

Charter on Access to Health in Developing Countries

Pharmaceutical Product Pricing

July 2014

Our Promise

Merck KGaA, Darmstadt, Germany is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors dedicated to enhancing the quality of human life around the world. 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 healthcare innovations in developing countries.¹ We are committed to improving health for these underserved populations, who lack access to health solutions including prevention, diagnostics and treatments. By enhancing availability, accessibility and affordability of our products, and by raising awareness in our communities, we work to provide high-quality, safe health solutions for all.

Our pharmaceutical pricing approach helps us ensure a sustainable supply of products for future generations of patients. Our approach allows us to recover the costs we incur by bringing products to market, including costs from research, development, manufacturing, regulation and distribution, among others. Through appropriate pricing we can continue investing in the discovery and development of new life-saving and life-enhancing medicines. We recognize the importance of affordable access to medicines in developing countries. As a result, we commit to pricing our products responsibly and to engaging in innovative equitable pricing schemes in partnership with Governments and other key stakeholders.

¹ For a full list of developing countries, refer to Merck KGaA, Darmstadt, Germany's Access to Health Charter, Our Approach.



Access to Health in Developing Countries

An estimated 1.3 billion people have no access to effective and affordable health care. According to the World Health Organization (WHO), developing countries bear 93% of the world's disease burden, yet account for only 18% of world income and 11% of global health spending.² Providing access to health in these countries is a complex 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 workers 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, nutritional supplements 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. These medicines are currently distributed in 74 developing countries including 35 countries in Africa, 18 in Asia and 12 in Latin America. Our products are available in nearly two thirds of Least Developed Countries (LDCs) including countries such as Afghanistan, Benin, Burkina Faso, Ethiopia, Haiti, Mali, Myanmar, Nepal, Senegal and Sudan.

Determining Prices in Developing Countries

The prices of our pharmaceutical products help to cover the costs of our research, manufacturing and marketing. We invest around € 1.5 billion annually into research and development (R&D)³ to enhance the efficacy of existing medicines and to create new drugs for previously untreated conditions. Prices also secure a return to our investors, thereby attracting the capital needed for continued investments in innovation.

The retail price of our health solutions in developing countries are frequently affected by factors beyond our control. These factors include import tariffs, distribution costs, third party mark-ups and domestic taxes. As a result, patients in these countries where access to health is most limited may pay inflated retail prices.⁴ For instance, in Brazil the tax burden of medicines is 33.9%, representing over a third of the final price paid by consumers.⁵ Fortunately, Brazil's Congress is currently considering a tax exemption on medicines.⁶

² Denis Drechsler and Johannes Jütting, Private Health Insurance for the Poor in Developing Countries? 2005

³ Merck KGaA, Darmstadt, Germany Annual Report, 2013

⁴ World Health Organization and Health Action International Surveys, 2010

⁵ Focus Reports, Interview with Nelson Mussolini, Executive Director SINDUSFARMA, 2012

⁶ The Pharmaletter, Brazil's Congress will establish committee to evaluate tax exemption on medicines, 2014



Price-related impacts through innovative distribution scheme

EMD Serono was able to reduce the price paid by patients by as much as 44-55% for 6 prescriptive and over the counter products in Kenya. This price reduction was brought about through innovations in our distribution strategy. By streamlining our processes in Kenya through measures such as using fewer middle men in country to distribute our products and lowering credit costs, we were able to make our products more affordable to patients at the point of delivery. This demonstrates how lower prices can be an indirect outcome of more efficient distribution systems.

The price of medicines can be reduced by eliminating these duties and taxes. We support the tariff elimination agreement between the United States, Canada, Japan, Norway, Switzerland, and the European Union and its 27 Member States. This agreement asks countries to eliminate tariffs for pharmaceutical products and for chemical intermediates used in the pharmaceutical production. We call for this agreement's extension in developing countries. Drug prices can also be lowered by promoting fair competition, including competition between innovative and off-patent medicines.

Socially Responsible Pharmaceutical Pricing

We take a holistic approach to providing access to medicines in developing countries. The affordability of our health solutions are part of our wider patient value proposition, which includes accessibility, availability and awareness. We balance our commitment to improving access while maintaining a sustainable business model. This balance encourages long-term investment in innovative research and development and the production of high-quality, safe products that improve patients' lives.

We believe a sustainable health financing system contributes to medicine affordability. In the majority of developing countries, individuals do not have access to health insurance or other pooled mechanisms of health financing. As a result individuals must pay out-of-pocket for most health care, including medicines.⁷ For individuals that do have health insurance, co-payment levels for health products may be excessively high. These payment scenarios increase the risk of non-adherence and make households vulnerable to falling into or remaining in poverty – a factor that contributes to poor health.

We have adopted a policy of not filing or enforcing patent applications in the large majority of developing countries.⁸ We recognize that respectful and responsible handling of intellectual property is essential for improving access to health in developing countries, where governments and patients face significant resource constraints and access barriers.

⁷ The World Health Organization estimates that poor households spend between 60 to 90 percent of total health expenditures on medicines. Source: WHO/HAI Project on Medicine Prices and Availability, The Role of Health Insurance in the Cost - Effective Use of Medicines, 2011

⁸ For a full list of developing countries in which we do not file or enforce patents, refer to our A2H Charter on Intellectual Property. This commitment refers to situations in which Merck KGaA, Darmstadt, Germany has sole responsibility over the intellectual property strategy of a product.



We recognize that countries have different abilities to pay for our health solutions. We therefore commit to implement inter-country equitable pricing schemes. Such schemes are often implemented through innovative mechanisms. For example we support local manufacturing, an approach that can generate collateral and positive spillover effects locally. We also conduct yearly reviews of our pricing strategies to identify ways to expand access to health by aligning prices with affordability.

We offer intra-country differential prices to ministries of health and to social health insurance systems responsible for distributing health solutions via low priced tenders. These institutions play a critical role in financing the healthcare of patients who would not otherwise be able to afford treatment.

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



Glossary / Definitions

Abbreviation	Definition
IDF	International Diabetes Federation
LDC	Least Developed Country (United Nations)
R&D	Research and Development
WHO	World Health Organization

