

Charter on Access to Health in Developing Countries

Pharmaceutical Products Donations and Philanthropic Activities

July 2014

Our Promise

Merck KGaA, Darmstadt, Germany is a leading company for innovative and top-quality high-tech products. 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 affordability 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

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 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, 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.

How Product Donations Improve Access

Product donations are most 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 continue in perpetuity. 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 philanthropy has the potential to radically improve access to health.

Doing Well by Doing Good

We support various philanthropic 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 our donations can be monitored and evaluated for effectiveness. 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 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 Donations Policy, company rules, local laws and regulations.

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



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 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, anemia, growth retardation and cognitive impairment. A growing body of evidence indicating 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) under the brand name Cesol 600®. Today, PZQ remains the gold standard of effective treatment for schistosomiasis around the world.

Since 2007 Merck KGaA, Darmstadt, Germany PZQ donations have been conducted in partnership with WHO. We commit to increasing our donation from 25 up to 250 million tablets to WHO to contribute to eliminating schistosomiasis by targeting 100 million African school-aged children per year.

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 is outlined in the following five steps:

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

As part of our continuing commitment toward combatting schistosomiasis, we have recently proposed the creation of a global alliance in support of WHO's goal to eliminate schistosomiasis worldwide. As a founding member of this new global alliance, we have called upon different NTD (neglected tropical diseases) constituencies to join the alliance and combine efforts to address remaining gaps and challenges to meet the elimination target. We will work with WHO and all alliance partners to define the appropriate structure of this new initiative in order to ensure optimal operation.

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 local 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 that has improved health care and medicines supply in developing countries since 1985. As part of its portfolio, GPHF developed the GPHF-Minilab™, a mobile unit that can be used for rapid drug quality verification and fake medicine detection. The size of two suitcases, the GPHF-Minilab™ provides rapid, simple and inexpensive tests to verify the drug identity and content of 70 compounds. The GPHF-Minilab™ focuses on medicines for infectious diseases. In response to emerging needs and to requests from developing country governments and programs we continually invest in developing testing methods for new compounds.

In over 85 countries, approximately half of which are located in Africa and a third in Asia, more than 650 GPHF-Minilabs™ have been donated or provided at cost to organizations. Since 2012, over 50 GPHF-Minilabs™ have been donated to thirteen Ministries of Health or National Regulatory Authorities in developing countries to help strengthen their health systems and enhance their capacity. Data generated by the program has prompted global drug alerts generated by WHO.

The success of the GPHF lies in our ability to form partnerships with governments, non-governmental organizations and faith based organizations. For example, we work with the Ecumenical Pharmaceutical Network (EPN) and the Promoting the Quality of Medicines (PQM) programme run by the United States Pharmacopeia (USP) and 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 38,000 people in more than 65 countries. Through our global footprint we are well placed to help communities respond to emergencies. We consider donating products and providing other assistance regardless of the development status of the country. We partner with local governments, non-governmental organizations, and humanitarian and relief aid institutions to support vulnerable populations.



Responding to emergencies

In 2013, we provided emergency assistance to the victims of natural disasters in the Philippines (Typhoon Yolanda), India (Cyclone Phailin), USA (Oklahoma Tornado) and Germany (flooding). For instance, with funds from Merck KGaA, Darmstadt, Germany, the Philippine National Red Cross purchased a water tanker to deliver potable water to communities affected by Typhoon Yolanda. We also donated a variety of medicines and vitamins as well as manifolds and funnels.

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 every two years, and on the Merck KGaA, Darmstadt, Germany A2H website.

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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.

