

Charter on Access to Health in Developing Countries

R&D for Neglected Tropical Diseases and Priority Communicable Diseases

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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.

In an effort to improve access to health, we recognize the importance of Research and Development (R&D) into Neglected Tropical Diseases (NTDs)² and other priority Communicable Diseases such as malaria and diarrhea. We are committed to making a positive impact in the lives of those suffering from NTDs and other priority communicable diseases in developing countries through dedicating part of our R&D efforts to finding solutions for these unmet medical needs.

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

² WHO lists 17 NTDs: Buruli Ulcer, Chagas disease (American trypanosomiasis), Cysticercosis, Dengue/dengue haemorrhagic fever, Dracunculiasis (guinea-worm disease), Echinococcosis, Fascioliasis, Human African trypanosomiasis, Leishmaniasis, Leprosy, Lymphatic filariasis, Onchocerciasis, Rabies, Schistosomiasis, Soil-transmitted helminthiasis, Trachoma, Yaws.



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.³ 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.

Why Investments in Innovation are needed

R&D efforts and access to affordable medicines from the global community are currently limited⁴ in the area of NTDs and priority communicable diseases like malaria and certain diarrheal conditions. As a result, it is important to invest in innovative solutions to fight these diseases, especially considering the health burden they create.

NTDs are a group of parasitic and bacterial tropical infections. These diseases are responsible for a large health burden in developing countries, and they often disproportionately affect the poorest groups in society. The WHO has highlighted 17 NTDs that particularly impact poor and politically marginalized populations and that cause significant morbidity and/or mortality. More than 1 billion people – one-sixth of the world's population⁵ – are infected with one or more NTDs. An additional two billion individuals are at risk of infection, and half a million people die every year from NTDs.

The scale of malaria is unprecedented, with an estimated 3.4 billion people at risk, of which 1.2 billion are at high risk. The large majority of malaria deaths occur in sub-Saharan Africa. Communicable diarrheal diseases represent a major cause of death for children under the age of five in sub-Saharan Africa.

³ Denis Drechsler and Johannes Jütting, Private Health Insurance for the Poor in Developing Countries? 2005

⁴ Lancet Global Health, 2013; 1e371-379.

⁵ USAID NTD Program, Why Focus on NTDs? 2013



Our Commitment

EMD Serono's Translational Innovation Platform (TIP) houses our R&D efforts to combat NTDs and priority communicable diseases.

We abide by the following guiding principles for our R&D activities in this area:

- We realize that neglected diseases create a substantial burden on socioeconomic development in developing countries. We are committed to pursuing R&D efforts in this field through the development of new or adapted medicines (e.g. pediatric formulations), in order to improve the lives of the millions of patients in developing countries who suffer from neglected diseases.
- We believe the most effective way to advance and develop new approaches is to work through robust public-private partnerships and innovative alliances, and to adopt cross-cutting approaches in health and development. We strive to ensure equitable access to our products resulting from those partnerships.
- We collaborate with external partners to screen potential new drug targets for neglected diseases in developing countries against our compound database, on a case-by-case basis.
- We comply with the requirements of the World Medical Association's Declaration of Helsinki, the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice and the European Clinical Trial Directive. We include contract research organizations (CROs) relevant for clinical trials in developing countries.
- We commit to undertake clinical trials only in countries where we intend to register and ensure access to our medicines.
- We support R&D-related capacity building programs in developing countries by awarding grants to scientists for their continued education and training.



Our R&D activities

Merck KGaA, Darmstadt, Germany is currently involved in several areas of R&D for NTDs and priority communicable diseases with a focus on schistosomiasis and malaria. These initiatives are supported by R&D partnerships with centers of excellence in countries where these diseases are endemic.⁶

Innovating to Fight Schistosomiasis

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 blood loss. 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 continue working to optimize our existing product through film coated tablets, child-friendly flavors and reduced tablet sizes. In 2012 we also started a new public-private partnership to develop a pediatric formulation of Praziquantel for currently untreated pre-school age children. The product development program involves the participation of several partners from industry and from the public sector. The program involves full discovery and development, and it aims to achieve registration for a new pediatric product to treat schistosomiasis in children under the age of 6 years. In addition, we are further fostering R&D on schistosomiasis through research collaborations with endemic countries such as building the capacity of local manufacturing in Brazil.

⁵ Frost, L.J., Reich, M.R., How do good health technologies get to poor people in poor countries, Cambridge: Harvard Centre for Population and Development Studies, 2008

⁶ For more information about the Merck KGaA, Darmstadt, Germany Praziquantel Donation Program, refer to the A2H Charter on Product Donations and Philanthropic Donations.



Filling the Gaps for Research in Malaria

Malaria remains the most frequent cause of death for children in developing countries under the age of five. Despite an existing product portfolio and pipeline, there is an urgent need for new products to overcome the problem of increasing drug resistance and to achieve the goal of complete eradication.

We established a discovery program with external organizations and entered into a partnership with the non-profit Medicine for Malaria Venture (MMV) in 2013. The EMD Serono-MMV collaboration aims at further developing proprietary EMD Serono lead compounds as long-acting anti-malarials, which represent a major gap in the worldwide anti-malarial portfolio. This private-NGO partnership allows resource sharing and uses relevant networks to speed up development.

R&D Partnerships

We participate in multilateral and industry-wide initiatives around R&D for neglected diseases. We have established a dedicated organization within EMD Serono R&D to operate research programs for neglected diseases and to support several partnerships in endemic countries for local R&D programs. These partnerships are with: the African Institute of Biomedical Science & Technology (AiBST) in Zimbabwe, the Kenya Medical Research Institute (KEMRI) in Kenya and the University of Namibia (UNAM).

We continue to support and trigger screening of our internal compound library through an external collaboration with Swiss TPH (Swiss Tropical & Public Health Institute). Through this initiative we aim to identify potential molecules for schistosomiasis and related helminthic diseases.

We are engaged in education and training programs that support young researchers at centers of excellence in endemic countries. We also host researchers from developing countries at Merck KGaA, Darmstadt, Germany R&D sites. We support external Post Docs in endemic countries in collaboration with institutes like the AiBST. We also participate in a new fellowship program for African researchers called the European and Developing Countries Clinical Trials Partnership - European Federation of Pharmaceutical Industries and Associations (EDCTP-Efpia).

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



Glossary / Definitions

Abbreviation	Definition
AiBST	African Institute of Biomedical Science & Technology
CRO	Contract Research Organization
EDCTP-Efpia	European and Developing Countries Clinical Trials Partnership - European Federation of Pharmaceutical Industries and Associations
ICH	International Conference on Harmonization
KEMRI	Kenya Medical Research Institute
LDC	Least Developed Country
MMV	Medicine for Malaria Venture
MPDP	Merck KGaA, Darmstadt, Germany Praziquantel Donation
NGO	Non-Governmental Organization
NTD	Neglected Tropical Disease
PZQ	Praziquantel
R&D	Research and Development
Swiss TPH	Swiss Tropical & Public Health Institute
TIP	Translational Innovation Platform
WHO	World Health Organization

