

Charter on Access to Health in Developing Countries

Sustainable Supply Chains

November 2020

Our Promise¹

Merck KGaA, Darmstadt, Germany is a leading science and technology company in healthcare, life science and performance materials. As the oldest pharmaceutical and chemical company in the world, founded in 1668, we have developed countless innovations that improve people's lives.

Unfortunately, millions of people do not have access to the benefits of modern health care innovations in developing countries.² Access is a complex and multifaceted challenge with no one-size-fits all solution. We believe that access to health goes beyond a disease-specific approach.

All of our efforts are underpinned by our 4 As of Access: Availability, Accessibility, Affordability, and Awareness. About accessibility challenges, we commit to strengthening supply chains and aim to deliver health solutions and products to patients and healthcare professionals.

Creating stronger and more responsible supply chain drives shared value and captures profitability and socio-environmental benefits simultaneously. We abide by three guiding principles: ensuring quality and safety, integrating our supply chain and maintaining flexibility.

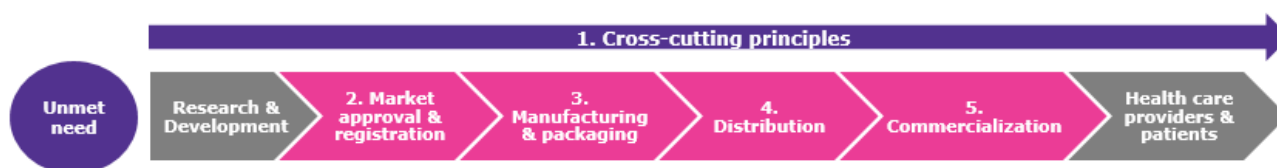
Merck KGaA, Darmstadt, Germany's understanding of responsible and sustainable supply chain relies on cross-cutting principles and optimizing four supply chain nodes, which are highlighted in the image below. Supply chains are a critical part of the access to health in developing countries yet are often neglected and overlooked.

¹ Note: This paper is part of Merck KGaA, Darmstadt, Germany's Charter on Access to Health in Developing Countries. The Charter is a living document and will continue to be updated with new position papers. For a full overview of the Charter, please visit our [website](#).

² Note: For a full list of developing countries, refer to Merck KGaA, Darmstadt, Germany's Access to Health Charter, Our Approach.



Figure 1: Stages of our supply chain³



Access to Health in Developing Countries

Across the globe, two billion people do not have access to medicines. At least half of the world's population lacks access to essential health services and 100 million people are pushed to poverty due to health expenses.⁴ Developing countries bear 87% of the world's disease burden,⁵ yet only account for 32% of global health spending.⁶ Providing access to health in these countries is a complex and daunting challenge. Improving access involves researching, developing and refining health solutions, creating efficient health systems and distribution channels, offering products at affordable prices and empowering health care practitioners and patients. All health stakeholders – both governmental and non-governmental – must pool their efforts to overcome health access barriers.

In contributing to provide access to health in developing countries, we work at the interface of medicines, diagnostics and chemicals, utilizing our local and global presence, expertise and core competencies. For instance, we produce a range of essential medicines that are included in the WHO Essential Medicines List. 67% of Merck KGaA, Darmstadt, Germany's medicines and products are listed on the WHO Essential Medicines List and/or as 1st line treatments.⁷ Our products are available in over half of Least Developed Countries (LDCs) including countries such as Afghanistan, Benin, Burkina Faso, Ethiopia, Haiti, Mali, Myanmar, Nepal, Senegal and Sudan.

Why Supplying the Base of the Pyramid is Important, yet Complex

Strong supply chains are essential to effective health care delivery, but many supply chains are currently not serving the base of the economic pyramid well enough. A well-functioning health supply chain is vital to providing broad geographic access to affordable, high-quality products. However, ensuring that supply chains effectively serve people in the bottom of the global economic pyramid can be a challenging task. It is estimated that only 61.5% of WHO Essential Medicines are available across 23 low and low-middle income countries across Africa, Asia, and Latin America.⁸

It is estimated that there are 3.5 billion people at the bottom of the pyramid, an improvement from 4 billion in 2002.⁹ These 3.5 billion people are living on an annual income of less than \$10,000 annually compared to the 4 billion living on less than \$1500 annually in 2002. This has provided opportunities to make technology and innovation more accessible to these populations.

⁴ WHO, "World Bank and WHO: Half the world lacks access to essential health services, 100 million still pushed into extreme poverty because of health expenses," 13 December 2017: <http://www.who.int/news-room/detail/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses>

⁵ Dalberg analysis (2018) based on DALYs lost across the World Bank's Low Income, Lower Middle Income and Upper Middle-Income country brackets in 2015, relative to losses across all income country brackets. Source: <http://ghdx.healthdata.org/>

⁶ Dalberg analysis (2018). Global health spending figure based on the population of the World Bank's Low Income, Lower Middle Income and Upper Middle-Income country brackets in 2015, multiplied by the 2015 health expenditure per capita (PPP, current international \$) and as a proportion of total health expenditure across all income country brackets. Source: <https://data.worldbank.org/>

⁷ 2018 Access to Medicines Index, Merck KGaA, Darmstadt, Germany's Report Card

⁸ Yaser et al., Essential Medicines Are More Available than Other Medicines around the Globe, *PLoS ONE*, 2014. Note: The WHO has a goal of reaching 80% availability.

⁹ Deepa Prahalad, "The new fortune at the bottom of the pyramid," *Strategy + Business*, 2 January 2019, Spring 2019, Issue 94 <https://www.strategy-business.com/article/The-New-Fortune-at-the-Bottom-of-the-Pyramid?gko=c5f11>

A critical component to doing this in healthcare is ensuring the supply chain systems are in place to ensure delivery of health solutions. This is particularly relevant for non-communicable diseases (NCDs) as supply chains as many of LMIC supply chains have been designed for infectious diseases.¹⁰

Supply chains in developing countries encounter a myriad of barriers in the first and last mile. First mile supply challenges typically reflect difficulties involved in the manufacturing, storage and distribution of products up until the product enters the destination country. These challenges involve forecasting, importation and customs. Inaccurate forecasts can lead to a sub-optimal distribution of health solutions. Navigating parallel import rules can be difficult.¹¹ Changing and complex country-specific custom procedures can delay supply of drugs, and often mean that medicines are stored in inadequate situations, which can often lead to product waste.¹²

Last mile challenges are related to distributing the products to patients that live in isolation because of, for example, poor road quality or lack of information.¹³ It is estimated that more than one billion people globally lack access to health care because they live too far from a doctor or clinic.¹⁴ Aside from difficulties associated with physically being able to deliver the products to remote locations, ensuring that all products are delivered with consistent quality is also a challenge. Slow and cumbersome distribution channels can expose medicines to high-risk situations. Product shelf life span is often inadequate due to prolonged transport lead times in resource-constrained countries. The distribution conditions are also a key aspect of the challenges we face, especially for the cold chain products that need to be kept under temperature and humidity-controlled conditions.

Another important element of supply chain systems is capacity-building. This entails the training of the people working throughout and across the supply chain. This not only contributes to building a strong and well-functioning supply chain throughout all the stages from manufacturing to delivery to patient but contributes to strengthening health systems and the health ecosystems.

There is no one-size-fits-all solution to these challenges, but we believe that supply chain innovation and working in partnerships are important elements of the way forward. More investment in innovation across the supply chain, by public and private stakeholders, would be beneficial in ensuring a broader reach of affordable, high-quality products. For example, product and packaging innovation could increase shelf lifespan of products, enabling them to maintain their quality and safety throughout the distribution chain. Innovative distribution practices are needed to adapt to different geographical contexts. In addition, it is important to recognize that pharmaceutical companies are unable to solve all the challenges associated with enhancing supply chains on our own. Working through partnerships will be imperative to address cross-cutting issues such as combating falsified drugs and improving distribution networks in the last mile.

Our Approach

Our call to holistically and comprehensively strengthen supply chain systems abides by the following commitments:

- **Cross-cutting principles:**
 - Ensuring the quality and safety of our products at every step of production and delivery.
 - Integrating supply chain steps and actors whenever possible to improve availability and

¹⁰ Prashant Yadav, "25 years of Health Product Supply Chain Reform: Market Forms of Organization versus Public Ownership," 2017 <https://wdi.umich.edu/wp-content/uploads/WDI-25-Years-of-Health-Product-Supply-Chain-Reform-WEB.pdf>

¹¹ Note: Parallel import is the import and resale in a country without the consent of the patent holder of a patented product that has been legitimately put on the market of the exporting country. This means that drugs sold at a lower price in one country can be imported into another country where the same drug is sold at a higher price.

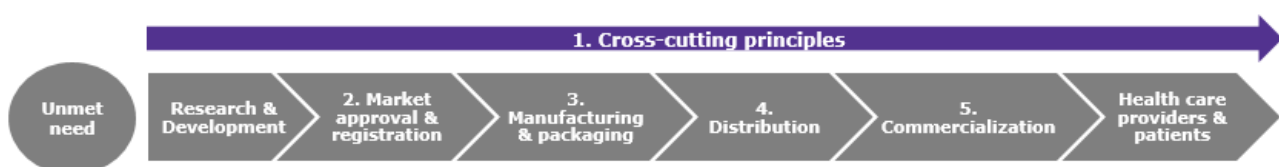
¹² USAID, Customs Clearance Issues Related to the Import of Goods for Public Health Programs, 2009

¹³ Forbes, Overcoming The Last Mile Challenge: Distributing Value to Billions, 2014

¹⁴ Last Mile Health, Healthcare for all, 2016

- affordability of our products.
 - Segmenting our Supply Chain & Logistics to adapt to market specificities and stakeholders.
 - Advancing multi-stakeholder dialogues to contribute towards improving supply chains.
 - Fostering innovation across the supply chain by improving R&D, manufacturing and distribution practices.
- **Market approval and registration:**
 - Ensuring we are adding value to underserved markets through understanding local gaps and needs prior to any marketing approval and registration process.
 - Following the highest standards and regulations in relation to approval and registration of health products.
 - **Manufacturing and packaging:**
 - Ensuring that we provide all of our patients around the world with products of the same quality.
 - Raising the standards of our external partners by training them in our own manufacturing and packaging standards.
 - Incorporating innovation in packaging and in Track & Trace initiatives to combat falsified drugs.
 - **Distribution:**
 - Distributing health solutions to patients in low- and middle-income countries. Where we are not able to serve patients directly, we are committed to exploring partnerships that will help us do so.
 - Increasing the competences of the distribution stakeholders, especially in Africa, in training them on demand forecasting, inventory management, Good Distribution Practices and process execution.
 - **Commercialization:**
 - Adhering to the highest ethical standards within commercialization.
 - Increasing responsiveness and forward integration to ensure more effective commercialization.

1. Cross-cutting principles



Our approach to enhancing supply chains is informed by principles that cut across the entire supply chain. First, we aim to ensure the quality and safety of all processes in the supply chain. This commitment translates into multiple measures throughout the supply chain, ranging from training our external manufacturing partners on best practices to monitoring transportation conditions in our distribution chain. Secondly, we recognize opportunities for integration of supply chain steps and actors to improve efficiencies and speed up product delivery. We coordinate our functional and divisional expertise in order to provide patients with the treatments they need in a timely and convenient manner.

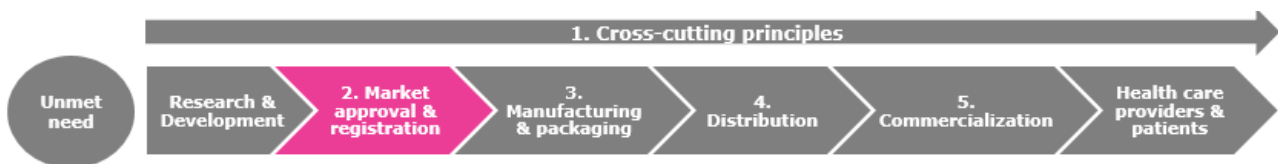
Lastly, we aim to overcome supply chain barriers by working in partnerships. Challenges to access to health in resource-limited settings are broader than supply chain issues, but we believe that many of the supply chain issues could be tackled more effectively by collaborating across industries and sectors. For example, we are one of the founders and an active partner of the Neglected Tropical Diseases (NTD) Supply Chain Forum.¹⁵

Access Delivery Mentorship: Collaboration with local distributors in Tanzania

Our partners and stakeholders have specifically requested supply chain support in order to address the critical “last mile” challenge of ensuring product is delivered to patient. Merck KGaA, Darmstadt, Germany is contributing to supply chain capacity-building through the Access Delivery Mentorship, created as a volunteer pool of supply chain experts who are sharing their knowledge and experience with local supply chain experts.

We collaborate with Business for Health Solutions (BHS), a Swiss-based NGO, who connects us with Tanzanian distributors to help address their supply and logistics challenges. We have seen improved inventory management and procurement processes through our pilot with a local distributor and we are expanding this collaboration with other Tanzanian distributors and is exploring scale-up opportunities in the region.

2. Market approval and registration



Market approval and registration creates the basis of subsequent nodes, such as manufacturing & packaging, distribution, and commercialization. Our decision to file for registration in many developing countries is informed by a systematic evaluation of socioeconomic factors. Taking several criteria such as prevalence, diagnosis and treatment rates (as well as high risk factors or sub-groups) into account, we determine which underserved markets Merck KGaA, Darmstadt, Germany’s product can create an impact in. In any marketing approval and product registration, we adhere to the highest standards; all of our activities are conducted in accordance with global standards and guidelines. We are always prepared for any relevant inspection by Health Authorities or organizations to support registration of our products.

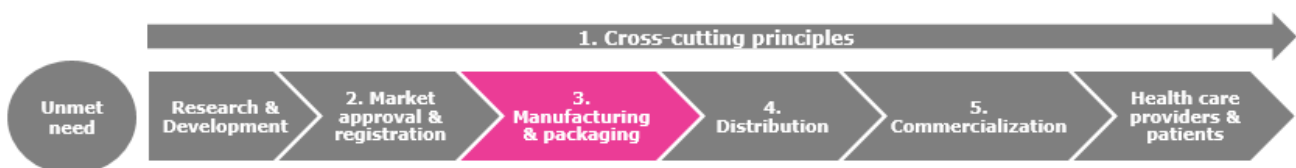
We have also integrated our Market Access & Pricing (MAP) team into our Integrated Business Planning (IBP) process, at global, regional and local levels, so that we have a full alignment between the markets demand planning and opportunities, and our registration and pricing strategies.

¹⁵ Note: For more information on how we partner with other stakeholders across the health spectrum, please see our Charter on Access to Health in Developing Countries: The Post-2015 Sustainable Development Goals.

Continuous supply of our portfolio during Covid-19 pandemic

During the Covid-19 crisis we have ensured that all our manufacturing sites could continue to operate. Due to the high stock of API that we kept and the internal/dual sourcing policy, we had no interruption in our facilities, which were able to continue their production of our medicines. We also had a close follow-up with our distribution partners to deliver our goods to all markets who needed them, despite very high transportation constraints. Even though we had higher costs for Merck KGaA, Darmstadt, Germany, we were able to avoid stockouts and continuously supply our patients. We have even been able to reduce our unfulfilled orders to our customers compared to the previous period before the pandemic.

3. Manufacturing and packaging



Manufacturing and packaging are central to our supply chain operations. Without an effective and innovative manufacturing and packaging system, the other parts of the supply chain cannot succeed. Our company is committed to provide all our patients around the world with products of the same quality. Within Merck KGaA, Darmstadt, Germany Biopharma, for example, we developed a ONE quality system, which includes an end-to-end auditing, training, manufacturing, batch traceability, recall process, quality control monitoring and technology transfer support that is deployed worldwide. The objective of the ONE quality system is to ensure that our products have the same level of quality, regardless of which country they were manufactured in.

We are committed to combating falsified drugs, and we have incorporated innovations into our packaging to prevent falsified drugs from entering our supply chain and inflicting harm on patients.¹⁶

We have sites in Indonesia, Brazil, Mexico, Russia and the North Africa region, which enable us to deliver our products directly to the population of the region to ensure proximity of the production with the patients we serve and minimize the delivery lead-times. We also keep buffer stock of bulk product at manufacturing site level, ready to be packed as soon as an order is received, to shorten the supply lead-time.

Virtual Plant Team

The Virtual Plant Team is an innovative operating model to support our contract manufacturing operations (CMO) network worldwide. The aim is to harmonize manufacturing standards between our in-house manufacturing plants and contract manufacturers in low and middle-income countries. Merck KGaA, Darmstadt, Germany contracts external manufacturing and packaging organizations in the countries and provides tailored support to build their capacity and ensure that the highest quality standards are applied globally.

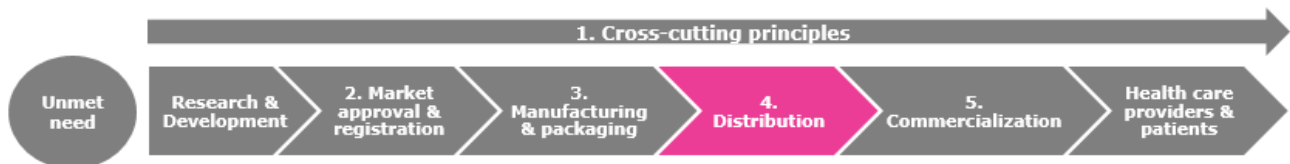
Virtual Plant Team has been recognized as a best practice example in the [2014](#), [2016](#) and [2018](#) editions of the Access to Medicine Index (ATMi).

¹⁶ Note: For more information on our work related to capacity building and technology transfer, please see our Charter on Access to Health in Developing Countries: Fake Medicines.

Merck KGaA, Darmstadt, Germany built Manufacturing Facility in Nantong, China

We have invested in the construction of a new manufacturing facility in Nantong to manufacture medicines in the country. Merck KGaA, Darmstadt, Germany is therefore the first and only multinational company in China to dedicate a large-scale green-field investment to the production of pharmaceuticals on China's essential drug list, indicating their level of importance to Chinese healthcare providers. Our company's investment in producing international-quality medicines locally for Chinese patients is an important move that is in alignment with China's healthcare priorities and sends a compelling message of the company's commitment to China and to key Chinese stakeholders.

4. Distribution



Efficient and effective distribution practices are a necessary component to unlock access to health barriers. Distribution is particularly connected to our availability and accessibility work.¹⁷ Even when the availability of drugs is secured through good manufacturing processes, patients cannot access medicines without a strong distribution chain. At Merck KGaA, Darmstadt, Germany, we use Good Distribution Practices as a guideline for delivering products. Our guidelines cover topics ranging from internal distribution networks to pharmacovigilance and effective recall procedures. We have designed a specialized system to monitor the temperature of all treatments shipped from Europe to the rest of the world. We perform regular audits to assess the capabilities of our distribution partners. Our local drug safety officers train our distributors in pharmacovigilance, while our quality assurance department builds distributor capacity in quality management.

As a healthcare company, we put the needs and concerns of our patients and health care practitioners first. Our feedback systems are designed to address individual queries and use input to improve services across our portfolio of products. We use global procedures to obtain, assess and respond to feedback on our products from patients and health care practitioners. In case a product needs to be withdrawn from the market, we partner with local and international health authorities to disseminate information about our product recalls. To ensure patient centricity, we track service levels in each country through the On-Time-In-Full (OTIF) performance indicator. Our policies, procedures and safety data exchange agreements comply with our Good Pharmacovigilance Practice (GVP) guide. We support WHO's pharmacovigilance policy perspective¹⁸ and EMA's guidelines.¹⁹

In all these areas related to distribution, we are committed to exploring innovative solutions in distribution to enhance patients' access to medicines. Like in manufacturing, innovation also serves an important purpose in distribution.

Merck KGaA, Darmstadt, Germany manages its demand and supply planning process with the help of state-of-the-art tools that provide full visibility on actual and future market demand. We generate a

¹⁷ For more information, please see the Merck KGaA, Darmstadt, Germany A2H Charter position on 'Our Approach'

¹⁸ WHO, Pharmacovigilance: Ensuring the Safe Use of Medicines - WHO Policy Perspectives on Medicines, 2004

¹⁹ European Medicines Agency, Good pharmacovigilance practices, 2015

statistical forecast, using Machine Learning, based on the past markets' consumption, then we add the market intelligence from all the stakeholders who have market knowledge. As such we have full transparency on the market needs at the SKU level and can ensure that the supply can take place properly. The tool provides real time data visibility and allows scenario planning. As such it is used by all countries and the reported data is considered as the single source of truth for the next 24 months by all the company stakeholders.

We have fully integrated this demand planning tool to the supply planning system, which allows to calculate a supply and production plan on a weekly basis considering the current available inventory, lead time and planning parameters. Having also an integrated visibility on our production lines capacity, we can ensure that our production facilities are able to produce and distribute the market needs. We have daily visibility on any change in the demand or supply, which allows us to proactively react in case of any discrepancy and ensure constant product availability to the patients who need our products.

In order to ensure constant supply of our products to the patients, even in cases of under-estimated demand or delays in the supply, we keep safety stock of finished goods (between 1 and 3 months) in all our Distribution Centers. We also keep enough inventory of semi-finished product and even a strategic stock of drug substance to ensure timely production at any time.

We also have a dual sourcing policy, ensuring active backup of our production facilities, so that we can source our materials from another site in case of capacity constraints in our primary facility.

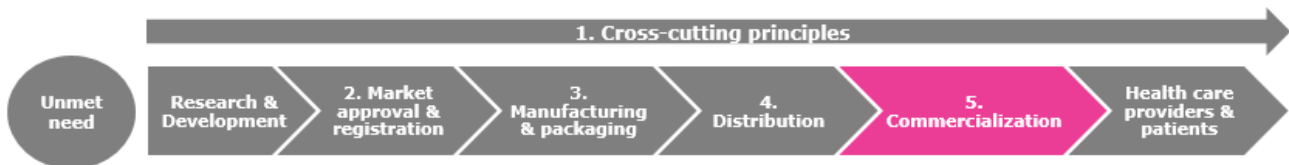
ONE Supply Chain for Africa

The objective of Merck KGaA, Darmstadt, Germany's ONE Supply Chain for Africa project is to reduce distribution costs by gaining economy of scale combining all of our three businesses and storing the products closer to the patients and customers in one virtual warehouse. By storing products in African hubs, Merck KGaA, Darmstadt, Germany remains closer to patients and can react more easily to demand fluctuations, thereby avoiding stock ruptures. By keeping our own stock, Merck KGaA, Darmstadt, Germany also shortens the supply chain and controls costs, which is likely to result in lower prices and therefore benefit the end patient. Overall, this initiative enhances affordability and availability of medicines for our patients across Africa.

La Botica in Peru

The implementation of this initiative was the result of an important teamwork of different functional areas of Merck KGaA, Darmstadt, Germany Peru Biopharma. The main purpose of this initiative is to improve the customer service to our final customers in terms of cold chain transportation, warehousing and delivery good practices. Through the continuous operations of the pharmacy of Merck KGaA, Darmstadt, Germany Peru as a direct sales channel to our final customers, we provide a better access to our products and also a better price than purchased through a distributor, guaranteeing also a quality and reliable service. The operations of La Botica are under responsibility of the Supply Chain team, with picking, packing, dispatching and delivering orders to customers.

5. Commercialization



Commercialization is the final node in our supply chain before the products reach health care providers and patients. When marketing our products, we apply Merck KGaA, Darmstadt, Germany's Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations that outlines our ethical marketing codes. We also comply with and support the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice²⁰ and the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Ethics for Pharmaceutical Marketing.²¹

Commercializing our products in developing countries requires reactivity to changing market needs, proximity to health centers and patients and collaboration with government and partners. By facilitating greater marketing and sales integration with external actors such as distributors we aim to make our commercialization processes more efficient. Furthermore, we use applications to track the stock coverage of our products thereby identifying risks arising from stock-outs. This allows us to take action in order to expedite supply and avoid, or at least minimize, the duration of stock-outs. Within commercialization, we are particularly focused on ensuring the affordability of our medicines to the patients in need.²²

Our goal is to avoid stock-outs and to ensure that patients have access to the health solutions they need when they need them. We work to avoid stock-outs by tracking how many of our orders are delivered on-time and in full through our sales and operational planning system. All our stock-outs are reported centrally, and we assess each situation to identify the lessons learned to minimize future shortages, working with a team dedicated to sales and operational excellence.

Global Batch Traceability (GBT)

Merck KGaA, Darmstadt, Germany's Global Batch Traceability tool provides batch traceability from the point of production, purchase and delivery to external customers. This tool increases the speed of data retrieval and improves analysis of the results via a graphical display of the batch history. Thanks to this process, we are able to run reliable and fast batch traceability reports and to have full visibility of finished products. In case of quality issues with a batch, our company would be able to know which box in which country to recall, thereby minimizing the duration of impacted product availability at a customer level.

²⁰ IFPMA, Code of Practice, 2012

²¹ EFPIA, Code of Ethics for Pharmaceutical Marketing, 2012

²² For more information, please see the Merck KGaA, Darmstadt, Germany charter 'Our Approach'

Merck KGaA, Darmstadt, Germany e-SHOP: Forward Integration of Supply Chain

We developed an e-shop solution for integrating non-Merck KGaA, Darmstadt, Germany companies in northwestern Africa into our supply chain and allowing them to place orders directly with us. The e-shop guarantees that orders are generated through direct management systems. By this forward integration, Merck KGaA, Darmstadt, Germany saves lead time, reduces failure regarding products & prices, and increases transparency on demand. This helps to reduce stock-outs. Merck KGaA, Darmstadt, Germany's e-shop has had very positive outcomes, including reduced cancellations due to miscommunication or multiple interfaces in the order process.

Merck KGaA, Darmstadt, Germany is proud of its commitment and contribution to recognizing the critical importance of supply chains to tackle access challenges in developing countries. We believe that safe and secure supply chains mechanisms play a vital role in ensuring patients' access to quality health solutions that enhance and save lives. By strengthening supply chain systems and capacities, we contribute to addressing access barriers and building responsible supply chains in low- and middle-income countries.

For additional information, please contact: a2h@emdgroup.com