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.

Research and development (R&D) play an essential role in further improving our sustainability performance. They are critical elements that determine the sustainability impact of our products, from their initial conception to market launch. Our business sectors create tailored sustainability strategies to develop products that benefit patients and customers. We are also improving the way we measure our progress, which includes the introduction of sustainability criteria within our product development processes.

In 2021, we partnered with the well-established patent information platform LexisNexis® PatentSight® to assess the sustainability impact of our intellectual property. Building on this, we will start disclosing the share of newly published sustainability-related patent families as of the reporting year 2022.

To develop pioneering solutions that have a positive impact on society and foster 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 in order 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 our R&D and innovation processes in line with our shared goals.

Our new **Group Science & Technology Office** leads the implementation of our combined strategy for innovation and "data & digital", enabling innovation across our business sectors while harnessing the power of highly advanced data and digital capacities. It aims to identify and integrate transformative technology trends into our business sectors while maintaining a company-wide view of our tech roadmap and innovation portfolio. In addition, it ensures the strategic fit of our innovation fields. Fostering data & digital 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.

Lastly, we are also investing in sustainable solutions via **M Ventures**, our strategic corporate venture capital fund. It complements our Life Science, Healthcare and Electronics business sectors by focusing 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. Firstly, investments that offer sustainable solutions relevant to our three business sectors may include novel solutions for reducing emissions or waste, green life science technologies or green electronics technologies. These solutions may be more energy- or resource-efficient or may create a product that has a lower carbon footprint or is designed for circularity.

Secondly, investments that leverage our core competencies to drive sustainability in other markets may include start-ups addressing sustainable foods, biomaterials or even hydrogen technology. An investment in these kinds of industries or markets would aim to use competencies within our company, such as how our life science technologies can be leveraged for sustainable foods.

Our commitment: Aiming for circularity

Within our R&D processes, we continuously improve and integrate sustainability KPIs to measure the **sustainability performance of our products and portfolio**. For example, our Life Science business sector developed Design for Sustainability (DfS) as well as the DOZN™ tool to enable the creation of more sustainable products for our customers. In addition, several circular economy initiatives are underway throughout the organization, some of which are in collaboration with external partners.

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 produce genuine meat grown in vitro. This research aims 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.

One major hurdle and cost driver in cultured meat production is cell culture media. To achieve production at scale, the media must be cost-efficient, suitable for effective growth and differentiation into specific cell types and free of any animal-derived material such as fetal bovine serum. Our flagship project MeatDia aims to launch suitable media formulations. We have established multiple **partnerships with leading start-ups** that are developing pilot-scale manufacturing facilities. Our goal is to supply these start-ups with both off-the-shelf basal media formulations and custom-developed species-specific complete media formulations.

Another technological challenge is the need for suitable bioreactor designs for efficient production of the required biomass. To accelerate our innovation projects in this space, we are collaborating with two leading academic labs. Together with a team at Tufts University, Massachusetts, USA, we aim to enable the production of whole-muscle cultured meat through textile bioengineering. At the same time, we will apply industrial printing technology to create of textured meat in collaboration with a team at the Technical University of Darmstadt, Germany.

Our M Ventures portfolio includes Mosa Meat, a pioneer in clean meat movement, and Formo, a company focused on making clean cheeses (such as mozzarella and ricotta) using recombinant protein synthesis.

Fruitful strategic partnership

We have been engaged in a strategic research partnership with the Technical University (TU) of Darmstadt for more than 15 years. With the realignment of this strategic research partnership in 2021, sustainability is now a fostered focus area of our collaborations. Together, we established the "**Sustainability Hub**" joint research platform. The hub focuses on research topics, including digitalization, alternatives to animal testing and recycling to support our Sustainability Strategy.

New approaches to life cycle modelling

The detailed life cycle assessment (LCA) of a product and the systematic evaluation of its environmental impact and energy balance from concept to end-of-life is an essential yet challenging process. When successfully implemented, it enables product improvements and contributes to our corporate sustainability goals.

The project "**Faster, easier, better? Life Cycle Modelling in the Information Age**" takes an interdisciplinary approach to addressing the challenges associated with life cycle assessment. This includes data collection and modeling using latest IT-technology for data collection and evaluation. This will be done in the context of political demands for new data, reporting and monitoring.

Simulation of energy-saving neuromorphic computer architectures

Modern computer centers consume large amounts of energy, but developments around neuromorphic computing have the potential to significantly reduce their energy requirements. Therefore, the project team of "**Energy Efficient Simulation of Energy Efficient Storage (EES)^2 for Neuromorphic Computing**" has set itself the goal of developing energy-efficient simulation tools that predict material properties in energy-saving neuromorphic computer architectures. Successful simulation helps to shorten product development cycles and increase energy efficiency.

Using 3D bioprinting to create cell culture models

During the development of new drugs and in toxicological studies, a wide variety of in vitro cell culture models as well as animal experiments are indispensable in order to evaluate the efficacy and safety of active

ingredients. However, the use of cell culture models and organ-like structures is currently limited as the systems are not connected to a vascular system that supplies them with oxygen. Therefore, the project team at TU Darmstadt, "**Generation of vascularized human liver tissue by integrating 3D-bioprinting and cellular self-assembly**" is working to create a 3D human liver model that can be supplied with oxygen. Within the scope of efficacy and toxicological studies, these models will behave significantly more like real human organs compared with the existing 3D cell culture models. Therefore, the project makes a valuable contribution to our 4R principles (Reduction, Replacement, Refinement, Responsibility) for reducing or avoiding animal experiments in the future.

Enabling the enzymatic degradation of plastics

The largest classes of commodity plastics used today, namely PP (polypropylene), PE (polyethylene) and PS (polystyrene), consist of carbon-carbon backbones, making enzymatic degradation very challenging. The project team at TU Darmstadt "**Sustainable Platform Technology for Enzyme-Mediated Recycling of Plastic (EnzyMe RoP)**" aims to enable the degradation of plastics with carbon-carbon backbones by creating novel enzymes tailored to these specific requirements. This is to be achieved by combining rational design and directed evolution technologies. The project will also form valuable synergies with our projects addressing plastic recycling from a whole value chain perspective.

Promoting visionary research

The 2021 Future Insight Prize in the Food Generator category focused on food technologies that could help secure sources of nutrition for growing global population. It was awarded during the Future Insight Virtual Event sponsored by our company to the groups led by Ting Lu, Professor for Bioengineering at the University of Illinois Urbana-Champaign, USA, and Stephen Techtmann, Associate Professor for Biosciences at the Michigan Technological University, USA, for their work on transforming non-edible biomass or plastics into food using microbial consortia. The 2022 Future Insight Prize will recognize achievements in energy technologies that help reverse the effects of climate change.

In 2021, for the first time, we offered sustainability **research grants** to the scientific community to stimulate innovative research on four key aspects of sustainability: circular economy, digitizing sustainability, new bio routes, and responsible & new resources. In total, we received more than 400 research proposals from around the world. Selected projects will receive funding in 2022.

Synergizing external ideas

Together with **M Ventures**, we reached out to the start-up community with our "**Sustainability Startup Initiative – SuStaIn**" **campaign** and through active scouting efforts in 2021. The aim was to collaborate with early-stage innovators and leverage the latest technologies to support our company in becoming more sustainable.

Sustainable products & packaging

We believe it is our duty to not only conserve resources when developing our products, but also to help our customers increase the sustainability of theirs. Packaging protects our products from external influences and ensures they reach our customers undamaged. Therefore, we are optimizing the size, weight and recyclability of our packaging while keeping our products safe and secure.

Our approach to sustainable product design

Our individual business sectors take different approaches to sustainable product design.

Life Science

In our Life Science business sector, we aim to reduce 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 **range of tools** that enable them to analyze product impacts in terms of materials used, energy and emissions, water, packaging, usability, innovation, circular economy as well as supplier- and manufacturing-related issues. We have developed sustainability criteria that can be used to rank a product’s performance in each of these areas. When developing a new product, our aim is to improve on as many of these criteria scores as possible.

To understand the potential environmental impacts throughout the product life cycle, we conduct streamlined product life cycle analyses. The findings from these analyses 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 2021, we piloted a **new version** of our “DfS: Development” pillar across various projects and prepared for its official implementation into our product development process, which will begin in 2022. The framework comprises additional criteria and a scorecard system that helps our development teams address and minimize any negative product- and supply chain-related factors and enables us to improve 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. For example, in the field of pharmaceutical research, we are working on a project to identify chemical synthesis routes for new drug substances that consume less resources than conventional solutions. 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 can then use this knowledge to avoid emissions into the air and water.

Electronics

In our Electronics business sector, we aim to reduce any adverse environmental impacts our products may have during their manufacture, packaging, transportation, use, and disposal.

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

We have complemented our product development process with the principle that it should avoid highly hazardous materials 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 in which we strive to ensure our products are:

- **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 these supply chains make positive contributions to global, social and economic development.
- **Supplied and used** in a manner that minimizes safety and environmental risks: As new products progress through their development cycles, their product sustainability requirements also evolve, including the identification of any physical, health or environmental hazards. We also define the practices for managing these hazards so that our products can be used safely and have a minimal ecological impact.
- **Contributing** to the sustainability goals of our customers: We seek to establish partnerships with our customers so that we can best understand how our activities and products can contribute to their sustainability goals.
- **Reviewed** to determine if more effective greener chemistry alternatives are available: Within this development cycle, a multi-functional team is working to establish a process that increases the emphasis on sustainability and green chemistry aspects.

In 2021, we launched a project to integrate the assessment of ESG criteria into our R&D portfolio management.

Our approaches to sustainable packaging

We aim to deliver our products in packaging that is safe and easy for customers to handle, while also working to make it as sustainable as possible.

Life Science

With more than 300,000 products in our Life Science portfolio – ranging from biochemicals and lab chemicals to filter materials and systems as well as instruments – we face a variety of challenges when it comes to packaging. We strive to improve the sustainability of this packaging to help us and our customers to reduce the 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 amount of packaging
- **Secure**: achieve zero deforestation
- **Switch**: improve plastic sustainability
- **Save**: maximize recycling

Based on these goals, we defined targets up to the end of 2022, which address the development of new product packaging and the improvement of existing product and distribution packaging.

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

Electronics

When introducing new packaging, we use a process that includes a safety review, evaluating package specifications and sizes, shipment frequency, route, carriers, emergency response capabilities, and elements of safety in the supply chain. All product containers undergo a review for chemical compatibility, purity, leak-tightness, and regulatory compliance. The presence of specific hazards and specific container sizes can necessitate a more detailed risk assessment. A packaging reduction and sustainability project for the thin films business offers new opportunities to advance our future sustainability goals. 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 coordinates the setting of targets as well as monitoring and reporting activities in accordance with our sustainability strategy. This dedicated sustainability team is integrated into and engaged with the business units and their functions. Its role is to reflect and realize business-related activities. We are also creating targeted working groups within the business units that are responsible for aligning their work in accordance with the Life Science sustainability strategy.

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

In 2020, we started the process of structuring 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:

A new organizational structure within Electronics ensures that our sustainability strategy is being implemented within this business sector. The Electronics Sustainability Council plays a key role as a cross-functional executive committee that oversees and signs off on relevant initiatives within Electronics sustainability programs. A dedicated team coordinates business-related sustainability activities. It includes a monitoring role and drives 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 the 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 2021, more than 1,400 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 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 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, our raw materials for the cosmetics industry meet the strict standards of the EU Cosmetics Regulation and are 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 employ a Group-wide standard entitled Access to Genetic Resources. Its objective is to define **requirements, roles and responsibilities** to ensure compliance with the Nagoya Protocol under applicable national legislation. We conduct comprehensive training on this standard across relevant units. In addition, each business sector defines specific procedures to help ensure they meet the requirements of our Group-wide standard.

In 2021, we continued our internal exchange within the Group to ensure cross-business alignment and to deliver ongoing training. These initiatives keep the relevant units informed of any changes to access and benefit-sharing.

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 our 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 2021, we established partnerships with universities in Canada, France, India, Switzerland, and the United States to 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 further reinforce learning while highlighting the importance of sustainability in the minds of future scientists.

Life Science: Greener solvents

Switching to bio-based solvents helps our customers reduce their carbon footprint - for example, trough our alternative, more environmentally compatible solvent Cyrene™. 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 will help us meet the growing demand for greener solvents.

In 2021, we introduced a large selection of bio-based laboratory chemicals through the USDA BioPreferred® program. These chemicals are certified by the U.S. Department of Agriculture to be derived from plants and other renewable agricultural, marine and forestry materials and to provide an alternative to conventional petroleum-derived products. Such products include sustainable solvents like bio-renewable acetone.

Life Science: Sustainable laboratory water use

Our Milli-Q® IQ 7000, IQ 7003, and IQ 7010 ultrapure and pure water purification systems use innovative, mercury-free UV oxidation lamps. Thanks to optimized components and processes, and a hibernation mode, they reduce electricity consumption by 22% to 35% compared with previous systems while preserving system water quality. The systems also reduce water consumption between 7% and 13%. Our innovative IQnano® ion-exchange media has reduced plastic consumption by 33% in the purification cartridges for the Milli-Q® IQ7000 and IQ7003 systems.

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 plastic and corrugated 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 1.9 metric tons of plastic and corrugated cardboard from entering our customers' laboratories.

Life Science: Expanding product recycling

We continue to expand our biopharma recycling program, where we collect product waste from research labs and biopharmaceutical manufacturing operations and **recycle it into plastic lumber**. This material can be used in many industries, such as landscaping, transportation and marine construction. The program now serves 16 major biopharma manufacturing customers and since its launch in 2015, has recycled more than 6,700 metric tons of plastic waste, which has reduced emission of CO_2eq by approximately 4,400 metric tons.

We are continuing to expand this program throughout the United States, while exploring 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: Sustainability in product design

In 2021 we started to systematically incorporate sustainability into our portfolio management process.

In one project, for example, sustainability criteria are developed and incorporated into the product development process from the outset. All ESG-relevant aspects of our materials and solutions will be identified and taken into account at each and every stage.The collection and evaluation of research, development and manufacturing metrics and their application within an ESG context are also in focus as they provide facts and information that can be used for the sustainable design of new manufacturing processes.

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 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. We are 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 plus AZ Remover 910 and Dynastrip 5008, Dynastrip 8889 and Dynastrip 8070T.

Electronics: PFAS replacement program

PFAS (per- and polyfluoroalkyl substances) feature 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 regulates glare and solar heat gain effectively 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. A Sustainable Business Value study found building occupants have higher productivity and take less sick leave where eyrise® products are installed.

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 2021, 77 of our cosmetic pigments and active ingredients had been confirmed to comply 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, vegan and plant-based raw materials as a critical product attribute. Therefore, more than 90% 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 2021, it allowed us to avoid the emissions of 9 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 have partnered with a biotech company and jointly developed a more sustainable bulk packaging design for the transport of our Millistak+® Pod Disposable Depth Filters. A life cycle assessment showed that we achieved a 24% reduction in the corrugated cardboard used, which translates to a 17% decrease in greenhouse gas (GHG) emissions throughout the life cycle of the packaging materials. In 2021, we saved around 12 metric tons of corrugated cardboard, and our customers now spend 70% less time opening and disposing of the packaging.

In 2021, we launched new bulk packaging designs for a subset of our Durapore® and Millipore Express® filter cartridges. Dedicated to high-volume clients, these solutions deliver both environmental and economic benefits to our customers compared with traditional individual or multipack packaging. As an example, changing from 3-pack to new bulk packaging for our 10" filter cartridges reduce the amount of corrugated cardboard by 55%. This translates to a 49% decrease in GHG emissions throughout the life cycle of these packaging materials. In addition, our customers spend approximately 50% less time unpacking, providing additional economic savings.

In 2021, we also initiated a pilot project to eliminate the use of transparent plastic envelopes that store packing slips on the outside of shipping boxes. While this seems like only a small change, it can deliver significant environmental and operational savings, from the plastic envelope itself to the time needed to attach it to the box. Our estimates suggest that once we implement this practice globally, eliminating these plastic envelopes could save 20 metric tons of plastic waste and over 80 metric tons of CO_2eq per year.

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 the goal of ensuring 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).

In 2021, we collected information from our strategic suppliers who represent about 85% of our fiber-based packaging materials spending. Overall, by volume, around 80% of corrugated packaging supplied by these companies is certified by at least one of the three sustainable forestry standards or is made of recycled material.

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. Our goal is to **reduce our use of EPS by 20% by end of 2022**.

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 2020, we began implementing an alternative cooler at one of our distribution centers in the United States to replace EPS in our cold-chain shipments. The Greener Cooler is made from renewable resources and is certified recyclable with corrugated materials. While the results of the pilot implementation were positive, in 2021 we re-analyzed the characteristics and requirements of the various insulated shipping containers used in our main U.S. sites to define a comprehensive validation plan.

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 2021, our products sold in Titripac® 10L packaging configurations avoided non-renewable packaging materials by 15.5 metric tons, resulting in a reduction of 73 metric tons of CO_2eq emissions across the life cycle of the packaging compared with 1L plastic bottles.

Save: How we maximize recycling of packaging

Many of our Life Science products need to be kept cool during shipping and are therefore packaged in special EPS boxes. To **mitigate waste**, we offer our customers in the United States the option of returning these boxes to us, and if they are still fully functional, we reuse them. In 2021, this amounted to approximately 9,000 boxes that were reused at least once, making it possible to save 2 metric tons of EPS.

Making product packaging more sustainable: Healthcare

We are in the process of developing a sustainable packaging strategy for our Healthcare business. The solutions we offer will ensure the safe and secure delivery of products to our customers while decreasing the environmental footprint of our packaging.

Slim packaging solutions

In 2021, we launched new slim packaging for Pergoveris®, Gonal-f® and Ovidrel® fertility pens, which is smaller in size and **free of single-use plastics**. With this new packaging, we have reduced the environmental footprint of these products by using fewer raw materials and reducing transport volumes. We project this new packaging can reduce transport-related emissions by approximately one third, or the equivalent of 360 metric tons of CO_2eq (WTW) per year.

Additionally, in 2021, we initiated several studies to investigate the reduction of packaging materials and develop reuse options for medical devices.

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.

Reusable packaging

Packaging for our specialty gas and thin films products is designed to be reused. Reusable packaging types include various sizes of cylinders and tube trailers for bulk specialty gases, along with smaller stainless steel and quartz containers for thin films. Once our customers have used the product within the container, the 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 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 can be traced and recycled more easily afterwards and restores value to the used plastic packaging.

The laser marking provides a unique identifier and serves as a “digital product passport” as the link between product and database. It can replace ink and labels, thus enabling even better 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, or electronic devices.

Health for all

Global health

At least half of the world's population does not have adequate access to health. 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** focuses on diseases that disproportionally impact underserved populations. These include neglected tropical diseases (NTDs) that are largely unknown in industrialized nations and attract little attention or funding. Our strategy also aims to improve patient access to medicine in low- and middle-income countries, including for non-communicable diseases. The goals of our Global Health strategy are:

- To eliminate schistosomiasis as a public health problem.
- To prevent and control **malaria** to the point of elimination.
- To prevent and control **high-burden non-communicable diseases** (NCDs), such as diabetes and hypertension, in low- and middle-income countries.

Our strategy is designed to improve health and overcome access barriers in an economically viable and sustainable way, thereby creating shared value for patients, society and our company. For us, this means developing business models that increase our company's value and competitiveness by **solving unmet health needs** and strengthening local health systems.

We follow three core operating principles:

- **Developing innovative solutions:** We develop new medicines, diagnostics, and vector control solutions for schistosomiasis and malaria through an integrated science and technology approach.
- **Engaging with cross-sector partners:** We participate in multi-stakeholder global health platforms to help achieve our goals and support the UN Sustainable Development Goals. We define partnerships for the implementation of treatment programs on the ground, for research and development programs and use access alliances.
- **Creating sustainable business models and opportunities via a shared value approach:** We strive to ensure that investments reach underserved populations. We leverage our portfolio from across our three business sectors to help sustainably improve health.

We also engage in building capacity and expertise across the value chain, with the intent of strengthening health systems and making them more resilient to health crises.

Eliminating schistosomiasis as a public health problem

Schistosomiasis, also known as bilharzia, is a tropical disease caused by parasitic worms. It is one of the most prevalent parasitic infections in sub-Saharan Africa and places a significant burden on public health systems and local economies. The disease affects almost 240 million people worldwide, with more than 90% of cases occurring in sub-Saharan Africa. It **kills an estimated 200,000 people** every year.

The ultimate aim of our schistosomiasis-related work is to eliminate the disease as a public health problem in accordance with the WHO NTD roadmap 2021-2030. We remain committed to the objectives of the London Declaration and support its successor, the Kigali Declaration on NTDs, through which participating companies, governments and private organizations commit to helping control and ultimately eliminate the twenty most prevalent NTDs, including schistosomiasis.

To achieve this goal, we adopted an integrated schistosomiasis strategy, which we are implementing in close collaboration with multiple partners worldwide. The approach focuses on five 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 R&D programs for innovative health solutions, new drug discovery activities, the development of new treatment options for children under the age of six, and new and more sensitive diagnostics. We are also strengthening research expertise and capacity through our collaborations with institutions in endemic countries.
- **WASH** (Water, sanitation and hygiene)**:** Since schistosomiasis is transmitted through contaminated water sources, we also support WASH projects that aim to prevent transmission of the disease by providing a sanitary infrastructure and new access-to- water technologies.
- **Health education:** We believe prevention is the most effective health intervention. Therefore, we invest in education and behavior change initiatives to raise awareness of the causes and dangers of schistosomiasis and teach people how to prevent it.
- **Advocacy and partnerships:** We are accelerating the progress towards schistosomiasis elimination by collaborating with partner organizations for our programs and initiatives as well as with the wider stakeholder community through the Global Schistosomiasis Alliance (GSA).

Preventing and fighting malaria to support elimination

According to World Health Organization (WHO) estimates, nearly half of the world's population is at risk of contracting malaria. More than 200 million cases of malaria and over 400,000 related deaths are recorded every year, with almost 70% occurring in children under the age of five. Over 90% of cases and deaths occur in Africa. Around the world, a child dies from the disease every two minutes.

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 are helping to deliver integrated and sustainable health solutions involving treatments, diagnostics and preventive measures to fight malaria in endemic countries.

Our Access to Medicine approach

We implement and support global health partnerships and shared value initiatives that improve access to our health solutions in low- and middle-income countries. By delivering quality health solutions, our Access to Medicine approach **addresses local needs** and helps to create long-term value for patients, our business and our stakeholders.

We continually seek to create sustainable business model opportunities that address gaps in public health systems. We recognize that we cannot eliminate the complex barriers to health access in emerging markets alone, which is why we form and enter partnerships for initiatives that complement our strategy. We apply this approach to neglected diseases, such as schistosomiasis and malaria, as well as to NCDs with high prevalence in these countries, such as diabetes and hypertension.

Roles and responsibilities

Our Global Health organization leads the implementation of our strategy regarding innovative solutions for infectious diseases and access to health in underserved populations. This unit is also responsible for Group-wide initiatives, programs and sponsorships relating to global health topics. Our experts collaborate closely with the Life Science, Healthcare and Electronics business sectors to leverage their strengths and competencies effectively.

Our Schistosomiasis Elimination Program guides our efforts to eliminate schistosomiasis in **close collaboration with external partners,** such as the World Health Organization (WHO).

Our Global Health Institute translates science, technology and digital approaches into integrated solutions to strengthen health systems. It uses a portfolio of projects for transformative treatments, diagnostics, technologies, and preventive measures against neglected tropical diseases, focusing on schistosomiasis and malaria.

Our Access to Health unit enables access to our company’s health portfolio in low- and middle-income countries through shared value initiatives that it implements in collaboration with our country teams.

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 (ATM) Index. It benchmarks 20 of the world's largest research-based pharmaceutical companies on activities and initiatives that experts consider most relevant for access to medicine in low- and middle-income countries, ranging from research & development and intellectual property sharing to capacity building and donations. We use this ranking system to inform and guide our access to health strategy.

The latest Index was published in January 2021. We ranked eighth and remain among the top ten companies, confirming our commitment to continuously improving sustainable access to high-quality health solutions for all. In addition, the ATM Index for 2021 **recognized us for our performance in research & development**, where we ranked fifth. The index also acknowledged our leading role in intellectual property sharing.

Fighting the global Covid-19 pandemic

Our Global Health unit is spearheading a wide range of initiatives to combat the SARS-CoV-2 virus and its impact on the world's most vulnerable countries. These efforts include direct measures, such as donating masks and protective equipment to Ethiopia and Zimbabwe, as well as more long-term sustainable initiatives (such as in Ghana) that **strengthen the overall resilience of health systems** against current and future health crises.

Read more about our contribution to this global challenge here.

Eliminating schistosomiasis: Five pillars

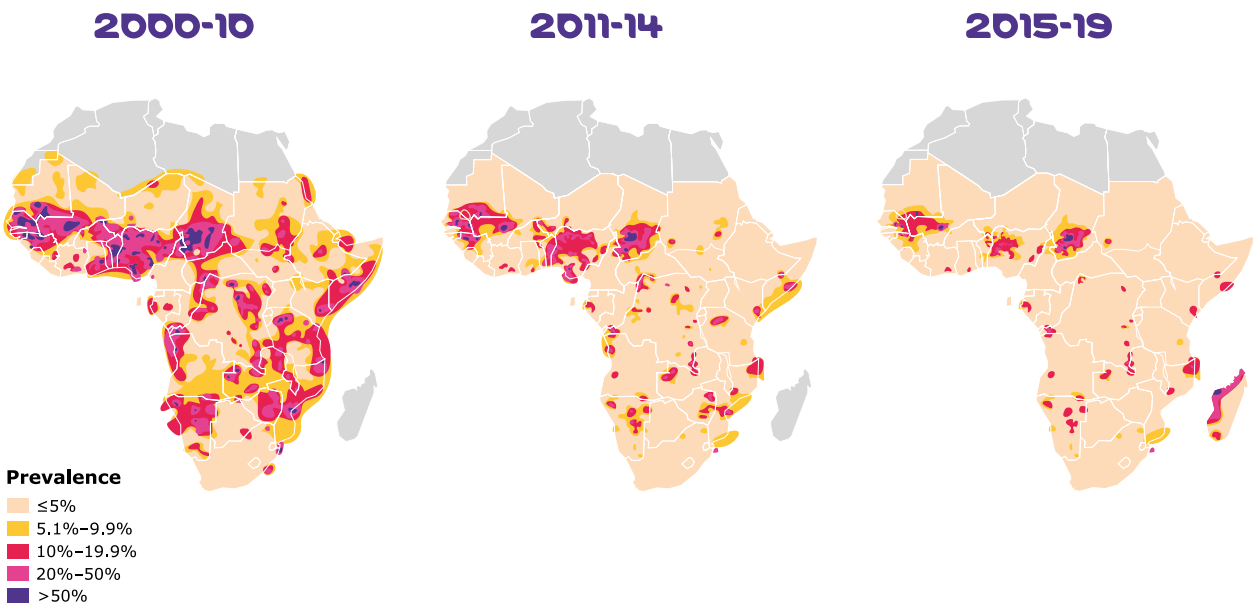
To contribute to the elimination of schistosomiasis, we adopted an integrated approach based on five pillars: Treatment, Research & Development, WASH, Health Education, and Advocacy & Partnerships.

Treatment

As part of our long-standing partnership with WHO, we are committed to donating up to 250 million praziquantel tablets every year. The donation is a major part of the integrated and coordinated approach we have adopted towards treating and eliminating schistosomiasis. Since 2007, we have provided **more than 1.5 billion tablets** to WHO for the treatment of schistosomiasis. To date, our tablets have been **distributed in 47 endemic African countries** to treat school-aged children. In 2021, we donated around 182 million tablets for distribution in 32 countries, 30 of which are in sub-Saharan Africa. Moreover, we maintain our commitment by ensuring we have sufficient production capacity to manufacture up to 250 million tablets per year.

Our efforts are showing very promising results. Data published by the Swiss Tropical and Public Health Institute (Swiss TPH) in December 2021 show that the estimated prevalence of schistosomiasis in school-aged children in sub-Saharan Africa decreased by almost 60% between 2000 and 2019.

Decreasing estimated prevalence of schistosomiasis on the African continent



Source: Swiss TPH

Research and development

Working in partnership with the Pediatric Praziquantel Consortium, we developed a **potential new schistosomiasis treatment** option for pre-school-aged children called arpraziquantel. The pivotal clinical Phase III trial was successfully completed in Côte d'Ivoire and Kenya and the program has now proceeded to the regulatory filing stage. In 2021, we signed a manufacturing agreement with Universal, a contract manufacturer in Kenya, for the large-scale production of the treatment upon its registration. The consortium has also launched an access initiative to prepare for deliveries of the new medicine to young patients in need.

In 2021, we also made progress on investigating a new generation of drugs to prevent and cure schistosomiasis. We identified a new candidate, which entered early drug development. In addition, together with researchers from the Medical College of Wisconsin (USA), we described for the first time the presumed mode of action of praziquantel. We also signed a memorandum of understanding with our partners, the Drugs for Neglected Diseases initiative (DNDi) and the Swiss Tropical and Public Health Institute (Swiss TPH), with the aim of combining our efforts on drug discovery, development and access activities.

More **sensitive diagnostics** to detect cases in low-endemicity settings are needed for the effective management and surveillance of schistosomiasis and are critical for the elimination of this disease. 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. In 2021, our strategic partnership with Janssen Pharmaceuticals evolved into a new consortium of partners to accelerate the development of an artificial intelligence-based diagnostic tool for the diagnosis and surveillance of schistosomiasis and soil-transmitted helminthiasis.

Our research & development programs integrate and invest in scientific, educational and training initiatives as well as activities that enhance capacity in low- and middle-income countries.

More information can be found in the chapter Building health capacity and awareness.

WASH

In 2021, we started a collaborative access to water program in Ghana. It encompasses an implementation research study to analyze water, sanitation and hygiene in 200 healthcare facilities as well as the quality of water in selected districts. Moreover, it aims to improve the healthcare infrastructure to provide safe water services to health centers as well as to train health workers on schistosomiasis case management.

Health education

In 2020, we extended our partnership with the NALA Foundation by an additional three years. This joint health education project – including WASH activities – focuses on southwestern Ethiopia. It aims to promote **long-term sustainable behavioral changes** via a community-based approach in the drive to eliminate schistosomiasis and other neglected tropical diseases.

Despite the challenges, including the Covid-19 pandemic, security issues and political instability, the reopening of schools enabled NALA to resume regular activities in 2021. These included 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: It decreased from 28% to 11% in Mizan Aman, and from 11% to 8% in the southern Bench zone.

More information can be found in the chapter Building health capacity and awareness.

Advocacy and partnerships

We work with international and local partners to advance the agenda for schistosomiasis control and elimination. For example, the Global Schistosomiasis Alliance (GSA) is a coordinated, multi-sectoral effort to combat the complex disease schistosomiasis. In early 2021, WHO released its new NTD roadmap, which sets global targets and milestones to prevent, control, eliminate or eradicate 20 neglected tropical diseases and disease groups between 2021 and 2030. The GSA contributed to WHO consultations during the roadmap conception phase.

Malaria: Treatment and prevention

Developing new therapeutic solutions

As part of our “As One Against Malaria” program, we are developing a new drug (M5717) for the prevention and treatment of malaria. In 2021, we completed a Phase Ib clinical trial to test the compound’s ability to prevent the disease and published the data. The project is now progressing to Phase II (proof of concept) for both the treatment and prevention of malaria. In addition to our clinical program, our collaborative drug discovery activities are delivering promising candidates that are progressing into the preclinical stage.

Preventing and controlling malaria transmission

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

Through laboratory tests conducted in Ghana, we are evaluating the efficacy and acceptance of a **new formulation of IR3535®** that is expected to provide longer-lasting protection. Positive results would enable IR3535® to serve as a preventive measure for personal use and a large-scale vector control method to support population-based national malaria control programs.

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.

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

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

One initiative supports our country teams in low- and middle-income countries to create and accelerate innovative business models that improve medicine access. The “India Fights Back for Head & Neck Cancer” public-private partnership between our company, the Indian Employees’ State Insurance Corporation and India Railways was established in 2021 as part of this initiative. It enables patients to receive faster access to early diagnosis and the right care and treatment.

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, in which expert volunteers from our Global Supply Network Organization share their knowledge with local African distributors, demonstrates our commitment to improving supply chain operations and increasing access to health.

We have also developed an evaluation ecosystem to track the impact of our access programs on patients, healthcare providers and health systems. It enables us to monitor our progress over time and to integrate recommendations from ESG ratings, such as the Access to Medicine Index, into our strategy.

Engaging stakeholders

Partnerships and dialogue are critical to addressing global health challenges and to improving access to health. 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 2021, we continued to engage with our partners and key stakeholders, including WHO, to advance global health discussions and address shared challenges, such as neglected tropical diseases. We collaborate with partners such as WIPO and DNDi as well as with academia in African countries. We engage in consortiums of partners, such as the Pediatric Praziquantel Consortium, alliances, including the Swiss Malaria Group, and advocacy groups, such as Uniting to Combat NTDs and GSA. In addition, we closely interact with foundations that support scientific research and health access, including the Bill & Melinda Gates Foundation and the Access to Medicine Foundation.

We also strengthened our **collaborations with the scientific community** through publications, patents and taking on active roles at international events. In 2021, we attended meetings of the Coalition for Operational Research on Neglected Tropical Diseases (COR-NTD) to address the spread of misinformation about NTDs. We also took part in the 12th European Congress on Tropical Medicine and International Health (ECTMIH), which discussed the current state of R&D in NTDs. We also presented our collaborative research and development projects on schistosomiasis at the 10th European and Developing Countries Clinical Trials Partnership (EDCTP) Forum.

Open innovation sharing

We consider it our 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 **safety and high quality** 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 are committed to **refraining 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 improving public access to clinical study data. We report on the patent status of our products via the publicly accessible database Pat-INFORMED. Furthermore, we support voluntary licensing agreements of all kinds, including non-exclusive voluntary licenses, legally binding non-assertion covenants and clauses that aim to widen access to health.

Moreover, we support the concept of patent pools and believe that these should be structured 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.

We provide access to patent information via our initiatives and partnerships. 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 serve the exchange of intellectual property. We aim to catalyze and 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 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.

Open innovation collaboration through WIPO Re:Search

We are member of the WIPO Re:Search Consortium. The initiative aims to create **new solutions** for people affected by neglected tropical diseases, malaria and tuberculosis. It also enables the **transfer of knowledge** and expertise to institutions in low- and middle-income countries.

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. In 2021, the library was accessed 20 times for screening in 17 indications.

Schistosomiasis research grants

We are dedicated to accelerating innovation and advancing science for the most neglected populations. That is why we catalyze research in an open innovation spirit and with the intention of reducing financial hurdles. Through our Schistosomiasis Research Grant Initiative established in 2021, we awarded 15 research projects with € 30,000 each. More than 70% of the participants came from low- and middle-income countries.

Drugs for Neglected Diseases initiative

Under the leadership of the Drugs for Neglected Diseases initiative (DNDi), we, along with other pharmaceutical companies, are involved in the Drug Discovery Booster project to discover novel medicines against neglected tropical diseases. In October 2021, we signed a memorandum of understanding with DNDi and the Swiss Tropical and Public Health Institute. It covers the areas of drug discovery and development as well as access activities in the field of schistosomiasis.

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

Prices of medicines

In 2019, pharmaceuticals accounted for between 7% and 34% of total health spending by OECD countries. However, advances in the research and development of innovative medicines are significantly transforming the healthcare landscape, allowing chronic diseases – the greatest cost drivers – to be treated more effectively and affordably.

Our approach to pricing medicines

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 geographical or 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 education 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 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 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 and applies our medicines portfolios for equal access initiatives. 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, Ireland and the United Kingdom, we continued in 2021 with innovative risk-sharing agreements that provide immediate access to Mavenclad® for patients with multiple sclerosis (MS). In addition, we expanded the value-based contracting model for Mavenclad® to ten more countries in Asia, Europe, Latin America, and the Middle East.

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. In India, for example, we collaborate with public sector representatives across the oil and gas, energy, and railway sectors to offer certain general medicine and endocrinology products to underprivileged patients at discounted prices.

Strategic tender activities

Our Biopharma 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 cancer drug Erbitux®, for example, to provide financial assistance to eligible underprivileged patients – in line with local laws and regulations. We have reached over 500 patients through this program every year since 2017.

We have been collaborating with national pharmacy chains in Mexico to provide patients with adherence support, discounts on blood tests and education on prediabetes and diabetes, thyroid and cardiovascular 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 conditions mentioned above.

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 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, information and skills so that they can drive innovation and 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, we must also ensure that health systems are prepared to address emergencies effectively and deliver care to people in need. We aim to sustainably strengthen the prevention, preparedness and resilience capabilities of health systems in low- and middle-income countries. Our efforts include the following aspects:

- **Using science and technology innovation** to improve local health-related capabilities.
- **Increasing country preparedness** by enhancing scientific and healthcare workforce competencies and capacities through a network of experts.
- **Forming partnerships to enhance 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 apply this approach throughout the entire value chain in our collaborative programs and in our health education initiatives with our local partners in low- and middle-income countries.

Beyond our engagement in these countries, we also collaborate with committed global partners to conduct educational campaigns for prevention, early diagnosis and awareness. We focus primarily on the diseases in which we have the greatest expertise and direct our attention towards the patients and specific groups we believe will benefit most from the information. 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 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 local 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:

- The implementation of clinical trials in African health centers to test arpraziquantel as a potential new treatment option for pre-school age children infected with schistosomiasis. These trials have enabled local healthcare professionals to acquire valuable experience in Good Clinical Practice in preparation for future studies.
- Our partnership with the University of Cape Town for malaria drug discovery activities that transfer expertise and support the employment and training of talented young scientists.
- PAVON (Pan-African Vivax and Ovale Network), a network of centers for excellence to strengthen malaria surveillance and pandemic preparedness implemented in more than ten African countries.

Manufacturing and supply chains

We manufacture some of our products directly in the regions where they are needed. At the same time, we 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 medicines where they are needed most.

- We apply this local production approach in our work with the Pediatric Praziquantel Consortium to enable countries to become self-sufficient with respect to serving populations in need. In 2021, we signed a manufacturing agreement with Universal, a contract manufacturer in Kenya, for the large-scale production of the new pediatric treatment upon registration.
- We partner with Business for Health Solutions (BHS) to build sustainable supply chains of local distributors in Africa through our Access Delivery Mentorship program. This program engages with our volunteer pool of supply chain experts and was piloted in Tanzania with three distributors and one manufacturer in 2021.
- We are collaborating with the East African Community (EAC) Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management at the University of Rwanda to build a professional supply chain curriculum tailored to local needs and challenges.

Education and awareness raising

We invest in **education and behavioral change initiatives** that raise disease awareness.

- 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.
- We are partnering with Foresight Global Health (FGH) to raise awareness about non-communicable diseases, with an initial focus on thyroid disorders, cardiovascular disease and prediabetes.
- In partnership with the Cardiological Society of India (CSI), the country's largest professional cardiology association, we launched an initiative that raises awareness in populations with a high risk of cardiovascular diseases. This project was conceived in 2021 as part of an employee initiative. The aim is to foster shared value projects by crowdsourcing innovative proposals from business teams in low- and middle-income countries.

Health infrastructure and training

We **build infrastructure and support training** with a strong focus on African countries. In 2021, we

- supported the creation of a new clinical ward in Côte d'Ivoire that enabled Phase II and III trials as part of the Pediatric Praziquantel Consortium program.
- helped set up integrated mobile health units in Cameroon for the diagnosis and treatment of female genital schistosomiasis (FGS), HIV, HPV, and cervical cancer for women aged 14-30. This initiative is also intended to improve the training and experience of local health professionals.
- supported the FAST (FGS Accelerated Scale Together) program to train more than 300 health professionals in sub-Saharan Africa, which resulted in over 200 action plans in 20 countries to address FGS.
- set up microscopy stations in Ghana and provided training sessions to improve local health workers' ability to detect cases of malaria and other diseases that can be diagnosed via blood samples.

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 working across the diverse landscape 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 2021, the theme was “I Am and I Will”.

March 22: World Water Day

World Water Day focuses on the importance of fresh water and raises awareness of the 2.2 billion people living without access to safe water. World Water Day supports the achievement of Sustainable Development Goal 6: Clean water and sanitation.

April 7: World Health Day

World Health Day creates awareness about a specific health theme each year to highlight a priority area of concern for the World Health Organization. In 2021, the theme was “Building a fairer, healthier world”.

April 25: World Malaria Day

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

May 25-31: Thyroid Awareness Week

In collaboration with the Thyroid Federation International (TFI), the annual awareness campaign – which, in 2021, took place with the slogan “Spread Your Wings – Be Thyroid Aware” – aims to highlight some of the lesser-known aspects of thyroid disorders.

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 2021, the day was promoted via “#MSConnections”.

August 20: World Mosquito Day

World Mosquito Day is a global commemoration of the discovery in 1897 that female Anopheles mosquitoes transmit malaria between humans. It aims to shine an international spotlight on the ongoing efforts to fight against mosquito-transmitted diseases.

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 to amplify the issue of unequal access to treatment in Europe. This year´s topic was “Challenge the Odds”.

November 10: World Science Day

World Science Day for Peace and Development highlights the important role of science in society and the need to engage the wider 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 campaign, which was themed “Access to Diabetes Care” in 2021, aims to keep diabetes in both the public and political spotlight.

December 12: Universal Health Coverage Day

International Universal Health Coverage Day aims to raise awareness of the need for strong and resilient health systems and universal health coverage.

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. Effective caregiving is intrinsically linked to the health, well-being and prosperity of women. 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). As the founding private-sector partner, we collaborate with representatives from several APEC governments to promote activities and policies that support women's economic empowerment.

Since 2019, the APEC Healthy Women, Healthy Economies Research Prize has spotlighted sex-disaggregated research that enables policy makers, business leaders and other stakeholders to identify and implement measures that improve women's health in APEC economies. This year's prize money of US$ 20,000 was awarded to a team of scientists for their research into the impacts of care work on women's economic participation.

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.

In 2021, we published a global report on the unmet physical, financial and emotional well-being challenges that unpaid carers face amid the Covid-19 crisis. Covering 12 countries on five continents, the report explained how these challenges differ by gender, socio-economic status, country, and the level of care needed. From this data we produced a series of policy recommendations for governments to create better support and protection for caregivers. We also looked at how employers can create caregiver-friendly workplaces and launched an internal campaign to raise awareness and provide support to our own employees with caregiver responsibilities.

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 resulting from their use. We continuously strive to improve our product safety and reduce the environmental impact of our business through innovative solutions and digital communication tools.

Our approach to safe chemical products

Product safety is one of our top priorities. Starting at the product launch stage, we investigate the potential adverse impacts that chemical substances may have. 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. Paper safety data sheets are still common in some countries and we can therefore 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 evaluating portfolio sustainability assessment concepts, which we will use to measure our adherence to existing and upcoming external and internal sustainability criteria. These concepts will also help us to create greater transparency regarding the most important aspects for improving sustainability.

Roles and responsibilities

Our Life Science, Healthcare and Electronics business sectors have organizational structures in place to implement our product safety strategy taking into account respective business requirements and customer needs. This approach includes registering chemicals, classifying hazardous substances and highlighting risks via the use of safety data sheets, labels and digital communications.

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. Our Group Chemicals Regulations Council monitors relevant regulatory developments.

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

In 2021, 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 during product launch

Safe and sustainable by design implies that product safety starts with development. Therefore, at an early stage in our product launch process, we analyze innovations in terms of their impacts on human health and the environment. We also 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 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 use 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 or during an internally agreed three-year review cycle. We have automated and standardized the majority 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 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 clinical studies to investigate the safety and efficacy of the medicinal product when used in humans. During clinical development, we diligently use all the collected data to continuously evaluate the medical product's **benefit-risk profile**. If we consider the medical product's benefit-risk profile to be positive, we then submit an application for marketing authorization to the relevant regulatory authorities.

Continual monitoring

Once we launch a new medicinal product, the number of patients being treated with it 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 and manage the benefit-risk profiles after its market release. Pharmacovigilance includes the process of monitoring a medical product on an ongoing basis to detect and assess safety signals as part of signal management activities. Continuous monitoring of adverse effects allows us to proactively and transparently minimize and communicate any risks. 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.

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

- Advanced benefit-risk management
- Big Data analytics (using real-world data)
- Advanced signal detection methodology
- Patient-centric adverse effects collection methods, such as our agReporter app

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 experts help to ensure 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.**

In order to implement our R&D Strategy 2023, our Global Patient Safety unit is on a journey of transformation. Our vision is to embed a deep knowledge of safety into early decision-making as we evolve **to practice predictive safety**. In 2021 we continued to refine our approach to benefit-risk assessments. For example, we applied a scoring system based on safety aspects and used it to determine the prioritization levels of our products. We also redesigned our pharmacovigilance processes using a business process management model that ensures cross-functional alignment between our corporate functions. We expect to complete the implementation of these processes in 2022.

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, ensuring 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. It endorses appropriate **measures to minimize risks**, such as updates to product information. This 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 reviews human-related ethical matters as appropriate.

Within the Global Patient Safety unit, the Benefit Risk Action team is responsible for signal management, benefit-risk assessment, risk management and all topics 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

We 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. In addition, we comply with and implement all new statutory pharmacovigilance regulations in the countries where we market our products.

Monitoring drug safety

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 2021, we had eight pharmacovigilance inspections.

Furthermore, we perform audits to ensure that all our units and subsidiaries involved in pharmacovigilance consistently meet all global requirements. In 2021, we conducted a total of 18 pharmacovigilance audits and found no significant deviations in our pharmacovigilance systems from these requirements and standards. We also audit our vendors and licensing partners involved in pharmacovigilance, which helps us improve our pharmacovigilance processes and comply with regulatory requirements. In light of the ongoing Covid-19 pandemic, we had to adjust our audit plan and methods by postponing several audits and conducting others remotely.

Redefining our approach to benefit-risk assessments

We have developed an improved benefit-risk strategy to help us transform from a reactive and compliance-driven organization into a proactive and benefit-risk-focused organization. By truly understanding the benefit-risk profiles of our products, we can enable early decision-making within the organization to protect the safety of patients. Ultimately, the aim is to be able to provide **the right medicine to the right patient at the right time**. As part of this initiative, we have also developed the concepts and principles for conducting benefit-risk assessments at each stage of product development and post-marketing.

We have concluded the pilot phase of our new benefit-risk strategy and are now following up with incremental implementation by the end of 2022.

Assessing the safety of our products

We have redesigned our pharmacovigilance processes, including elements that make up our Patient Safety product prioritization strategy. A product prioritization tool as a means to objectively score the safety-profile of our products has been used as a basis to define the product prioritization strategy. The scores categorize our products into a high-, medium- or low-risk category, thereby impacting the methodology for benefit-risk activities. These include individual case safety report (ICSR) management, signal management, our new benefit-risk strategy, and aggregate safety reporting. The new processes ensure the safety of our medicinal products throughout their lifecycles and enable us to focus our resources and expertise on high-priority assets. The drafts of these redesigned processes will be reviewed and finalized by the end of 2022.

Innovative safety signal detection

Through our tool for safety signal detection, we analyze and manage large amounts of global data, such as scientific studies and news about adverse effects. 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 2021, there were no 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 the required experience and knowledge to carry out their activities. We manage our training via a global learning platform and verify compliance with training our requirements by producing training completion reports.

All our approximately 23,000 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 ensure adherence to pharmacovigilance requirements.

Enhancing patient safety and sharing expertise with other countries

Reporting side effects with the agReporter app

In line with our goal to enhance patient safety, in 2020 we implemented a user-friendly mobile and web application called agReporter. The application was created for use by field nurses, sales representatives, healthcare professionals, pharmacists as well as non-medically trained users to **report any suspected side effects** or adverse events arising from the use of our medicinal products. Our application continues to reach more users through ongoing promotion and is now being used in approximately 50 countries in 14 different languages.

Pharmacovigilance in Access to Health

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

We want 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.

In 2021, we took part in several projects to improve patient safety in low- and middle-income countries. For example, we collaborated with the health authorities of Cameroon to discuss and align good pharmacovigilance practice needs and actions in the country, resulting in an agreement to set up new guidelines. An initial draft was proposed to the relevant health authorities in April 2021.

Off-label use

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 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 both with government authorities and with national and international organizations. Together, we want to tackle product-related crime and raise awareness of the issue among stakeholders as well as 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 pro-actively conduct investigations both online and offline im 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 2021, 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 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 meeting the terms of the Guideline for Operators published by the European Commission. In 2021, we reported 745 orders placed for relevant substances. In addition, we received seven inquiries from authorities regarding specific suspected cases that we helped to resolve. We evaluate the effectiveness of our measures for avoiding product misuse based on, among other things, the number of incidents suggested to us by the authorities and solved.

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 introduced robust security measures for products and supply chains.

We 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” (bV) by the Luftfahrt-Bundesamt (German Federal Aviation Office) as well as the ISO standards 28000 and 28001 regarding supply chain security management.

In addition, we are introducing a Group-wide security audit management program, which is intended to further increase transparency and the security level performance within our organization and prove our compliance with security requirements. For this purpose, we are developing key figures to support this process. These key figures 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 102 different active ingredients quickly and effectively. In connection with Covid-19, two additional active ingredients were added to the Minilab’s range of methods. Currently, a total of 933 Minilabs are in use. In 2021, 41 Minilabs were delivered, all but one went to 22 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 staff 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.