

Position on Counterfeit Medicines

Background

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging.¹

Counterfeiting of healthcare products is a serious and growing concern because it causes fake and potentially dangerous products to enter the marketplace. Moreover, it can undermine confidence in product safety and effectiveness while putting patients' health and lives at risk.

There is abundant evidence of essential medicines as well as life-saving medicines being counterfeited worldwide. In addition, distribution of medicines through questionable entities posing as legitimate online pharmacies continues to be a serious problem. A review of internet drug outlets revealed that more than 95 percent of these so-called pharmacies do not follow basic patient safety and pharmacy practice standards.²

Our Position

Astellas takes a firm position against counterfeit medicines and other illicit activities that perpetuate the illegal medicines trade. However, Astellas recognizes that the company cannot tackle this issue alone and that it has no official power to intervene directly. Furthermore, Astellas will not assume liability for damage claims related to counterfeit products.

Our goal in this regard is to help ensure that patients receive only genuine, legitimately distributed Astellas products. Given the potential for negative impact to patients' health caused by counterfeit medicines and the risk that Astellas' products may be the target of counterfeiting, Astellas operates an Anti-Counterfeit Committee. This committee governs internal product security activities targeting counterfeiting, diversion and theft, and a team comprising experts from relevant divisions takes several countermeasures as follows:

- Astellas fully cooperates with health & regulatory authorities, law enforcement entities and other pharmaceutical companies on a local, regional and global level with regard to inquiries, enforcement actions and other activities related to counterfeit medicines. Astellas maintains active membership in the Pharmaceutical Security Institute (PSI), a trade organization that provides a platform for member companies to share intelligence on pharmaceutical crimes affecting their products, collaborates on investigations of mutual interest and interacts regularly with key pharmaceutical-focused law enforcement contacts globally.



- Astellas monitors both virtual (internet) and physical markets to ensure a current and comprehensive understanding of activities involving our products occurring outside of the legitimate supply chain.
- Astellas develops technical security measures (authentication and anti-counterfeit technologies) and the processes to manage them for our most at-risk products.

References

1. Previous World Health Organization (WHO) definition of counterfeit medicines. Term has changed to Substandard, Spurious, Falsely Labeled, Falsified and Counterfeit (SSFFC) Medical Products, which is not widely used in industry as of yet.
2. National Association of Boards of Pharmacy (NABP) Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators, July 2012.