

PUBLIC POLICY STATEMENT

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.

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. Identification of a widely accepted, global definition of this term has thus far been a challenge. Merck therefore relies on its corporate definition of “counterfeit” to drive its patient safety focused Anti-Counterfeiting strategy. Our corporate definition of counterfeiting at Merck is as follows:

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 recognized as a global public health issue, actual estimates of the full magnitude of counterfeit medical products are not available. However, existing data suggest that the problem is more pronounced in developing countries with significant incidents also occurring in developed parts of the world.

Unfortunately, criminal networks around the world have become increasingly sophisticated, taking advantage of millions of patients by selling low-cost counterfeit, misbranded, unapproved drugs via various methods, including direct-to-physician sales, brick and mortar licensed and unlicensed pharmacy sales, and through internet sites.

In the past few years, we have seen an increase of counterfeit pharmaceuticals in highly regulated supply chains. For example, counterfeit injectable cancer drugs were introduced to the standard supply chain through direct sales to physicians in 2012 and 2013, and these counterfeit drugs were administered to patients. In 2014, there were instances of counterfeit versions of injectables identified in unlicensed pharmacies in the United States. Both examples share a common threat profile, as they resulted from the previous introduction of medication intended for distribution outside of the United States which in itself is a significant patient safety risk, as such misbranded medication often only contains foreign language instructions and may not be properly stored.

Internet sites that masquerade as legitimate pharmacies and serve as a clearinghouse of unapproved and dangerous counterfeit drugs that unsuspecting patients can buy, even without a prescription also

pose a significant patient safety threat. Since it is relatively easy to create internet presence for counterfeit drugs, there are currently thousands of these illegitimate sites.

In the United States, the National Association of Boards of Pharmacy has reviewed more than 10,000 illegitimate internet sites and has disclosed alarming results: only three percent of the sites appear to be in compliance with pharmacy laws and practice standards.

For these health and safety reasons, Merck continues to oppose reimportation of prescription drugs into the United States, as has been proposed by the United States Congress in recent years.

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 encompasses both its Anti-Counterfeiting and Supply Chain Security strategies. We carefully manage our supply chain through strict policies and procedures designed to keep the legitimate drug distribution system safe and secure.

In the United States, for example, Merck has implemented terms and conditions of sale for our medicines and vaccines to reduce the potential for counterfeit products to enter the supply chain by requiring that customers purchase Merck products directly from Merck or a Merck authorized distributor.

Other practices used by Merck to deter counterfeiting include publishing the names of authorized distributors on Merck's website and auditing of distributors. Product security features deployed on Merck products are also a key measure taken to protect our patients. Our pharmaceutical products are protected with best-in-class product security features, with features and level of security determined via a global, risk-based assessment methodology. Coupled with our advanced forensic detection capabilities, Merck is able to accurately authenticate all finished products in its portfolio.

Further to this commitment, 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. Merck also conducts proactive threat assessments and investigations aimed at further identifying and mitigating patient safety threats associated with illicit medicines.

As counterfeiters have become more sophisticated, counterfeit products have become so similar in appearance to authentic products that, without laboratory testing, it is often difficult to tell the authentic from the counterfeit medicines. To this end, we have launched a global Forensic Services program that significantly enhances our capacity and capability for the robust forensic analysis of suspect counterfeit, diverted and illicit medicines. The Forensic Services program focuses on both the identification and characterization of illicit medicines, and will further support our efforts in the detection, characterization, and enforcement of criminal enterprises engaged in the manufacture and distribution of illicit medicines. The global Forensics Services capacity is supported by dedicated laboratories in the US, Europe, and Asia. These labs follow international standards and best practices

for forensic testing, including the WHO Guidance On Testing Of Suspect Falsified Medicines and ISO 17025.

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 and in educating the public about the risks of counterfeit products and how to protect against them. This effort includes a multi-pronged approach to communicate the threat that counterfeit medicines pose and to mitigate this threat as effectively as possible, recognizing that it cannot be entirely eliminated.

Collaboration and information-sharing in order to raise public and stakeholder awareness of the issue and risks is 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. Our Global Security staff provides law enforcement and customs training worldwide. Additionally, Merck actively collaborates with international law enforcement agencies that prioritize the investigation, prosecution, and disruption of counterfeit medicines and associated criminal enterprises.

Merck Product Integrity operations are driven by intelligence-led decisions to identify, prioritize, and aggressively pursue large-scale criminal enterprises responsible for introducing counterfeit and other illicit medications into the supply chain. We then share that information with our counterparts at other pharmaceutical companies and government agencies. Along with our industry counterparts, Merck works with governments, law enforcement agencies, industry groups and other stakeholders to support robust policies and programs to prevent counterfeit medicines and vaccines from reaching patients. In addition, Merck has strong corporate procedures in place to promptly investigate suspected instances and manage confirmed cases of counterfeit Merck products any place in the world.