

# Charter on Access to Health in Developing Countries

## Our Approach

July 2014

**“Social and environmental responsibility are not a luxury to us that we only uphold during boom years, but rather are an integral part of our corporate culture.”**

*Karl Ludwig Kley, Chairman of the Executive Board*

**“In Access to Health, there are many challenges that require innovative solutions. Through our sustainable access to health initiatives, we are making a difference.”**

*Dr Stefan Oschmann,*

*Member of the Executive Board of the Merck KGaA, Darmstadt, Germany, CEO Pharma*

## 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.<sup>1</sup> 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.

Access to Health (A2H) is a strategic priority for the Merck KGaA, Darmstadt, Germany Group. Our A2H strategy is designed to contribute to overcoming barriers to access for underserved populations and communities in developing countries in a business integrated and sustainable manner. Recognizing that access is a complex and multifaceted challenge with no one-size-fits-all solution, our programs and initiatives are tailored to global, regional and local needs. We take a holistic approach working in partnerships to achieve results. Our A2H work cuts across our business and is a component of our Corporate Responsibility strategy. A2H is sponsored by Dr. Stefan Oschmann, a member of our Executive Board of the Merck KGaA, Darmstadt, Germany Group and CEO of the Pharmaceuticals Business.

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<sup>1</sup> For a full list of developing countries, refer to Annex I.



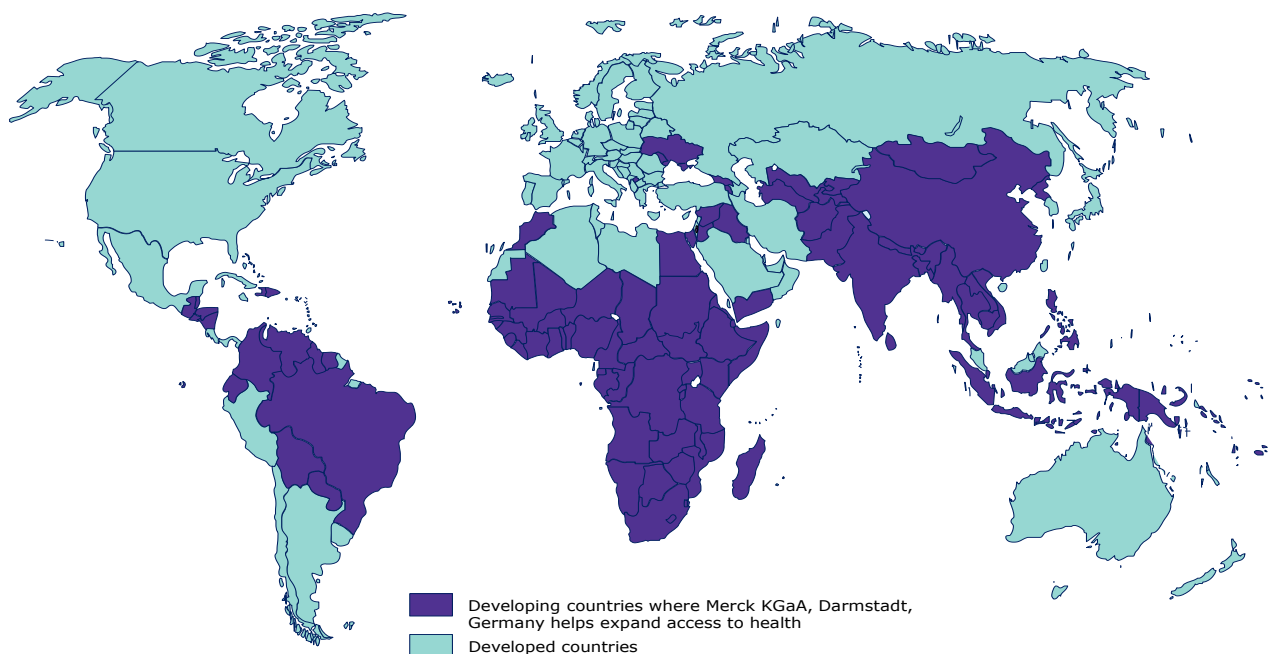
## Access to Health in Developing Countries

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.<sup>2</sup> 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.

We are currently helping to expand access to health in all developing countries through commitments made in our A2H Charter and our targeted activities. We involve all our divisions, affiliates and employees in our access work. Our employees abide by high ethical standards, including this A2H Charter for Developing Countries, company rules, local laws and regulations. Our products are produced in manufacturing plants that meet global Good Manufacturing Practices (GMPs) and Good Distribution Practices (GDPs).

**Figure 1: Countries in which we help expand access to health**



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



## Our Four A's of Access

Our vision is to become a valued partner in addressing and contributing sustainably to global health needs of underserved populations and communities, regardless of their location and ability to pay. In all we do, we uphold our core values and the principles of quality, collaboration, accountability, transparency and respect for human rights. We leverage our core competencies, expertise, knowledge and experience across the health value chain in order to address barriers in access to health in developing countries. We aim to achieve this goal through a strategic focus on our Four As of Access.

**Figure 2: Our Four As of Access**



- **Availability:** Research, develop and refine health solutions that address unmet needs and are tailored to local environments across the spectrum of prevention, diagnostics, treatment, care and support.
- **Accessibility:** Strengthen supply chain and develop localised health solutions to deliver and reach out efficiently at the point of care, thereby allowing public and private health workers and partners, communities and patients with consistent access to health solutions, irrespective of their geographical location.
- **Affordability:** Assist public and private health workers and partners, communities and patients who are unable to pay for the health solutions they need.
- **Awareness:** Empower public and private health workers and partners, communities and patients with appropriate tools, knowledge, information and skills towards quality and informed decision making around the spectrum of prevention, diagnostics, treatment, care and support.

Our approach to delivering initiatives along our Four As of Access involves a four step process:

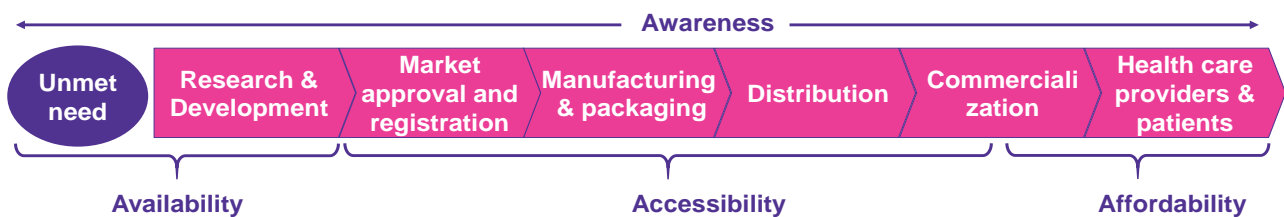
- **Diagnose:** We identify unmet needs of underserved populations and communities in developing countries.
- **Design:** We develop business-integrated approaches to provide support given our expertise, knowledge, capacity and core competencies and our partners' experience.
- **Implement:** We implement innovative solutions in collaboration with our partners to meet needs in a sustainable way.
- **Evaluate:** We monitor and evaluate programs to ensure that we achieve the outcomes desired, and where necessary we reorient our program to optimize results. We report on results through our dedicated A2H Website and the Merck KGaA, Darmstadt, Germany Corporate Responsibility report.



Our Four As of Access and our aim to deliver outcomes through a needs-based approach help ensure that we offer patients access to high quality safe health solutions irrespective of their location and ability to pay. In all our Access to Health initiatives, we support principles that are non-discriminatory and that respect human rights.

There is a growing consensus in the global health community and within the pharmaceutical industry that sustainable access requires an integrated approach across the health value chain.

**Figure 3: How our Four As of Access integrate into the health value chain**



Our approach is also outcome-oriented. We believe that it is important to monitor and evaluate our access to health programs in order to better understand how we are meeting patients' needs. We commit to developing quantitative and qualitative indicators across all Four As of Access which will be evaluated regularly to help us assess our strengths and areas where we can further strengthen our efforts to expand access to health.

### Committed to Improve Access in Africa

Since 1911, we have been developing our knowledge, expertise and partnerships in Africa. Recently we committed to expand our presence and the availability of our health solutions across the African continent. "Possibilities exist that extend far beyond what we are currently doing in Africa. And those who establish a foothold in growth markets like these early on will always have an advantage over latecomers." - Karl Ludwig, Chairman of the Executive Board

Our strategy on expanding access in Africa emphasizes raising awareness among the population and developing capabilities within the healthcare system. The transfer of knowledge in research and development, production, quality management and medical education is our chosen way of helping the healthcare system and healthcare industry to become sustainable.

Since 2012, we have established six sub-Saharan Africa affiliates in Ethiopia, Kenya, Mozambique, Angola, Nigeria and Ghana. In addition to providing high-quality pharmaceutical products, we partner with governments, healthcare institutions, health workers and academics as well as foundations and NGOs. Through capability advancement programs in collaborations with Universities, R&D partnerships with research institutes and fighting fake medicines together with local authorities, we are helping to bring down the barriers to health.

For more detailed information on our Charter positions, and information on our current engagements, please consult our A2H website and our Corporate Responsibility Report.



## Partnering for Change

We recognize that we cannot work alone to address all the access gaps and achieve the change we seek. We believe that partnerships, collaboration and dialogue are key to delivering sustainable access results and making great things happen. We engage and collaborate with our partners including multilateral organizations, governments, non-governmental organizations, civil society, foundations, research institutions and academia, health care professional associations, patient organizations, think tanks and private sector partners.

We believe in transparency. We publish our Access to Health Charter positions, make potential conflicts of interest known to our partners, and disclose any political contributions or lobbying activities undertaken in developing countries. In our dealings with partners, we commit to avoid practices that hamper healthy competition in developing countries.

We abide by and support the codes of major pharmaceutical associations to support partnerships aimed at delivering greater patient benefits and supporting higher quality patient care. These codes include the:

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 2012 Code of Pharmaceutical Marketing Practices
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations
- EFPIA Disclosure Code 2014
- 2014 Consensus Framework for Ethical Collaboration, the first collaborative platform of five global healthcare organizations (International Alliance of Patients' Organizations (IAPO), International Council of Nurses (ICN), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), International Pharmaceutical Federation (FIP), and World Medical Association (WMA))

We have participated in the United Nations Global Compact since 2005. We abide by the Compact's ten principles and in doing so promote and enforce fundamental values in human rights, labor standards, environmental protection and the fight against corruption. The Merck KGaA, Darmstadt, Germany Human Rights Charter serves as our framework to guide our decision-making to ensure we uphold the human rights of all the patients and partners we work with in countries as well as at the global and regional levels. We are signatories to the Business for Social Responsibility (BSR) Principles on Access to Healthcare.

We are a member of the Gates CEO Roundtable for Global Health and are a signatory to the January 2012 London Declaration on Neglected Tropical Diseases (NTDs). The London Declaration is an unprecedented public-private effort to eradicate, eliminate and intensify control of 10 of the 17 NTDs in order to contribute to the WHO 2020 NTD targets. Other London Declaration signatories include: the World Health Organization, World Bank, endemic NTD countries, governments of the United States, United Kingdom and United Arab Emirates, the Bill & Melinda Gates Foundation and 13 biopharmaceutical companies.

We participate in a wide variety of networks, programs and fora such as the African Network for Drugs and Diagnostics (ANDI) and the WHO's Special Programme for Research and Training in Tropical Diseases (TDR). We sponsor the Geneva Health Forum and its associated Geneva Innovation Network, and we are a member of Rx-360, responsible for developing a global quality system that helps ensure patient safety. We work closely with the International Alliance of Patients' Organizations (IAPO) and local counterparts to promote patient awareness and to advance patient-focused initiatives, such as universal health coverage and the production of biosimilars for developing countries.



Through engagement with numerous stakeholders on access-related issues, we foster dialogue and collective action around the barriers to access in developing countries, captured in our Four As of Access. Our list of partners includes government and UN representatives, NGOs and civil society, patients, academia, investors, professional and industry organizations, as well as think tanks and the private sector.

We have launched the “access dialogue series”, a Merck KGaA, Darmstadt, Germany sponsored platform of information exchange and best practice sharing among public and private sector stakeholders, – such as access experts, civil society, academia, patients, governments, UN organizations and the private sector. The access dialogues enable us to collaboratively address the access challenges for underserved populations in developing countries and to inform our dedicated strategy and initiatives. Our objective is to initiate a creative shift towards a proactive and collaborative approach around our Four As of Access for underserved populations in developing countries. This process is intended to be an open space for insightful and critical dialogue on how Merck KGaA, Darmstadt, Germany and partners can best use our respective capacities, experience, expertise and competencies to sustainably address access barriers. Our dialogues address innovation, donations, clinical trials, transparency, counterfeiting, R&D for NTDs, pharmacovigilance, innovative pricing and supply-chain/delivery challenges, universal health coverage, as well as innovative intellectual property and access.

We are sponsors, speakers and contributing participants at conferences and multi-stakeholder fora focused on developing countries, such as the first World Bank neglected tropical disease Conference and the International Symposium on Schistosomiasis. We contributed to the European Commission’s Tajani Initiative on access to medicines in developing countries with a focus on Africa. We are participating in EU/UN access-related consultations, including the EU Consultation for strengthening the private sector role in achieving inclusive and sustainable growth in developing countries. We sponsor a series of access seminars with the European Commission and Parliament hosted by the European Federation of Pharmaceutical Industry Associations (EFPIA). These seminars focus on important access issues in developing countries, including R&D for neglected diseases; clinical trials; technology transfer; the affordability and delivery and supply chain challenges.

Finally, we support international efforts to raise the profile and the potential of global health in the development landscape through a cross-sectoral and holistic approach. We are committed to the Millennium Development Goals (MDGs) and represented the German biopharmaceutical industry during the dedicated German MDGs consultation with the private sector. Moving forward, we will collaborate with partners on defining priorities and delivering on commitments and goals for the post-2015 development agenda.

For additional information, please contact: [a2h@emdgroup.com](mailto:a2h@emdgroup.com)



## Glossary / Definitions

Abbreviation	Definition
<b>A2H</b>	Access to Health
<b>ANDI</b>	African Network for Drugs and Diagnostics
<b>BSR</b>	A global nonprofit business network dedicated to sustainability
<b>CEO</b>	Chief Executive Officer
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Associations
<b>EU</b>	European Union
<b>FIP</b>	International Pharmaceutical Federation
<b>GDP</b>	Good Distribution Practices
<b>GMP</b>	Good Manufacturing Practices
<b>HiHDI</b>	High Human Development Country with high inequality (United Nations)
<b>IAPO</b>	International Alliance of Patients' Organizations
<b>ICN</b>	International Council of Nurses
<b>IFPMA</b>	International Federation of Pharmaceutical Manufacturers and Associations
<b>LDC</b>	Least Developed Country (United Nations)
<b>LIC</b>	Low-Income Country (World Bank)
<b>LMIC</b>	Lower-Middle-Income Country (World Bank)
<b>MDGs</b>	Millennium Development Goals
<b>MHDC</b>	Medium Human Development Country (United Nations)
<b>MPMBP</b>	Merck KGaA, Darmstadt, Germany Pharmaceutical Marketing Best Practices
<b>NGO</b>	Non-Governmental Organization
<b>NTD</b>	Neglected Tropical Disease(s)
<b>R&amp;D</b>	Research and Development
<b>TDR</b>	Special Programme for Research and Training in Tropical Disease
<b>UN</b>	United Nations
<b>WHO</b>	World Health Organization
<b>WMA</b>	World Medical Association

Term	Definition
<b>Developing country</b>	Countries as per the World Bank and United Nations listed in the Annex, often referred to as low- and middle-income countries, January 2014.



## Annex – List of Developing Countries 2014

Country	Classification	Country	Classification
<b>East Asia &amp; Pacific</b>		<b>South Asia</b>	
Cambodia	LIC	Afghanistan	LIC
China	MHDC	Bangladesh	LIC
Fiji	MHDC	Bhutan	LMIC
Indonesia	LMIC	India	LMIC
Kiribati	LMIC	Maldives	MHDC
Korea, Dem. Rep.	LIC	Nepal	LIC
Lao PDR	LMIC	Pakistan	LMIC
Micronesia, Fed. Sts.	LMIC	Sri Lanka	LMIC
Mongolia	LMIC	<b>Sub-Saharan Africa</b>	
Myanmar	LIC	Angola	LHDC
Papua New Guinea	LMIC	Benin	LIC
Philippines	LMIC	Botswana	MHDC
Samoa	LMIC	Burkina Faso	LIC
Solomon Islands	LMIC	Burundi	LIC
Thailand	MHDC	Cameroon	LMIC
Timor-Leste	LMIC	Cape Verde	LMIC
Tonga	MHDC	Central African Rep.	LIC
Tuvalu	LDC	Chad	LIC
Vanuatu	LMIC	Comoros	UC
Vietnam	LMIC	Congo, Dem. Rep.	LIC
<b>Europe &amp; Central Asia</b>		Congo, Rep.	LMIC
Armenia	LMIC	Cote d'Ivoire	LMIC
Georgia	LMIC	Equatorial Guinea	MHDC
Kosovo	LMIC	Eritrea	UC
Kyrgyz Rep.	LIC	Ethiopia	LIC
Moldova	LMIC	Gabon	MHDC
Tajikistan	LIC	Gambia, The	LIC
Turkmenistan	MHDC	Ghana	LMIC
Ukraine	LMIC	Guinea	LIC
Uzbekistan	LMIC	Guinea-Bissau	LIC
<b>Latin America &amp; Caribbean</b>		Kenya	LIC
Belize	MHDC	Lesotho	LMIC
Bolivia	LMIC	Liberia	LIC
Brazil	HiHDI	Madagascar	LIC
Colombia	HiHDI	Malawi	LIC
Dominican Rep.	MHDC	Mali	LIC
Ecuador	HiHDI	Mauritania	LMIC
El Salvador	LMIC	Mozambique	LIC
Guatemala	LMIC	Namibia	MHDC
Guyana	LMIC	Niger	LIC
Haiti	LIC	Nigeria	LMIC
Honduras	LMIC	Rwanda	LIC
Nicaragua	LMIC	Sao Tome and Principe	LMIC
Paraguay	LMIC	Senegal	LMIC
Suriname	MHDC	Sierra Leone	LIC
Venezuela, RB	HiHDI	Somalia	LIC
<b>Middle East &amp; North Africa</b>		South Africa	MHDC
Djibouti	LMIC	South Sudan	LIC
Egypt, Arab Rep.	LMIC	Sudan	LMIC
Iraq	MHDC	Swaziland	LMIC
Jordan	MHDC	Tanzania	LIC
Morocco	LMIC	Togo	LIC
Syrian Arab Rep.	LMIC	Uganda	LIC
West Bank and Gaza	LMIC	Zambia	LMIC
Yemen, Rep.	LMIC	Zimbabwe	LIC





LIC	Low-income Country	World Bank income classification
LMIC	Lower-middle-income Country	World Bank income classification
LDC	Least Developed Country	UN Human Development Index
MHDC	Medium Human Development Country	UN Human Development Index
HiHDI	High Human Development Country with high inequality	UN Inequality-Adjusted Human Development Index

List of countries and classification is drawn from the 2014 Access to Medicine's methodology.

