

Charter on Access to Health in Developing Countries

Falsified Medicines

November 2020

Our Promise

Merck KGaA, Darmstadt, Germany is a leading science and technology company in healthcare, life science and performance materials. 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.

We have a long-standing commitment to ensuring pharmaceutical safety and quality. Emanuel Merck cemented the company's position in 1851 with the claim, "I shall always guarantee the purity of my preparations." Unfortunately, the growing threat of falsified medicines undermines efforts to assure access to safe and quality health care. This is especially true in developing countries where the prevalence of these medicines is highest. Falsified medicines can result in treatment failure and can even be fatal in extreme cases. As a global health community, we have a long road ahead of us in ensuring patient safety. We at Merck KGaA, Darmstadt, Germany are committed to ensuring patients receive effective drug therapy. We raise awareness, build capacity and partner with key stakeholders to sustainably combat falsified medicines.

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 into 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 KGaA, Darmstadt, Germany's medicines and products are listed on the WHO Essential Medicines List 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.

The Risks of Substandard and Falsified Medicines in Developing Countries

Every day, millions of people take medicines to treat conditions from the common cold to life-threatening diseases like cancer. For most patients, these medicines help make them healthier. Regrettably, a growing number of people receive falsified medicines – particularly in developing countries.⁶ The International Policy Network estimates that each year 700,000 deaths are caused by falsified drugs for malaria and tuberculosis– diseases most prevalent in developing countries.⁷ The WHO estimates that 72,000 to 169,000 children may be dying each year from pneumonia due to substandard and falsified antibiotics and 116,000 deaths from malaria could be caused every year by substandard and falsified antimalarials in sub-Saharan Africa.⁸ Falsified medicines may also lead to collective risks for a population, such as the emergence of drug resistance to antibiotics or antimalarials.

An estimated 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, according to research from the WHO.⁹ The WHO estimates that 50% of the medicines sold by illegal internet pharmacies are counterfeits. The full scope of this global problem is difficult to establish due to under-reporting and lack of enforcement, as the trade in

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 2018 Access to Medicines Index, Merck KGaA, Darmstadt, Germany Report Card

⁶ An estimated 1 in 10 medicinal products in LMICs is substandard or falsified. Source: WHO, General information on counterfeit medicines, January 2018 <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

⁷ IPN Press release, Fake drugs kill over 700,000 people every year, <http://archive.is/jpW8i>

⁸ WHO, "A study on the public health and socioeconomic impact of substandard and falsified medical products," November 2017 <http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/>

⁹ WHO, "1 in 10 medical products in developing countries is substandard or falsified," 25 November 2017 <http://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>

falsified medicines is highly lucrative and hard to trace. However, it is clear that access to effective, good quality health solutions is severely compromised by the fake medicine business.

Fighting Falsified Medicines

Safety, quality, efficacy and security remain at the core of our commitment. We perform thorough and regular checks on our distribution network and supply chain partners to ensure compliance with our requirements. We are a leader in the pharmaceutical industry's attack on falsified medicines: We were the first company to fully comply with the U.S. Drug Supply Chain Security Act by serializing all our products in the United States. We are committed to stopping criminals that threaten the well-being of patients. Therefore, we work closely with domestic, regional and international law enforcement agencies to identify criminal activity and prosecute those responsible.

Our Commitment to Quality, Safety and Security

All of our products comply fully with global Good Manufacturing Practices (GMPs) and Good Distribution Practices (GDPs). Additionally, we combat counterfeiters through initiatives such as:

- Tamper-evidence: we have developed and implemented tamper-proof seals for selected products
- Authentication protocols: we have introduced Merck KGaA, Darmstadt, Germany -proprietary overt & covert authentication features on our products.
- Identification systems: we have launched track-and-trace programs on selected products worldwide

Our Anti-Counterfeiting Operational Network (MACON) is a cross-functional group of internal experts with expertise in law enforcement, IP protection, product security, supply chain management, quality assurance, drug safety and security. This group monitors global markets, internet activity and legislative developments and oversees the implementation of all anti-counterfeiting measures at Merck KGaA, Darmstadt, Germany. It also ensures any incidents are promptly reported to the relevant law enforcement and regulatory bodies.

We believe that falsified medicines, put patients' lives at risk. We therefore support a variety of initiatives that go beyond our products. We work with partners to raise awareness about falsified medicines and to discourage counterfeiters. For example, we help educate patients about the dangers associated with unlicensed pharmacies and the signs of product tampering.

Working together with government authorities and health care professionals, we help assess the authenticity of medicines and prosecute those responsible for fakes to the fullest extent of the law.

Our support to 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 has 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 identity and content of 80 compounds. The GPHF-Minilab particularly focuses on verifying medicines for infectious diseases. In response to emerging needs and to requests from developing country governments, they continually invest in the development of testing methods for new compounds.

GPHF has donated or provided at-cost more than 800 GPHF-Minilabs™ to organizations in over 100 countries, located predominantly in Africa and Asia. Since 2012, they have made donations to Ministries of Health and National Regulatory Authorities in thirteen developing countries. These Minilab donations help strengthen health systems and enhance healthcare capacity. Data generated by the program has prompted WHO global drug alerts.

The success of the GPHF lies in their ability to catalyze collaboration and partnerships with governments, non-governmental organizations and faith based organizations. For example, they 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).

In addition, GPHF has recently formalized a partnership with the Ghana-based Center for Pharmaceutical Advancement and Training (CePAT). Through this collaboration we will build local and regional capacity in pharmaceutical quality assurance throughout sub-Saharan Africa. The GPHF also offers training courses to familiarize users with the fake medicines testing procedures.

We support the implementation of pharmacovigilance systems. These systems and our regular training program ensure that patients receive products that meet international quality and safety standards. We work closely with local health authorities, national pharmacovigilance centers and pharmaceutical associations to develop and implement best practices in pharmacovigilance.

Safety Starts with Pharmacovigilance

We are implementing pharmacovigilance systems for all our marketed products in compliance with Merck KGaA, Darmstadt, Germany 's Global Standards and local regulations. To date, we have pharmacovigilance hubs in developing countries across Africa, the Middle East, Asia Pacific and Latin America. In each region, we appoint a Regional Safety Manager and Local Drug Safety Officers (LDSOs), responsible for risk management and ensuring alignment with global standards and procedures. We have undertaken pharmacovigilance training of staff and third parties including in Algeria, Brazil, China, India, Indonesia, Morocco, Philippines, Thailand, Tunisia and Venezuela.

The problem of falsified medicines is too great for us to tackle alone. We partner with key stakeholders and participate in global initiatives, such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) "Fight the Fakes" campaign. "Fight the Fakes" seeks to raise awareness about the dangers of falsified medicines and to support policies reducing the proliferation of unsafe drugs. We work alongside the International Federation of Pharmaceutical Manufacturers and Associations, the NCD Alliance, the World Medical Association, The Foundation Chirac, Interpol and others who have joined the fight against falsified medicines. In addition, we are an active member of the Pharmaceutical Security Institute (PSI). We support these institutions by providing research, policy support, technical advice and financial contributions in their fight against falsified pharmaceuticals.

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

Glossary / Definitions

Abbreviation	Definition
CePAT	Center for Pharmaceutical Advancement and Training
EPN	Ecumenical Pharmaceutical Network
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GPHF	Global Pharma Health Fund
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
LDC	Least Developed Country
MACON	Merck KGaA, Darmstadt, Germany Anti-Counterfeiting Operational Network
NCD	Non-Communicable Disease
PSI	Pharmaceutical Security Institute
PQM	Promoting the Quality of Medicines Programme
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Term	Definition
Falsified medicines	Falsified medicines (termed by WHO as spurious/false-labelled/falsified/counterfeit medicines) are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source
Substandard medicines	Substandard medicines do not meet the appropriate quality requirements and may therefore be ineffective and potentially harmful to patients. A lack of good manufacturing practices, insufficient or inappropriate regulatory standards, and inconsistent regulatory enforcement contribute to the growth of substandard medicines.