products

Offering innovative solutions for a better life, our Healthcare, Life Science and Performance Materials business sectors stand for high-quality products and the utmost in standards.

Our healthcare products – whether prescription medicines or over-the-counter products – help people across the world live healthier lives. However, approximately 1.3 billion people worldwide lack access to sustainable healthcare. We are working to alleviate this situation, for instance by creating health solutions to serve developing health systems and emerging countries.

Our Life Science products make it possible to perform pioneering research; our innovative technologies make lab work easier and more cost-efficient. At the same time, we seek to optimize our sustainability footprint while helping our customers achieve their own sustainability goals.

Our Performance Materials business sector develops products for sophisticated applications, from effect pigments for coatings and cosmetics, to high-tech materials for the electronics industry. Innovations such as our liquid crystals technology make displays more energy-efficient and thus help save power.

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our principles

The safety of our products is the bedrock of our corporate responsibility. When used properly, they should pose no risk to patients, consumers, customers, or the environment. To ensure this across all three of our business sectors, we have implemented globally applicable policies, standards and processes.

We steer our global processes for chemical product safety via our Group-wide Product Safety Chemicals policy, which covers all relevant national and international regulations of the chemical industry. These include, among others, the Globally Harmonised System of Classification and Labeling of Chemicals (GHS) and its implementation in regional and national legislation, as well as the EU chemicals regulation REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals).

Patient and consumer safety is our number-one priority in everything we do. Throughout the entire lifecycle of our medicines and consumer health products, we provide patients, consumers and physicians with up-to-date product safety information based on risk-benefit evaluations. To this end, our experts process safety-relevant information from various sources such as clinical trials, adverse reaction reports and scientific literature. Our Global Chief Medical Officer is the voice of the patients; he bears ultimate responsibility for the safety of our biopharmaceuticals, with support from our Medical Safety and Ethics Board (MSEB). Our Global Drug Safety unit continuously monitors and evaluates the safety and risk-benefit ratio of our biological medicines worldwide (pharmacovigilance). For our Consumer Health products, this function is performed by the Global Product Safety unit. Overall responsibility for the safety of our over-the-counter products falls under the Chief Medical Officer of our Consumer Health business, supported by the Safety & Labelling Committee (SLC). For products in our Allergopharma business, we have developed comprehensive clinical efficacy and safety profiles that are continuously updated. To guarantee the safety of our patients, we have established a global pharmacovigilance system that we continually work to optimize.

Through our compliance policies for our Biopharma and Consumer Health businesses, we set standards for responsible pharmaceutical marketing practices. These aim to ensure that patients and healthcare professionals have access to the relevant information, and that patients receive effective treatment.

progress

Resolutely fighting product-related crime

Across the globe, the pharmaceutical and chemical industries are confronted with product-related crime. Counterfeit medicines in particular pose a major challenge because they represent a threat to public health. We strive to protect customers and patients from harm as well as safeguard our reputation. To this end, we collaborate with law enforcement, foster internal and external expert networks, and take appropriate measures to protect our products against counterfeiting.

Since October 2015, we have been consolidating our various measures Group-wide to leverage synergies between our business sectors, making our battle against product-related crime even more effective.

Our Group-wide Anti-Counterfeiting Operational Network – MACON for short – is responsible for globally monitoring and implementing all anti-counterfeiting measures for our products. This network, comprised of experts from various units such as Legal/Trademarks, Product Security, Export Control, Supply Chain, and Quality Assurance, is coordinated by our Corporate Security unit. In 2015, we expanded the network to include representatives from Global Drug Safety as well as representatives from various legal entities.

In 2015, we discovered multiple underground laboratories that were counterfeiting several of our products. In order to bolster our fight against product-related crime, we launched a dedicated Anti Product Crime unit at the beginning of 2016. Furthermore, we are working on a Product Investigation Standard with product crime case studies in an effort to enhance the knowledge base and processes within our legal entities.

Laboratory animal facilities: Utmost in quality standards

As a science and technology company whose products include pharmaceuticals, we are required to conduct animal studies in order to satisfy statutory regulations, not to mention ethical and scientific principles. For us, it goes without saying that our lab animals be handled, cared for and fed in a manner appropriate to the species. Our animal facilities meet the most stringent international quality standards. But our efforts go beyond this, in the form of a Group-wide network headed by our Corporate Animal Welfare Officer and populated by experts in animal welfare and laboratory animal science. This network is in charge of our own strict standards, ensuring compliance throughout our company. We expect comparable standards from contract research organizations and industry partners as well, guaranteeing their compliance via a certification and audit program. In 2015, we furthermore initiated a similar certification and audit program to monitor suppliers and manufacturers of products of animal origin such as blood sera, hormones and antibodies.

For the animal facilities of our Biopharma business, we set out to attain accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). In 2015, four of our five animal facilities were accredited to AAALAC standards, while the fifth one is currently undergoing the accreditation process. In addition to certifying our facilities, we also constantly review our compliance with national guidelines and legislation.

FAST FACT

We adhere to the 3R principle of animal welfare by reducing the number of animals needed (Reduction); by minimizing the potential pain, suffering, or distress for the animals before, during and after testing (Refinement); and by replacing animal testing with alternative non-animal test methods, such as in-vitro tests or computer simulations (Replacement).

Early access to life-saving medicines

Our Biopharma business develops medicines that help people suffering from serious diseases. Before these medicines are granted regulatory approval, we conduct clinical studies involving patients from across the globe. These trials always comply with all applicable laws and regulations. In addition, we adhere to the most stringent statutory, ethical and scientific standards.

However, not all patients have the opportunity to participate in a clinical trial. They must often wait for a new pharmaceutical product to be approved. Through our Early Access Program, we are, under specific circumstances, enabling patients to gain early access to potentially life-saving medicines. Patients with serious conditions can obtain medicines that have already been clinically tested but have not yet obtained marketing approval. Here as well, we meet the most stringent statutory, ethical and scientific standards, which are laid out in the position paper we published in 2015. For instance, we only consider those patients for whom all other suitable therapies have proven ineffective. In addition, we perform a thorough assessment of all available data to ensure that the potential benefits surpass the potential risks for our patients.

Liquid crystals help conserve energy

Through our products, we help customers and end users save energy. Take for example the development of innovative liquid crystal technologies for displays, a field in which we are the global leader. Our liquid crystals utilize 15% more light from the display's backlighting, thus reducing the device's energy consumption by up to 30%.

With the July 2015 acquisition of a 100% stake in the start-up Qlight Nanotech, we have bolstered our leadership in this sector. This company, headquartered in Jerusalem, is developing a quantum material technology that will help further enhance the color spectrum and energy efficiency of displays.

Consolidating resources to fight infectious diseases

The experts of our Global Health innovation platform are partnering with leading global health institutions and organizations to develop innovative, affordable, and implementable health solutions for children in developing countries. We are focusing our efforts here on neglected diseases, in particular schistosomiasis and related helminth diseases, as well as malaria and co-infections.

Since July 2012, we have been working, within the Pediatric Praziquantel Consortium, on the development of a pediatric formulation of praziquantel, the existing 'gold standard' treatment for schistosomiasis. The current treatment is only available for adults and school-age children. No suitable drug formulation is available for the high-risk group of preschool children (under the age of six), which accounts for about 10% of the estimated nearly 260 million schistosomiasis patients worldwide. In 2015 we completed the Phase I bioavailability trials with healthy subjects in South Africa, as well as a taste study with children in Tanzania. In June 2015, the Consortium was awarded a prestigious research grant from the Japanese Global Health Innovation Technology Fund, making it the second time the Consortium has received this honor.

Since February 2013, we have been partnering with the Medicines for Malaria Ventures (MMV) in the battle against malaria. Since current treatments are increasingly succumbing to drug resistance, this initiative is focusing on the development of new antimalarial compounds. In March 2015, we obtained the rights to a new, highly promising compound that we'll continue developing for both treatment and prevention of

malaria; the project is in the preclinical phase. In addition, our Healthcare and Life Science business sectors are currently developing a kit for malaria based on the MUSE cell analysis system; the device will assess the presence and type of malaria parasite and potentially measure co-infection with HIV.

FAST FACT

Our anti-malaria activities are part of "One Merck KGaA, Darmstadt, Germany for Malaria", an integrated strategic approach that seeks to develop new treatments along with diagnostics and insect repellent. Through digital health initiatives and educational campaigns, we support governmental malaria control programs in African countries.

Knowledge sharing via the WIPO Re:Search innovation platform

We are a member of the United Nations WIPO Re:Search initiative (WIPO = World Intellectual Property Organization), an open innovation platform to accelerate discovery for neglected tropical diseases (NTDs). The consortium seeks to accelerate early discovery for infectious diseases, in particular neglected tropical diseases, through the sharing of intellectual property and knowledge. In 2015, we finalized our first collaboration with the University of Buea in Cameroon, which aims to repurpose compounds from our library to develop a treatment for onchocerciasis, also known as river blindness. Through this collaboration, we are helping to build research capacity, knowledge and expertise in developing countries.

More efficient HIV treatment in rural regions

Of the more than 35 million people infected with HIV worldwide, 25 million live in sub-Saharan Africa alone. However, many patients in this part of the world lack access to regular medical care, particularly in rural areas. For people infected with HIV, CD4 cell counts provide an indication of the disease's progression. Patients with a low count of these cells in their blood have an increased risk of opportunistic infections.

In October 2015 our Life Science business sector launched the Muse Auto CD4/CD4%, a system that medical professionals - even those in small rural clinics - can use to quickly check patients' CD4 cell counts. The advantages? With the Muse system, they no longer need to send blood samples to urban hospitals, and each test requires very little in terms of materials and manpower. The new system is smaller and faster than its predecessor the Guava and can even be used for children.

The Muse Auto CD4/CD4% system has been granted regulatory approval in five African countries (Angola, Ivory Coast, Cameroon, Nigeria, and Zimbabwe) as well as Myanmar, and we are currently working with customers such as the Institute for Human Virology in Nigeria to evaluate the device.

Transporting products safely - Minimizing climate impact

As an international company, we ship large quantities of chemicals everyday to our customers and facilities worldwide. Safety is our top priority. All deliveries need to reach their destinations intact, with proper labeling and the necessary documentation. In addition to safety measures, we have been working for years to systematically reduce our transport-related carbon emissions. This is why, in 2012, we started reducing our use of air shipping for chemicals, switching instead to sea freight. This move enabled us to save around € 2.2 million and more than 3,500 metric tons of CO_2 by 2015. We intend to implement further such initiatives in 2016.

Smart technology for clean water

Today's world faces numerous challenges, the greatest of which is providing burgeoning megacities with clean water, treating wastewater and managing waste in a sustainable manner. To help solve these issues, we offer intelligent, forward-looking technologies. One prime example of this is the German-Chinese research project

known as Semizentral, which we officially joined in 2015. The term "Semizentral" stands for an interurban, semi-centralized approach to supplying and treating water, wastewater and organic waste, while recovering water, energy and nutrients. This public-private partnership is led by the Technische Universität (TU) Darmstadt, which is partnering with Tongji University in Shanghai as well as the Qingdao Technological University. The research work headed by TU Darmstadt is funded by the German Federal Ministry of Education and Research.

The first resource recovery center (RRC) pilot plant is now operating in Qingdao, a metropolis in eastern China. This facility treats wastewater from homes, which can then be used as service water, mainly for toilet flushing. This approach significantly lowers the freshwater consumption of an entire city district of roughly 12,000 inhabitants. An integrated bio-gas plant utilizes sewage sludge and bio-waste to generate all the energy needed by the RRC. Our Life Science business sector is contributing its knowledge in the area of water analysis; we have provided test kits and measuring instruments, teaching university staff how to use these tools. The RRC represents a technological milestone in the development of efficient, modular water infrastructure. In May 2015, Semizentral won a GreenTec Award, Europe's biggest environmental and business prize, in the urbanization category. On top of that, in November 2015 the project placed in the top three in the research category of the 2015 German Sustainability Award.

Healthy Women, Healthy Economies

Women in the workforce can have a profound impact on a country's productivity and prosperity; they can help drive economic development. However, many emerging countries and developing healthcare systems fail to leverage this potential. For many women, this is partially attributable to their health - poor health correlates to reduced productivity and impacts women's ability to participate in the economy. Moreover, women's health needs in the workplace, including the high burden of non-communicable diseases, are often ignored. Thyroid disorders occur 8-10 times more frequently in women than in men, for instance. A little known fact is that cardiovascular diseases are the primary cause of death among women worldwide - people tend to think of these diseases as being mainly an issue for men. Yet, according to studies conducted under the Healthy Women, Healthy Economies initiative, better health outcomes are a prerequisite for increasing women's participation in the economy.

Under this public-private partnership, we have joined forces with the Asia Pacific Economic Cooperation (APEC) to empower women's economic development and improve their health. With support from Merck KGaA, Darmstadt, Germany as well as the Philippine, Mexican and U.S. governments, representatives from the public and private sectors as well as non-governmental organizations worked together to develop a policy toolkit aimed at better supporting women in the following five areas:

- Workplace health and safety
- Health access and awareness
- Work-life balance
- Sexual and reproductive health
- Gender-based violence

The toolkit was launched in the Philippines in September 2015, and the first set of projects has since been initiated. In October, the toolkit was presented in Mexico City to a conference of female legislators representing 160 countries. Furthermore, the 21 APEC member states have set the goal of incorporating toolkit components into their legislation by the end of 2019.