

Counterfeiting of Medical Products



Producing, distributing, marketing and/or selling counterfeit medical products are serious criminal offenses, and the threat of these actions has become a significant global public health risk and reality.

Consistent with our longstanding commitment to provide high quality, safe and effective medical products to patients who need them, Merck maintains a comprehensive Product Integrity program that is focused on securing the legitimate supply chain, investigating and supporting enforcement actions against counterfeiters, and promoting advocacy and awareness measures that protect our patients from the negative impacts of counterfeit and illicit medical products. This includes best in class supply chain security and product security systems, advanced investigative and forensics capabilities, and close cooperation with government agencies, other pharmaceutical manufacturers, wholesalers, distributors, health professionals, consumer groups, and other relevant organizations to protect patients against the threat of counterfeit and illicit medical products.

Background

Counterfeiting of medical products is a threat to patient safety around the world. The term “counterfeit” as it relates to medical products has multiple definitions that vary depending upon the individual economy, politics, or intellectual property laws of each country. Therefore, Merck relies on its corporate definition of “counterfeit” to drive its patient safety focused Product Integrity strategy:

Unauthorized use of trademark, trade name, other identifying mark, imprint or device, or any likeness thereof, to adulterate, falsely purport or falsely represent a product's or material's identity, source or history.

Though estimates of the full magnitude of counterfeit medical products are not available, available data suggest that there is an increase in the number of global confirmed events of counterfeit medical products, that counterfeiting has become more sophisticated, and that counterfeit medical products is a global problem.¹

Criminal networks around the world have become increasingly sophisticated, taking advantage of millions of patients by selling counterfeit, misbranded, or unapproved drugs

via various methods, including direct-to-physician sales, brick and mortar licensed and unlicensed pharmacy sales, and through internet sites. This illicit trade can be economically motivated, in which the counterfeiter provides a supply of lower-cost counterfeit and illicit medical products. The illicit trade can also take advantage of limited access or supply of authentic, approved products by selling a supply of counterfeit and illicit medical products, often at higher prices than legitimate products.

The penetration of counterfeit medical products into legitimate supply chains is a significant threat to patient safety that is more pronounced in low and lower-middle income countries (LMICs) with less regulated supply chains and less capacity and resources to implement and enforce protective efforts. Illegitimate supply chains, such as internet sites that masquerade as legitimate pharmacies, serve as a clearinghouse of unapproved and dangerous counterfeit medical products that unsuspecting patients can buy, even without a prescription, and pose a significant patient safety threat in both LMIC and high-income countries. The Alliance for Safe Online Pharmacies reports that, at any given time, 95% of the roughly 35,000 online pharmacies worldwide operate illegally, in violation of state and/or federal law and pharmacy practice standards.²

Merck's commitment

Consistent with our longstanding commitment to provide high quality, safe and effective medicines and vaccines to patients who need them, Merck maintains a comprehensive Product Integrity program that is focused on securing the legitimate supply chain, investigating and supporting enforcement actions against bad actors, and promoting advocacy and awareness measures that protect our patients from the negative impacts of counterfeit and illicit medical products.

We carefully manage our supply chain through strict policies and procedures designed to keep the legitimate drug distribution system safe and secure, working closely with customers and distributors to reduce the potential for counterfeit products to enter the supply chain. Merck products are also protected by advanced security features which, coupled with our advanced forensic detection capabilities, allows us to accurately authenticate all finished products in our portfolio. Furthermore, Merck reviews every reported incident of suspected counterfeiting, diversion, or tampering associated with our products, responding in alignment with local regulatory requirements and in support of our global patient safety mission.

As counterfeiters have become more sophisticated, counterfeit products are commonly visually indistinguishable from authentic products. Without laboratory testing, it can be difficult to tell the authentic from the counterfeit medical products. To this end, we maintain a global Forensic Services program that significantly enhances our capacity and capability for the robust forensic analysis of suspect counterfeit medical products. The

global Forensics Service capacity is supported by dedicated laboratories in the US, Europe, and Asia. These labs follow international standards and best practices for forensic testing of medical products, including the World Health Organization Guidance On Testing Of Suspect Falsified Medicines³ and ISO 17025 standards.⁴

Merck is committed to cooperating with relevant government agencies, other pharmaceutical manufacturers, wholesalers, distributors, health professionals, consumer groups, and key related organizations in fighting the problem of counterfeit pharmaceutical products. We collaborate closely with international law enforcement agencies to prevent counterfeit medical products from reaching patients, sharing information with our counterparts at other pharmaceutical companies and government agencies in support of global efforts to identify, prioritize, and aggressively pursue large-scale criminal enterprises responsible for the manufacture and distribution of counterfeit medical products.

Collaboration and information-sharing to raise public and stakeholder awareness of the issues and risks are a crucial focus of our Product Integrity efforts. Through active partnerships with other pharmaceutical companies and associations focused on security, patient safety and public health, Merck provides effective advocacy on high-priority anti-counterfeiting policy initiatives. We also take a multi-pronged approach to educating the public about the risks of counterfeit medicines and how to protect against them, recognizing that these risks cannot entirely be eliminated. Lastly, we inform and advocate for policies that protect against the threat of counterfeit medical products and oppose policies that threaten patient safety.

¹ "2022 Global Situation Report", Pharmaceutical Security Institute, June 2023

² <https://buysaferx.pharmacy/wp-content/uploads/2021/03/ABOUT-ASOP-MARCH-2021-FINAL.pdf>

³ https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs1010-annex5-testing-suspect-samples.pdf?sfvrsn=df47cb5_2&download=true

⁴ <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>