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# Counterfeiting of Medical Products

Producing, distributing, marketing and/or selling counterfeit medical products are serious criminal offenses, and the threat of these actions is 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, MSD 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 to protect our patients, consumers, and our company reputation 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, regulators, other pharmaceutical manufacturers, wholesalers, distributors, healthcare professionals, consumer and patient groups, and other relevant organizations.

## Our Commitment

Counterfeiting of medical products is a global threat to patient and public safety, affecting both developed and developing countries. The definition of the term "counterfeit," as it relates to medical products, varies across jurisdictions depending on a country's economy, politics, or intellectual property laws. Therefore, MSD 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.*

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 risk of counterfeit products entering the supply chain. MSD products are also protected by advanced security features and advanced forensic detection capabilities, enabling accurate authentication of all finished products in our portfolio. We also review every reported incident of suspected counterfeiting, diversion, or tampering

associated with our products, responding in line with local regulations and supporting 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 distinguish authentic medical products from counterfeit medical products. To this end, we maintain a global Forensic Services program that strengthens our capacity and capability for robust forensic analysis of suspected 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 Medicines[i] and ISO 17025 standards[ii].

MSD is committed to cooperating, as may be necessary, with relevant government agencies, regulators, other pharmaceutical manufacturers, wholesalers, distributors, healthcare 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, MSD 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 be eliminated entirely. Lastly, we inform and advocate for policies that protect against the threat of counterfeit medical products and oppose policies that threaten patient safety.

## Background / Context

According to the World Health Organization (WHO)[iii], an estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified. However, no country remains untouched, and the true scale is likely higher due to underreporting. With the expansion of internet connectivity and e-commerce, those engaged in the manufacture and distribution of counterfeit products have gained access to a global marketplace.

Criminal networks around the world have become increasingly sophisticated, exploiting patients by distributing counterfeit, misbranded, or unapproved medicines through multiple channels, including direct-to-physician sales, licensed and unlicensed pharmacies, and online platforms such as websites, social media, and marketplaces. These activities can also be economically motivated, with counterfeiters supplying products at higher prices during shortages, or as lower-cost alternatives to legitimate products.

Illegitimate supply chains, such as internet sites that masquerade as legitimate pharmacies, serve as a distribution channel for dangerous and unapproved counterfeit products that unsuspecting patients may purchase, even without a prescription, posing a significant global health risk.

The infiltration of counterfeit medical products into legitimate supply chains further heightens risks to patient safety, with countries characterized by less regulated supply chains, limited resources to implement and enforce protective measures, corruption, and low penalties facing increased vulnerability.

[i] 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
[ii] https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[iii] https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products