

Charter on Access to Health in Developing Countries

Intellectual Property Rights

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.

Intellectual property protection is required for us to make investments in the research and development needed to enhance therapeutic efficacy of our existing health solutions and to create new therapies for future generations. We are focused on finding innovative solutions, including respectful and responsible handling of intellectual property, to promote sustained and affordable access to health in developing countries.

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.

Why Intellectual Property Matters

While roughly 30,000 diseases are known, effective treatments exist for only around one-third of them. Even when treatment options exist, they sometimes have low efficacy or undesirable side effects. We invest around € 1.5 billion annually into research and development (R&D)³ to enhance the efficacy of existing medicines and to create new drugs for previously untreated conditions. We have been making major investments in R&D since our founding as a pharmacy in 1668 in Darmstadt, Germany.

Developing new medicines entails significant risks and costs. Investment in R&D can take 10-15 years before delivering an effective health solution, if any. Pharmaceutical companies therefore need a strong, transparent and predictable legal framework for intellectual property rights and patent enforcement that awards sufficient time and protection to recover R&D costs. Intellectual property protection enables companies to continue making strategic investments in R&D over the long term. Without such protections, the vast majority of innovative and generic drugs available today would likely have not been developed.

Respectful and responsible handling of intellectual property is not a barrier for access to health. Today, most medicines that address the highest burden of disease in developing countries are not protected by patents. Ninety six percent of WHO Essential Medicines⁴ —necessary to satisfy the priority healthcare needs — are off patent.

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

³ Merck KGaA, Darmstadt, Germany Annual Report, 2013

⁴ WHO Essential Medicines List http://www.who.int/medicines/services/essmedicines_def/en/



Supporting Global Standards

The World Trade Organization (WTO) has established a framework for international intellectual property protection. This framework includes issues relevant to the pharmaceutical industry, such as patent protection, compulsory licensing and the protection of submitted regulatory data. We support the WTO's standards for intellectual property rights, including the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁵ and subsequent amendments such as the Special Declaration on the TRIPS Agreement and Public Health at the Doha Ministerial Conference in November 2001 (Doha Declaration). The Doha Declaration exempted LDCs from complying with TRIPS provisions until January 1st, 2016. We support this exemption of LDCs and an extension of the exemption beyond 2016.

The TRIPS Agreement requires WTO members to provide patent protection for a minimum term of 20 years from the patent application's filing date. Given the time it takes for research and development, clinical evaluation and regulatory approval, the average effective patent life for medicines is less than 10 years. We believe the patent term length defined by the WTO strikes the right balance between promoting innovation and increasing access to health. We do not support extending the patent term longer than the WTO-defined 20 year minimum in developing countries.

Patents ensure temporary exclusive rights for marketing an innovative product. However, we respect the right of developing countries to enact compulsory patent licensing in specific situations, as embodied in TRIPS Article 31 and as modified by the Doha Declaration. The TRIPS Agreement permits national governments to allow third party production of the patented products or processes without the patent owner's consent in cases of "national emergency or other circumstances of extreme urgency or in cases of public noncommercial [i.e., government] use." We support the use of compulsory licenses as defined and regulated by the TRIPS Agreement. We believe that in some cases, approaches other than compulsory licensing may be more appropriate and would avoid undermining innovation in the pharmaceutical industry. For example, differential pricing and voluntary licensing can achieve improved health outcomes in developing countries.

We support responsible regulatory data protection policies. These policies encourage innovator companies to conduct costly clinical trials and to invest in additional research and development. In addition, WTO members are required by the TRIPS agreement to protect data submitted for pharmaceutical regulatory approval against unfair commercial use. After a defined period of time, generic manufacturers may utilize the originator data to obtain generic medicines approval.

Socially Responsible Intellectual Property

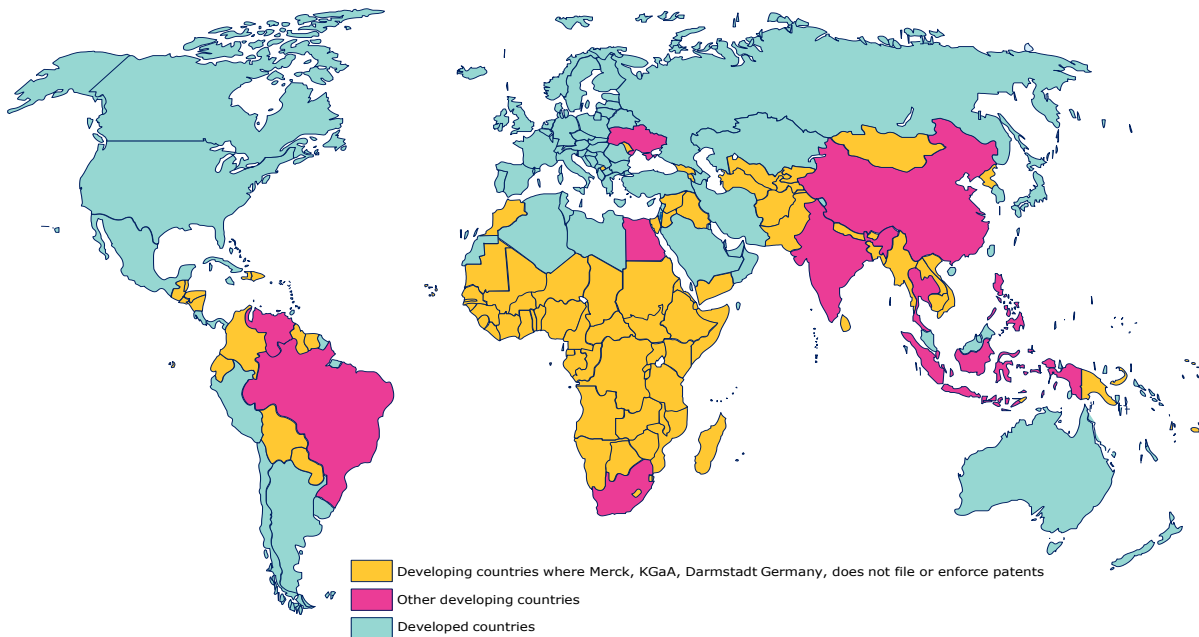
We have adopted a policy of not filing or enforcing patent applications in the large majority of developing countries.⁶ We recognize that respectful and responsible handling of intellectual property is essential for improving access to health in developing countries, where governments and patients face significant resource constraints and access barriers. In markets where we file patent applications, we commit to enhancing data sharing with researchers and improving public access to clinical trial information. We make publically available information about the patent status of our products (see Annex II).

⁵ WTO TRIPS Agreement http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

⁶ For a full list of developing countries in which we do not file or enforce patents, refer to the Annex I. This commitment refers to situations in which Merck KGaA, Darmstadt, Germany has sole responsibility over the intellectual property strategy of a product. In public-private partnerships and donation programs we encourage our partners not to file or enforce patents in these developing countries.



Figure 1: Our patent commitments in developing countries



We believe that introducing more regional pharmaceutical manufacturers in the market can promote innovation and help improve access to health in developing countries. We support a variety of innovative solutions for handling intellectual property. For example, our product development partnerships and technology transfer agreements have helped expand the availability of affordable innovative medicines in many developing countries.

Biosimilars in Brazil - Our Partnership with BioNovis

In April 2014, Merck KGaA, Darmstadt, Germany entered into a formal partnership with Bionovis, a joint venture of four Brazilian pharmaceuticals companies, for the production of biosimilar products for the treatment of cancer and auto-immune diseases. Non-communicable diseases such as cancer are a growing burden in developing countries, whose health care systems were initially aimed at treating infectious diseases. As part of this partnership Merck KGaA, Darmstadt, Germany will transfer the technology for the production of the drugs during the next five years, with some tech transfer starting already this year.

The Merck KGaA, Darmstadt, Germany-BioNovis partnership is part of a wider program of the Brazilian government, launched in June 2013. The program aims to engage public and private laboratories in the domestic manufacture of 14 biological drugs. This plan is expected to boost innovation and knowledge in the biosimilars field in Brazil. The program will also reduce costs for the Ministry of Health by replacing expensive imported biosimilars with domestically produced drugs. The Merck KGaA, Darmstadt, Germany-Bionovis partnership exemplifies our commitment to finding innovative approaches to intellectual property that broaden access to essential medicines.



We commit to providing the highest quality standards to protect the safety of our patients by improving local manufacturing capabilities. We enter into technology transfer agreements with generic manufacturers to ensure that our medicines are manufactured with internationally-recognized standards of Good Manufacturing Practices (GMP). Our support to local manufacturing - and the transfer of and access to technology, skills and intellectual property - is contingent on compliance with our quality and safety standards.

We support voluntary licensing agreements of all kinds including non-exclusive voluntary licenses (NEVLs) and legally binding non-assert declarations or clauses that are focused on improving access. We focus these agreements on medicines to treat non-communicable diseases such as cardiovascular diseases, diabetes, cancer, and chronic pulmonary diseases which represent a growing health burden in developing countries. We welcome requests for such licenses from manufacturers that can meet our quality and performance standards. When we grant a license, we commit to supporting technology transfer that ensures the delivery of high quality products.

Our R&D partnerships are designed to address diseases impacting developing countries and to help advance our partners' R&D and manufacturing capabilities. Collaborative and access-oriented partnerships are an increasingly important mechanism by which companies can leverage their intellectual property.

Collaborative Dialogue on Access and Intellectual Property

We have launched a collaborative stakeholder dialogue on innovative approaches to intellectual property rights and access to health. The dialogue is designed to generate insightful and critical discussions on how our capacities, experience and competencies can address affordability challenges. Led by our access and intellectual property functions and sponsored by our Global Head of R&D, we feature leading intellectual property platforms, including UNITAID's Medicines Patent Pool (MPP), Drugs for Neglected Diseases Initiative (DNDi) and WIPO Re: Search. We aim to share information and best practices with key stakeholders including intellectual property experts, civil society, academia, patients, governments, UN organizations and the private sector. We also use input to inform our Access to Health Strategy.

Patent pools can be useful in addressing barriers to access in developing countries. A patent pool allows the development and commercialization of products that require access to multiple patents controlled by different parties. Members of a patent pool agree to jointly develop and commercialize a medicine using complementary technologies, or to make technologies available to interested parties. We support the concept of patent pools. However, we believe patent pools should be structured to improve access to life-saving medicines, and should therefore avoid anti-competitive effects and geographic limitations. We believe patent pools should stimulate the development of health solutions. We consider joining patent pools if they are relevant to our portfolio, and if they meet efficacy, quality and safety requirements.



Joining WIPO Re:Search

The Merck KGaA, Darmstadt, Germany Innovative Access and Intellectual Property (IP) Advisory Board was an opportunity for Merck KGaA, Darmstadt, Germany to learn about different intellectual property platforms and how we can contribute towards addressing issues around IP. Following the meeting, Merck KGaA, Darmstadt, Germany joined WIPO Re:Search, a collaboration between the World Intellectual Property Organization (WIPO) and BIO Ventures for Global Health (BVGH) which is dedicated to sharing innovation in the fight against neglected tropical diseases (NTDs), malaria, tuberculosis (TB). The platform is founded on the belief that intellectual property and knowledge can be used creatively to stimulate the invention of new health solutions while also ensuring that these solutions are accessible by under-served populations. WIPO Re:Search has a diverse array of partners including those from leading pharmaceutical companies, academic institutions as well as other private and public research institutions. As a member of WIPO Re:Search, research centers will have access to our compounds which will help them to develop much needed solutions for patients in developing countries.

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



Glossary / Definitions

Abbreviation	Definition
DNDi	Drugs for Neglected Diseases Initiative
GMP	Good Manufacturing Practices
IP	Intellectual Property
LDC	Least Developed Country (United Nations)
MPP	Medicines Patent Pool
NEVL	Non-exclusive voluntary licenses
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



Annex I - Developing Countries in which Merck KGaA, Darmstadt, Germany does not file or enforce patents

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



LIC Low-income Country

LMIC Lower-middle-income Country

LDC Least Developed Country

MHDC Medium Human Development Country

HIHDI High Human Development Country with high inequality

World Bank income classification

World Bank income classification

UN Human Development Index

UN Human Development Index

UN Inequality-Adjusted Human Development Index



Annex II – Patent Status of Merck KGaA, Darmstadt, Germany’s products in Developing Countries

Products	Active ingredient(s)	Compound patent	Technology protection				Year of patent expiry
			Processes	Formulation	Indication	Combination	Developing countries
Oncology							
Erbix	Cetuximab	Yes	No	No	No	Yes	No
UFT	Uracil and Tegafur	Yes	No	Yes	No	Yes	No
Cardiometabolic Care							
Cefixime	Cefixime	No	No	No	No	No	No
Concor	Bisoprolol Fumarate	Expired	No	No	No	No	No
Concor COR	Bisoprolol Fumarate	Expired	No	No	No	No	No
Concor Plus	Bisoprolol Fumarate and Hydrochlorothiazide	No	No	No	No	No	No
Euthyrox	Levothyroxine Sodium	No	No	Yes	No	No	05/2019 (PK)
Glucophage	Metformin Hydrochloride	No	No	No	No	No	No
Glucophage powder	Metformin Hydrochloride	No	No	No	No	No	No
Glucophage XR	Metformin Hydrochloride	No	No	Yes	No	No	03/2019 (ARIPO; AM, AZ, KG; MG; MD; TJ; TM; VN)
Glucovance	Metformin hydrochloride and glibenclamide	No	No	Yes	No	Yes	07/2019 (ARIPO; EG; MA; MG; VN)
Lodoz	Bisoprolol fumarate and hydrochlorothiazide	No	No	No	No	No	No

Nicorandil	Nicorandil	No	No	No	No	No	No
Praxilene	Naftidrofuryl oxalate	No	No	No	No	No	No
Global Special Products							
Acarbose		No	No	No	No	No	No
Bifonazole		No	No	No	No	No	No
Bumadizone		No	No	No	No	No	No
Calcitonin		No	No	No	No	No	No
Calcium D3	Colecalciferol and tricalcium phosphate	No	No	Yes	No	No	No
Campral	Acamprosate calcium	Yes	No	No	No	No	No
Colpotrophine		No	No	No	No	No	No
Cyanokit	Hydroxocobalamin acetate	Yes	Yes	Yes	No	No	No
Dexamethasone		No	No	No	No	No	No
Dexa-Neurobion		No	No	No	No	No	No
Diclofenac		No	No	No	No	No	No
Digitoxin		No	No	No	No	No	No
Diltiazem		No	No	No	No	No	No
Dolo-Neurobion	combination	No	No	No	No	No	No
Enalapril+Nitrendipin		No	No	No	No	No	No
Epipen		No	No	No	No	No	No
Floratil	Saccharomyces boulardii	No	No	No	No	No	No
Fosinopril		No	No	No	No	No	No
Fosinopril+HCT		No	No	No	No	No	No
Ibercal		No	No	No	No	No	No

Jodthyrox	Levothyroxine sodium and potassium iodide	No	No	Yes	No	No	No
Lansoprazole		No	No	No	No	No	No
Lofepramine		No	No	No	No	No	No
Neurobion	B vitamin combination	No	No	No	No	No	No
Novothyral	Levothyroxine sodium and liothyronin sodium	No	No	Yes	No	No	No
Olmesartan		No	No	No	No	No	No
Prednisolon		No	No	No	No	No	No
Stagid	Metformin EMBONATE	No					No
Sucralfate	Sucralfate	No	No	No	No	No	
Symbion		No	No	No	No	No	No
Topotecan		No	No	No	No	No	No
Vigantol		No	No	No	No	No	No
Fertility							
Cetrotide	Cetrorelix, GNRH antagonist	Yes	Yes	Yes	Yes	No	03/2022 (KG;MD; TJ; TM; UZ)
Colposeptine	Chlorquinal-promestriene vaginal tablets	No	No	No	No	No	No
Colpotrophine	Promestriene cream	No	No	No	No	No	No
Colpotrophine	Promestriene vaginal capsules	No	No	No	No	No	No
Crinone	Progesterone	No	No	No	Yes	No	09/2014 (MA)
Fem7	Estradiol Hemihydrate patches	No	No	Yes	No	No	04/2014 (PK; NG)
Geref	Sermorelin Acetate - Growth HORMONE RELEASING FACTOR	No	No	No	No	No	No

Gonal-F	Recombinant FSH (Follitropin-alpha)	Yes	Yes	Yes	No	No	04/2024 (KG; MD; TJ; TM)
Luveris	Recombinant IH (Lutropin-alpha)	Yes	Yes	Yes	No	No	04/2028 (KG; MD; TJ; TM)
Metrodin	Highly purified urinary FSH (Urofollitropin)	Yes	No	No	No	No	No
Ovitrelle	Recombinant HCG (Choriogonadotropin- alpha)	Yes	Yes	Yes	No	No	02/2021 (KG; MD; TJ; TM)
Pergoveris	FSH + IH (Follitropin-alpha and Lutropin alpha)	No	No	Yes	No	No	06/2024 (KG; MD; TJ; TM)
Profasi	Urinary HCG (Choriogonadotropin)	No	No	No	No	No	No
Saizen	Somatropin (recombinant growth hormone)	No	Yes	Yes	No	No	No
Stilamin	Somatostatin	No	No	No	No	No	No
Ukidan	Urokinase	No	No	No	No	No	No
Neurology							
Kuvan	Sapropterin Dihydrochloride	No	Yes	No	04/2028	No	No
Rebif (Interferon-Beta 1A)	Interferon BETA	No	No	Yes	No	No	No
Thyrozol	Thiamazole Tablets	No	No	No	No	No	No

Key:

ARIPO - African Regional Intellectual Property Organization

AM - Armenia

AZ - Azerbaijan

EG - Egypt

KG - Kyrgyzstan

MA - Morocco

MG - Madagascar

MD - Republic of Moldova

NG - Nigeria

PK - Pakistan

TJ - Tajikistan

TM - Turkmenistan

UZ - Uzbekistan

VN - Vietnam

