non-communicable diseases and reach their economic potential, we are committed to the **Healthy Women, Healthy Economies** initiative – a public-private partnership founded within the Asia-Pacific Economic Cooperation (**APEC**).

Since 2019, the APEC Healthy Women, Healthy Economies **Research Prize**, which we support, has highlighted sex-disaggregated research that enables policymakers, business leaders and other stakeholders to identify and implement measures that improve women’s health in APEC economies. The 2022 prize of US$ 20,000 was awarded to Zheng Ruimin, Director of the Women's Health Care Department at China’s National Center for Women and Children's Health, for an innovative study that developed a comprehensive, accessible and affordable maternal depression screening strategy.

Embracing Carers

Embracing Carers® is our global initiative led in collaboration with prominent caregiving organizations from around the world. Embracing Carers® is designed to increase awareness, action and discussion around the frequently overlooked needs of unpaid caregivers.

To follow up on our 2021 survey, Embracing Carers® worked with global carer advocacy organizations to conduct focus groups with carers to better understand their problems and what can be done to address their needs. This information forms the basis of planning to provide greater support for caregivers, particularly with respect to their mental and emotional health needs.

Product safety & quality

Chemical product safety

Many of our chemical products have intrinsic hazardous properties. Therefore, we are working to minimize the potential risks to both human health and the environment that arise from their use. We continuously strive to improve the safety of our products and reduce the environmental impact of our businesses through innovative solutions and digital communication tools.

Our approach to safe chemical products

Product safety is one of our top priorities. During the product development phase, we investigate the potential adverse impacts of chemical substances. Along the entire value chain of our products – **from raw materials to manufacture and commercialization** – we provide relevant information on their hazardous properties and how to deal with them. These instructions facilitate the safe handling and use of our products in line with all regulatory requirements. We publish this information primarily on the relevant digital channels. As paper safety data sheets are still common in some countries, we can also provide these upon request through our customer service.

We support the implementation of the **European Green Deal** and are preparing to integrate the relevant chemicals sustainability aspects into our business strategies. We are currently developing a portfolio sustainability assessment framework for our Electronics and Life Science business sectors and are preparing to test its suitability and practicability in pilot projects.

Roles and responsibilities

Our Life Science, Healthcare and Electronics business sectors have organizational structures to implement our product safety strategy in line with their **respective business requirements and customer needs**. This approach includes registering chemicals, classifying hazardous substances, and highlighting risks using safety data sheets, labels and digital communication tools.

Our **Group standards** provide a framework for governing the set-up of effective operational processes for product safety, hazard communication and chemicals regulatory compliance throughout our business sectors. In addition, the Group Chemicals Regulations Council fosters cross-sectoral alignment of strategic regulatory activities required for existing and emerging chemicals regulations as well as sustainability and identifies potential impacts for our company.

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

Legal requirements and internal guidelines

Our internal guidelines define the roles, responsibilities and basic processes required to comply with national and international regulations. In addition, we have also endorsed **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 chemicals registration activities. These requirements are expanding globally, with a growing number of countries adapting their local rules in line with existing regulatory frameworks such as **REACH**. We are well placed to comply with regulations of this kind in important markets, such as China, India, Japan, Korea, and Taiwan. Using the Globally Harmonized System for Classification and Labelling of Chemicals (**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 to legal requirements and scientific developments to stay ahead of trends and best practices.

In 2022, there were no incidents of non-compliance with regulations specifically concerning potential health and safety impacts and the labeling of our chemical products.

Safety analysis of our products

Safe and sustainable by design implies that product safety starts during development. Therefore, at an early stage of our **product development process**, we analyze innovations in terms of their impacts on human health and the environment. We continuously evaluate the intrinsic hazards of both our existing and new products to create relevant product safety information in line with all applicable rules.

Product safety information

Chemical product safety is all about protecting human health and the environment from adverse impacts resulting from the use of chemical products throughout their life cycle. To achieve this, we provide **all relevant information** to our customers and the public, which helps to raise awareness of the hazards and build a greater understanding of how to mitigate risks and use the products safely.

To obtain all the relevant information on hazard profiles, we employ industry-standard **digital tools** that gather all information available on 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. We have automated and standardized most of our hazard communication processes.

For products with little available information, 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

We employ the latest digital tools and continuously explore new technologies to share information with our product users.

Our Life Science customers and all interested stakeholders 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**). Customers can retrieve this information by scanning a barcode on the product label or entering identifiers such as material numbers, names or CAS numbers.

Through our ScIDeEx™ web tool, anyone can check whether using a particular chemical is safe within the boundaries specified in the 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

The safety of patients treated with our medicines is our top priority. Our pharmaceutical products must be effective in treating the respective disease while posing the lowest possible risk to patients. That is why we aim at continuously monitor any risks or 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 medicinal products always outweigh the risks for patients. Every new medicine goes through a series of precisely defined development stages. Before any medicinal product 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 which dosage. This testing also helps us determine the dose that humans can safely tolerate. Only when this is complete do we perform human **clinical studies** to investigate the safety and efficacy of the medicinal product. During clinical development, we diligently use all the collected data to continuously evaluate the medicinal product's **benefit-risk profile**. If we consider the medicinal product's benefit-risk profile to be positive, we then submit an application for marketing authorization to the relevant regulatory authorities.

Continual monitoring of product safety risk profiles

Once we launch a new medicinal product, the number of patients being treated with the product increases significantly. In rare circumstances, there may be adverse and potentially serious effects that were not detected during clinical development, which is why we continuously monitor risks and assess the benefit-risk profiles of the products after their market launch. **Pharmacovigilance** includes the process of monitoring a medicinal product on an ongoing basis to detect and assess safety signals as part of **signal management** activities. Our pharmacovigilance system and our pharmacovigilance business continuity management ensure continuous monitoring of adverse effects, allowing us to proactively and transparently minimize and communicate any risks. Emergency response procedures for business continuity are managed in accordance with global and local business continuity plans, tested in regular, defined intervals or with mock scenarios. In addition, we always provide healthcare professionals and patients with the **latest information on the safety** of all our marketed medicinal products. The scope of continuous safety monitoring includes the entire life cycle of a product, ranging from development, market launch and commercialization to expiration of the marketing authorization.

As part of our R&D Strategy 2023, we achieved our objective of developing and implementing proactive benefit-risk management, process optimization, automation, and pharmacovigilance oversight. Furthermore, we continue monitoring our service objectives through our **pharmacovigilance quality strategy** and annual quality plan. We also regularly monitor our performance and compliance through the internal and external reporting of key performance indicators (KPIs).

The capabilities we have developed and strengthened in this area include:

- Advanced benefit-risk management
- Safety data analytics in support of benefit-risk strategy implementation (taking into account and integrating real-world data)
- Advanced signal detection methodology
- User-friendly methods for collecting adverse effects

Based on regulatory approval conditions for newly approved medicinal products, we develop and update educational materials for patients and healthcare providers in accordance with the requirement to communicate any known and potential risks and ways to minimize them. 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.

Roles and responsibilities

Our Global Patient Safety unit is responsible for pharmacovigilance. It continuously 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 vision is to embed a deep knowledge of safety into early decision-making as we evolve **to practice predictive safety.**

Our experts help to ensure that all information on the risks and adverse effects of our medical products 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.**

Our **Healthcare Quality** unit processes quality complaints related to our products. Whenever quality defects could have an impact on patient safety or lead to adverse effects, Global Patient Safety becomes involved.

Our Global Patient Safety unit hosts a Pharmacovigilance Intelligence Council that focuses on changes in pharmacovigilance legislation and its impacts on our global and local pharmacovigilance systems. This initiative enables us to make strategic decisions and govern changes in pharmacovigilance requirements, which fosters our target to ensure continuous compliance with regulatory requirements.

Our Medical Safety and Ethics Board

Our Medical Safety and Ethics Board (MSEB) oversees the safety and benefit-risk assessments of our medicinal products throughout their clinical development and commercialization. This internal board is chaired by our Chief Medical Officer and comprises experienced physicians, scientists and experts from our company. Throughout a medicinal product’s entire life cycle, the MSEB reviews and assesses important medical safety risks and benefit-risk issues and endorses appropriate **measures to minimize risks**, such as updates to product information. The MSEB furthermore reviews human-related ethical issues as appropriate.

The cross-functional Benefit Risk Action team is responsible for signal management, benefit-risk assessment, risk management and all topics related to 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, chaired by the Global Patient Safety unit. Important issues may be submitted to the MSEB for final assessment.

Our commitment: Guidelines and statutory requirements

Our aim is to follow international guidance and standard procedures, such as the International Council for Harmonisation (**ICH**) guidelines and the Good Pharmacovigilance Practices (GVP) established by the European Medicines Agency (**EMA**) and national health authorities. Furthermore, we aim at complying with all new statutory pharmacovigilance regulations in the countries where we market our products.

Inspections and audits for drug safety monitoring

Regulatory authorities conduct periodic inspections to verify that we comply with statutory requirements as well as our own internal pharmacovigilance standards. We follow up on the findings of health authority inspections and take necessary actions to ensure the ongoing compliance of our pharmacovigilance system. In 2022, we had four pharmacovigilance inspections.

Furthermore, we perform audits to ensure that all our units and subsidiaries involved in pharmacovigilance consistently meet all global requirements. In 2022, we conducted a total of 19 pharmacovigilance audits and found no significant deviations in our pharmacovigilance systems from these requirements and standards. We also conducted 16 external audits at our vendors and licensing partners involved in pharmacovigilance, helping us improve our pharmacovigilance processes and comply with regulatory requirements.

Applying our proactive safety strategy to benefit-risk assessments

With regard to product safety risk assessments, we have implemented an improved benefit-risk management strategy in order to become a proactive and benefit-risk-focused organization. In this context, we developed in 2021 the concepts and principles for conducting benefit-risk assessments at each stage of product development and post-marketing. Along with the implementation of the redesigned benefit-risk strategy, the new Benefit Risk Action Team co-leadership model was rolled out in 2022. This redesigned approach will enable us to understand in even greater detail the benefit-risk profiles of our products, enabling early decision-making within the organization to protect patient safety. Ultimately, the aim is to be able to provide **the right medicine to the right patient at the right time**.

Product safety assessment and emergency response procedures

A product prioritization tool as a means to objectively score the safety profile of our products has been used as a basis to define our product prioritization strategy. The scores categorize our products as being either high-, medium- or low-risk and subsequently defining our approach for benefit-risk activities and product safety surveillance. These include individual case safety report management, signal management and management of emerging safety issues, risk management, safety communication, our new benefit-risk strategy and aggregate safety reporting. This ensures the **efficient management of safety risks** of our medicinal products throughout their lifecycles.

If our safety risk assessments identify any emerging safety issues, safety observations that require urgent safety measures, or other new safety information that potentially impacts the benefit-risk balance of the product, we promptly notify health authorities via the respective emergency response procedures. These steps include seeking health authority approval for further actions and communicating the information to relevant healthcare professionals. In addition, we promptly share this information with our business partners and clinical trial investigators, enabling them to take proper actions where the medicinal product concerned is used.

Innovative safety signal detection

Through our tools for safety signal detection, we analyze and manage large amounts of global data, such as scientific studies and news about adverse events. This tool helps us comply with regulatory timelines for safety signals and other safety-related factors and ensures that all signal data, documentation and decisions are captured in one place. It also enables 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.

Up-to-date labeling and product information

Our product information explains to healthcare professionals and patients how to correctly use the respective product and make informed treatment decisions. 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. In addition, should the medicine contain ingredients that could impact the environment, the package leaflet may also contain information about how to dispose of the product correctly. We review and update all product information documents, such as package leaflets, to ensure our medicinal products contain the latest information on safety, efficacy and pharmaceutical formulation. In accordance with regulatory requirements, we submit all modifications to our leaflets to the respective regulatory authorities for approval. In 2022, there were no significant reportable incidents of non-compliance with regulations concerning the labeling of our medicinal products.

Internal and external training

Our pharmacovigilance experts are regularly trained so that they gain and maintain the required experience and knowledge to carry out their activities. We manage our training via a global learning platform and verify compliance with our training requirements by producing training completion reports.

Our approximately 24,000 Healthcare employees receive **basic pharmacovigilance training** once a year that covers the procedure for reporting adverse effects or special circumstances associated with the use of our products. In addition, other training courses keep employees up-to-date with respect to their professional expertise as well as internal standard operating procedures and other relevant requirements. These continuing education and training efforts help us to ensure adherence to pharmacovigilance requirements.

Enhancing patient safety and sharing expertise with other countries

We exchange experience and share our expertise by contributing to initiatives hosted by various non-profit organizations, for example, the TransCelerate Biopharma. As an active member of TransCelerate, we have directly contributed to initiatives such as intelligent automation opportunities in pharmacovigilance, pharmacovigilance agreements optimization, and the interpretation of guidance documents and regulations.

Reporting side effects via app

In line with our goal to enhance patient safety, we implemented a user-friendly mobile and web application in 2017 for use by field forces, sales representatives, healthcare professionals, pharmacists and non-medically trained users to **report any suspected side effects** or adverse events arising from the use of our medicinal products. In the reporting year 2022 we continued to further rolled-out the application, which is now available in 14 different languages, used in more than 50 countries.

Pharmacovigilance in Access to Health

We strive to continue expanding pharmacovigilance expertise worldwide, especially in countries where healthcare workers need to build this expertise.

We continue our efforts to increase the contribution of pharmacovigilance in our **Access to Health** strategy. The key aspects of this strategy include fostering pharmacovigilance initiatives in safety data-sharing with health authorities and sustainably building pharmacovigilance capacity with reputable partners in underserved countries. For example, we have maintained a stable partnership with the Tunisian health authority over many

years to actively help establish the national pharmacovigilance system via various initiatives. These include the good pharmacovigilance practice guideline that was published in August 2022.

In 2022, we continued to raise awareness for **Patient Safety Day** via our affiliates in several countries, including Australia, China, Hong Kong, India, Indonesia, Korea, Malaysia, the Philippines, Singapore, Taiwan, Thailand, and Vietnam.

In other initiatives, we contributed to the review of draft guidance documents for clinical trials and provided feedback to the health authorities in China. We also participated in the review and feedback of draft regulations for good pharmacovigilance practice before its rollout by the Eurasian Economic Union. In addition, we collaborated with the health authority in Chile to test and provide feedback about the new Integrated Vigilance System.

Access to approved medication for unapproved uses

We may 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, based on an individual risk-benefit assessment, may wish to administer a product to a patient suffering from a disease for which it is not approved.

We promote our medicines strictly within the scope of their specific marketing approval. Any medical-scientific information about the use of our products beyond their existing marketing authorization is provided by qualified medical personnel in response to unsolicited inquiries. The information shared must be backed by scientific evidence and be factually balanced, clearly stating that it applies to unapproved use. In addition, we do not permit our employees to give any recommendations regarding individual patient care or treatment.

Product-related crime

In low- and middle-income countries as well as industrialized countries, illegal, counterfeit and substandard medicines pose a significant risk to public health. In addition, chemicals may be misused for criminal purposes, such as the manufacture of illicit drugs. We take resolute action against both of these criminal activities.

Our approach to product-related crime

Our company develops and manufactures pharmaceutical and chemical products of the highest quality. We take resolute action against product-related crime in order to protect our patients and customers from the harm caused by illegal products. For this purpose, we have implemented a Group-wide strategy, which focuses on identifying and responding to the availability of counterfeit medicines as well as ensuring the integrity of our products and supply chains. Moreover, we are committed to collaborating with government authorities as well as national and international organizations. Together, we want to tackle product-related crime and raise awareness of the issue among stakeholders and the wider public.

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 and warehouses, or while in transit.

Roles and responsibilities

The Corporate Security unit coordinates our approach to tackling product-related crime on the strategic level. A cross-functional team supports the operational implementation of the strategy. The team comprises experts from various units, including Legal/Trademarks, Product Security, Export Control, Supply Chain, Patient Safety, Regulatory Affairs, and Quality Assurance. Furthermore, all our sites have product crime officers who serve as central, local points of contact and act as the interface between both local and global stakeholders, internal and external alike.

Our commitment: Group-wide guidelines and standards

Globally applicable regulations are a key part of our approach to effectively and efficiently tackling product-related crime. The Group-wide guideline entitled “Illicit Trade & Product Crime Prevention” describes our goals and measures for reducing product-related crime and minimizing its impact. Our Group-wide Product Crime Incident Management standard sets out mandatory requirements for effectively managing incidents of product-related crime.

How we are tackling product-related crime

1. Detecting counterfeit medicines and taking them out of circulation

A team of experts examines, evaluates and processes every notification we receive regarding suspected counterfeit medicines. Our response always complies with both the regulatory requirements and our own wider objectives for tackling counterfeit products. We proactively **conduct investigations** both online and offline in order to identify and disrupt the availability of illicit products in legitimate and illegitimate channels. We document all incidents using a central, Group-wide reporting system. Moreover, we support the prosecution of criminals by working closely with the authorities. As a member of the Pharmaceutical Security Institute (**PSI**), we routinely share intelligence about product crime with other pharmaceutical companies.

In 2022, our internal experts examined and pursued numerous incidents, including **counterfeits identified within the legitimate and illegitimate supply chains** as well as theft and illegal diversion.

2. Tracking system for chemical substances

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

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

3. Protecting the integrity of our products and supply chains

We intend to ensure the integrity of our supply chains on the one hand and reduce the likelihood of illegal medicines circulating on the other hand. For this reason, we have a robust security measures for products and supply chains.

We do our best to fulfill the regulatory requirements on **product serialization** and the implementation of track-and-trace technologies as prescribed in many countries and regions. This includes clear bar coding of individual and collectively packaged products for transport so that they can be traced in the supply chain.

Using a risk-based approach, we apply our own product security features on certain products. This enables the rapid and reliable authentication of our products.

We monitor our supply chain closely and we regularly **audit our distributors and contract manufacturers** to ensure that they comply with our GMP and GDP standards (good manufacturing practice/good distribution practice). Moreover, we carry out special risk-based safety tests on suppliers of pharmaceutical packaging and contract manufacturers.

The security measures at some of our most important global sites are certified externally in accordance with internationally recognized standards, including requirements of the U.S. customs authority’s C-TPAT (Customs-Trade Partnership Against Terrorism) initiative, the AEO-C/S (Authorized Economic Operator) certificate of the European Union, approval as a “recognized shipper” by the Luftfahrt-Bundesamt (German Federal Aviation Office) as well as the ISO standards 28000 and 28001 regarding supply chain security management.

In 2022, we introduced a Group-wide security audit management program, which will help to further increase transparency and the security level performance within our organization and maintain our compliance with security requirements. For this purpose, we have developed key figures to support this process, which will be supplemented by the existing audit management tool.

Furthermore, we sponsor global initiatives to protect patients. For instance, we support 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 107 different active ingredients quickly and effectively. In 2022, five additional active ingredients for cardiac care were added to the Minilab's method inventory. Currently, a total of 969 Minilabs are in use. In 2022, 42 Minilabs were delivered, of which 39 went to eleven countries in sub-Saharan Africa.

4. 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 people Group-wide on the subject to strengthen their competencies. All employees involved in security, such as product crime officers, participate in appropriate **training programs**. We are continuously evolving these programs and adapting them to new trends.