

Charter on Access to Health in Developing Countries

Equitable Pricing in Low- and Middle-Income Countries

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Access to Medicine: An Urgent and Unmet Need

As a leading science and technology company, we discover and develop for life in all its vibrancy, drawing on our unique expertise in healthcare, life science and performance materials. At Merck KGaA, Darmstadt, Germany, we work to achieve progress for people, communities, populations and society. Our global network of scientists, experts and thought leaders is driven by the passion to explore and the prospect of making a meaningful difference in 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.

However, we are conscious that access to medicine remains an unmet need for much of the world, particularly, in low- and middle-income countries:

- Globally, approximately two billion people have no access to basic medicines and healthcare¹, while 100 million people are pushed to extreme poverty due to health expenses each year.²
- Up to 90% of the population in low- and middle-income countries purchases medicines through out-of-pocket payments.¹
- Developing countries bear 87% of the world's disease burden,³ yet only account for 32% of global health spending.⁴

Providing access to health in the low- and middle- income 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.

¹ Access to medicines: making market forces serve the poor (2017), source: <https://www.who.int/publications/10-year-review/chapter-medicines.pdf>

² Tracking Universal Health Coverage: 2017 Global Monitoring Report (December 2017), source: <https://www.worldbank.org/en/topic/universalhealthcoverage/publication/tracking-universal-health-coverage-2017-global-monitoring-report>

³ 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/>

⁴ 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/>



Our Promise and Commitment to Equitable Pricing

We want to help ensure that all patients have access to the most effective medicines for their needs, which is why we are working to prevent cost from becoming a barrier to treatment. We are committed to fair, flexible and sustainable pricing – both within and across countries.

With this commitment, Merck KGaA, Darmstadt, Germany has increasingly stepped up its effort in the strengthening of equitable pricing strategies and improvement of access to medicine. We have dedicated resources in order to continuously enhance the company's understanding of the payer and healthcare landscape and affordability and ability to pay to explore effective ways of engagement with payers in developing markets.

We recognize that different health systems have different needs and affordability challenges. To ensure multiple socio-economic factors including gross domestic product, disease prevalence, inequality, income level and public health system/funding are considered in pricing decisions, we are applying differential pricing principles. We adapt our prices also based on local market considerations such as health system capacity, infrastructure, education standards, and unmet medical and treatment needs. Adapting biopharmaceutical prices to account for the ability to pay in different geographical or socio-economic segments is an important means of increasing patient access. Depending on the individual country characteristics, we actively support flexible pricing, differential pricing, and patient access programs.

In contributing to provide access to health in developing countries, we work at the interface of medicines and diagnostics utilizing our local, regional and global presence, expertise and core competencies.

Our Equitable Pricing Initiatives in Low- to Middle-Income Countries

We recognize that countries have different abilities to pay for our health solutions and that affordable access to medicines is important. As a result, we commit to pricing our products responsibly and to engaging in innovative, equitable pricing schemes within and across countries in partnership with Governments and other key stakeholders.

As part of our inter-country equitable pricing schemes, our pricing approach provides a consistent platform for flexible and equitable pricing for all franchises and countries to reflect countries' different abilities to pay, which has then been further enabled by a growing local manufacturing footprint and capacities. The established guidelines and pricing framework are also 'future-proof' as they may also apply to pipeline products when they enter the market. We also conduct regular reviews of our pricing strategies to identify ways to expand access to health by aligning prices with affordability.

Within countries, we also offer intra-country differential prices in several ways to improve access of medicines to patient groups with lower income such as:

Segmentation-based pricing / Governmental programs

We work in close partnership with governments and other stakeholders on innovative, differential medicine pricing schemes and we supply products at affordable prices to certain countries in Africa, Asia, Latin America, and the Middle East.

In India, for instance, we cooperate with public sector representatives across the oil and gas, electricals and railway sectors to offer discounted prices for certain general medicine and endocrinology products to patients with a limited ability to pay.

Moreover, we regularly participate in government tenders for products that are used in public hospitals serving low-income patients. Many of these tenders take place in low to middle-income countries.

Merck KGaA, Darmstadt, Germany's active support of Brazil's Farmácia Popular program, where the government reimburses 90%-100% of the cost of the drugs at participating retail pharmacies, is another example of our commitment to addressing affordability challenges in developing markets through governmental programs.

High-Quality Affordable Second Brands and Off-Patent Products

We are committed to provide high-quality medicines at affordable prices to patients in the low-income segment through making off-patent products available in the forms such as second 'low priced' brands of existing brands or branded off-patent products.

We offer branded off-patent products particularly in low- to middle-income countries together with our selected reliable partners, who can provide consistently high-quality products to Merck KGaA, Darmstadt, Germany's standards. This helps meet the urgent need for affordable, high-quality medicines required to treat endemic diseases. As of September 2020, we have launched several branded off-patent products in the Philippines, Brazil, Mexico and Chile. We are also in the process of registering more of these products in developing markets.

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. In Brazil, for instance, 11 of our high-quality products are available in a lower-priced format. We have also established high quality affordable brands in countries including Mexico, the Philippines, Poland, and South Africa.

Patient Access Programs

Patient access programs (also called patient assistance programs) are one of Merck KGaA, Darmstadt, Germany's commonly utilized approaches to help grant access to patients who can't afford their medication. Through these programs, we help qualified patients through financial assistance in line with applicable local laws and regulations.

Public-Private Partnerships

Collaboration and partnership are a cornerstone of our equitable pricing initiatives. Merck KGaA, Darmstadt, Germany is always actively seeking to generate opportunities for strategic collaborations and initiatives that strengthen its roadmap towards providing accessible health solutions. We believe the multi-partner and multi-sector approaches are critical to addressing affordability and access challenges, particularly in times of crisis such as pandemics.

Merck KGaA, Darmstadt, Germany, India for example signed a strategic public-private partnership in December 2019 with the Ministry of Railways (the Indian Railways) and the Ministry of Labor and Employment (Employees State Insurance Corporation) respectively to support and drive key interventions in the areas of cancer awareness and capability enhancement. This program aims to expand access and in the process improve care, for over 126 million beneficiaries in India.

Innovative Pricing and Contracting Mechanisms

Outcome-based contracts are an innovative approach used to pay for medicines that often involve greater risk-sharing among payers and biopharmaceutical companies. As a result of these arrangements, payers can make a medicine more accessible to patients and biopharmaceutical companies agree to share the financial risk and be reimbursed based on how well medicines work for patients. Our company has initiated several innovative contracting agreements for our innovative new products.

Sustainable Pricing for Future Innovations and Generations

The affordability of our health solutions is part of our wider patient value proposition and equitable and sustainable pricing commitment, which encompasses affordability, accessibility, availability and awareness. As part of our sustainable pricing approach, we continuously seek to improve access to our medicines in low-middle income countries while also investing in R&D to deliver innovations which help to create, improve and prolong lives for today's and future generations.

Acknowledgment of our Equitable Pricing Commitment

Our approach to improving patient access helps to ensure a sustainable supply of products for future generations of patients. As a signal of our dedication to improving access for patients, we have been consistently placed in the top companies that aim to improve access in international rankings.

- In the 2012, 2014, 2016, 2018 and 2021 Access to Medicines Index assessments, we have continuously ranked in the top 10.
- We are part of the industry's Access Accelerated Initiative which aims to improve the prevention and treatment of non-communicable diseases (NCDs) in low- and middle-income countries. NCDs include, for example, cancer, diabetes, cardiovascular and neurological diseases.
- For the past 10 years, we have been helping the fight against schistosomiasis. Through a collaboration with the World Health Organization (WHO), our tablet donation program has provided over 700 million tablets to sub-Saharan Africa allowing more than 150 million patients to be treated, most of them children.
- Merck KGaA, Darmstadt, Germany's strength in areas such as presence in LMICs, A2H at board level, and inter- and intra- country equitable pricing was acknowledged in the MSCI annual report (2020).
- Merck KGaA, Darmstadt, Germany was ranked 1st decile amongst 383 peer companies and recognized in its access to medicine in underserved regions in the ISS ESG rating (2020).
- Furthermore, in the Sustainalytics 2020 ESG Rating, Merck KGaA, Darmstadt, Germany excelled in areas such as equitable pricing for developing countries, defined criteria for equitable pricing country selection, products with inter- and intra- tiered pricing in LICs and LMICs.

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Glossary / Definitions

Abbreviation	Definition
BHEL	Bharat Heavy Electricals Limited
EAP	Early Access Program
ESG	Environmental, Social and Governance
GDP	Gross Domestic Product
IR	Indian Railways
LDC	Least Developed Country (United Nations)
LIC	Low-income country
LMIC	Low- to middle- income country
MAP	Market Access and Pricing
NTPC	National Thermal Power Corporation
ONGC	Oil and Natural Gas Corporation
R&D	Research and Development
WHO	World Health Organization