

Charter on Access to Health in Developing Countries

Pharmaceutical Products Donations and Philanthropic Activities

April 2019

Our Promise

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.

Unfortunately, millions of people still lack access to the benefits of modern health care innovations in developing countries.¹ We are committed to improving the health of 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 communities, we work to provide quality, safe health solutions for all.

Taking responsibility is an integral part of our corporate culture. We see ourselves as part of society and strive to be a thoughtful and active neighbor in our local and global communities. Our commitment to social responsibility is demonstrated through our health care projects and donation programs that improve the accessibility and availability of our health solutions. Our philanthropic activities include providing disaster relief in emergency situations, with a geographic focus on the countries in which we work. Our health initiatives focus on improving the health and well-being of communities and on developing sustainable health solutions.

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

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.² 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 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 public and private, must pool their efforts to overcome health access barriers.

In contributing to providing access to health in developing countries, we work at the interface of medicines, diagnostics, medical solutions including devices, and digital approaches, 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's medicines and products are listed on the WHO Essential Medicines List and 29 and/or as 1st line treatments.⁵ 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.

How Product Donations Improve Access

Product donations are particularly impactful when they are either large-scale long-term initiatives targeting elimination of a disease, or short-term responses to emergencies such as natural disasters. When product donations contribute to disease elimination, they create health benefits that help communities at large. In emergency situations, donations provide life-saving and life-enhancing support to affected communities. In both cases, partnering with other health actors and offering complementary education programs help improve outcomes.

There is a growing consensus in the global health community and within the pharmaceutical industry that sustainable access needs to go beyond product donations toward improving health care infrastructure, supporting technology transfer, and implementing policies that recognize the needs of developing countries. This type of holistic approach to private-sector contributions to health has the potential to radically improve access to health in general.

Doing Well by Doing Good

We support various global health projects to improve living conditions and health standards in the countries in which we work. We donate our products in response to specific needs and requests for assistance, and in situations where we can monitor that the donations are used appropriately and reach the intended recipients. Our product donations are primarily targeted at developing countries. We prioritize donations based on expressed need and expected impact, in consultation with our partners and host governments. Our Praziquantel Donation Program and all other

² Please see: <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>

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/>

⁵ Based on 2018 ATM Index analysis

headquarters-initiated donation programs are conducted in alignment with the WHO Revised Guidelines on Product Donations, to avoid undermining local health care systems and to offer stop-gap solutions to improve access to health. In addition, Merck KGaA, Darmstadt, Germany employees are expected to abide by our internal policies such as Group Policy of Contributions to Society which defines community involvement for our company along with the objectives we pursue. This policy also sets out roles and responsibilities, emphasizing that our activities should have a long-lasting, positive effect on the community. With this in mind, we focus our efforts on long-term projects. Other internal policies include the Biopharma Healthcare-Related Donations Policy. In all our endeavors, we comply with applicable laws and codes.

Our Praziquantel Donation Program

Schistosomiasis, also known as bilharzia, is the second most common parasitic disease after malaria. The disease affects nearly 250 million people worldwide with more than 90% of cases occurring in sub-Saharan Africa. An estimated 200,000 people die every year from the effects of schistosomiasis such as liver and kidney infections, bladder cancer, and anemia. Other health issues associated with schistosomiasis include malnutrition, growth retardation and cognitive impairment. A growing body of evidence indicates that infection with schistosomiasis increases susceptibility to infections such as HIV/AIDS and tuberculosis.

Our involvement with schistosomiasis began in the 1970s. In collaboration with Bayer, we developed a medicine called Praziquantel (PZQ). Today, PZQ remains the gold standard of effective treatment for all forms of schistosomiasis around the world.

Since 2007 Merck KGaA, Darmstadt, Germany PZQ donations have been conducted in partnership with WHO. In 2012 we committed to increasing our donation from 25 to up to 250 million tablets per year to contribute to the elimination of schistosomiasis by targeting 100 million African school-aged children.

We recognize that achieving elimination requires interventions beyond product donations. As a result, we are broadening our intervention scope to achieve long term sustainable solutions. Our holistic, integrated approach includes the following five steps:

- Extending the Merck KGaA, Darmstadt, Germany Praziquantel Donation Program until elimination
- Increasing annual donations of PZQ
- Broadening our support to include educational programs
- Optimizing the current formulation of PZQ
- Developing a pediatric formulation of PZQ

As part of our continuing commitment toward combatting schistosomiasis, we have recently initiated the creation of a global alliance in support of WHO's goal to eliminate schistosomiasis

worldwide. As a founding member of the Global Schistosomiasis Alliance (GSA), we have called upon different NTD (neglected tropical diseases) constituencies to join forces and combine efforts to address remaining gaps and challenges to meet the elimination target. We are working with WHO and all alliance partners to pursue the elimination objectives in a coordinated and integrated way.

We recognize that providing access to health in developing countries cannot be achieved by working alone. We welcome the opportunity to work with both public and private sector partners. Our partners' on-the-ground like WHO ensure that donations are administered safely to patients. When we directly distribute donated products, we work with in-country staff and relevant parties to ensure our donations are delivered to the intended beneficiaries and comply with national and international guidelines. For instance, we ensure the destruction of expired medicines. In addition to our pharmaceutical donation programs, our corporate responsibility encompasses other access to health initiatives. We are equally committed to supporting the development of health infrastructure through programs that are effective, efficient and sustainable. We contribute to improving access to health through a holistic approach that supports national health systems and reinforces local health priorities.

Merck KGaA, Darmstadt, Germany Supports the Global Pharma Health Fund

We are proud to be the founder and exclusive supporter of the Global Pharma Health Fund (GPHF), a charitable organization working for better health care and access to quality-assured medicines in developing countries since 1985. As part of its portfolio, GPHF developed the GPHF-Minilab™, a mobile mini-laboratory that can be used for fake medicine detection where the contents contain none, much too little, or the wrong active ingredient. Having the size of a heavy-duty suitcase, the GPHF-Minilab™ provides fast, simple and affordable tests to verify drug identity and content on 90 active principles. The GPHF-Minilab™ focuses on medicines to treat infectious diseases. Based on further needs and on requests from developing country governments and programs, we continually invest in developing new test methods for additional priority medicines.

In 97 countries, approximately half of which are in Africa and a third in Asia, over 800 GPHF-Minilabs™ have been donated or provided at cost to organizations responsible for running or controlling the countries' drug supply chain. Since 2012, over 80 GPHF-Minilabs™ have been donated to thirteen Ministries of Health or National Regulatory Authorities in developing countries to help in strengthening their health systems and enhancing their drug testing capacity. Data generated by the Minilab project work have prompted several global medical product alerts issued by the World Health Organization (WHO).

The success of the GPHF is based on our ability to form partnerships with governments, non-governmental and faith-based organizations. For example, we work with the Ecumenical Pharmaceutical Network (EPN) and the "Promoting the Quality of Medicines" (PQM) program run jointly by the United States Pharmacopeia (USP) Convention and the United States Agency for International Development (USAID).

GPHF recently formalized a partnership with the Ghana-based Center for Pharmaceutical Advancement and Training (CePAT) to build local and regional capacity in pharmaceutical quality assurance throughout sub-Saharan Africa.

We are ready to act locally when called upon for assistance. We employ approximately 50000 people in more than 65 countries. Through our global footprint we are well placed to help communities respond to emergencies. We partner with local governments, non-governmental organizations, and humanitarian and relief aid institutions to support vulnerable populations.

Responding to emergencies

We provide emergency assistance worldwide. In 2017, for instance, we supported the victims of the civil war in Yemen through product and monetary donations. Moreover, we provided aid when several hurricanes hit the United States (Texas, Florida and Puerto Rico) and we helped the victims of the earthquake in Mexico.

The value and impact of Merck KGaA, Darmstadt, Germany's community engagement programs are reported in the Merck KGaA, Darmstadt, Germany Corporate Responsibility Report, which is published annually and on the Merck KGaA, Darmstadt, Germany A2H website.

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

Glossary / Definitions

Abbreviation	Definition
A2H	Access to Health
CePAT	Center for Pharmaceutical Advancement and Training
EPN	Ecumenical Pharmaceutical Network
GPHF	Global Pharma Health Fund
LDC	Least Developed Country
PQM	Promoting the Quality of Medicines Programme
PZQ	Praziquantel
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

**Annex: Updated WHO Guidelines for Drug Donations
March 2010**

1. All medicine donations should be based on an expressed need, should be relevant to the disease pattern in the recipient country, and quantities should be agreed between donor and recipient.
2. All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the NEML is not updated. Or, if a national list is not available, it should appear on the WHO model lists of essential medicines, unless specifically requested otherwise and provided with a justification by the recipient.
3. The presentation, strength, and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in the recipient country.
4. All donated medicines should be obtained from a quality-ensured source and
5. should comply with quality standards in both donor and recipient countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.
6. No medicines should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples.
7. After arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year. Large quantities of donated medicines become a logistical challenge, even with a long shelf-life. Therefore, based on the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.
8. All medicines should be labelled in a language that is easily understood by health professionals in the recipient country. The label on each container should contain at least the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date.
9. Donated medicines should be presented in pack sizes that are suitable for the recipient and appropriate to the setting in which they will be distributed or dispensed.
10. All medicine donations should be packed in accordance with international shipping requirements and should be accompanied by a detailed packing list that specifies the contents. The weight per carton should preferably not exceed 30 kilograms. Shipments of medicines should not be mixed with other supplies unless they are shipped as kits with predetermined contents.
11. Medicine donations should be jointly planned, and collaboration between donors and recipients should begin early. Medicines should not be sent without prior consent of the recipient.
12. In the recipient country the declared value of a medicine donation should be based on the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.
13. Costs of international and local transport, warehousing, port clearance and (customs) storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency, unless specifically agreed otherwise with the recipient in advance.