Position on Counterfeit/Falsified Medicines

Background

A counterfeit medicine[1] is a medicine that has been 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. Similarly, falsified medicines[1] are medical products that deliberately/fraudulently misrepresent their identity, composition or source. As the distinctions between these two terms are subtle, for the purpose of this document both terms will be used in the same context.

Counterfeiting/falsification of healthcare products is a serious and growing concern because it causes ineffective 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, including life-saving medicines, being counterfeited/falsified globally. In addition, distribution of medicines through questionable entities posing as legitimate online pharmacies continues to be a serious problem, while spread of the corona virus disease (COVID-19) has further increased the demand for online pharmacies.
A review of internet drug outlets in the US revealed that 94.8 percent of these so-called pharmacies do not follow basic patient safety and pharmacy practice standards.[2] Instances of illicit medicine sales through social media by unauthorized/unlicensed parties are also increasing very rapidly.

With the increase in internet connectivity, questionable entities trafficking in counterfeit/falsified medicines have gained access to the global marketplace. Although this issue impacts all countries, countries where there are weak or non-existent regulatory systems bear the greatest risk of counterfeit/falsified medicines. It was observed that 1 in 10 medical products in the supply chain of low-and middle-income countries was counterfeit/falsified according to the research by WHO.[3]

Our Position

Astellas takes a firm position against counterfeit/falsified 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.

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/falsified medicines and the risk that Astellas' products may be the target of counterfeiting/falsification, Astellas operates an Anti-Counterfeit Committee. This committee

governs internal product security activities targeting counterfeiting/falsification, diversion and theft, and a multi-functional team of subject matter experts who undertakes countermeasures as follows:

- Astellas fully cooperates with health & regulatory authorities, law enforcement entities and other pharmaceutical companies on a global level with regard to investigations, enforcement actions and other activities related to counterfeit/falsified 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. As the terms “counterfeit” and “falsified” were both used to form the basis of legislation in numerous countries and are referenced in national policies of drug regulators, health authorities and private sector entities across the globe - abandoning one term in favor of the other is simply not feasible for all stakeholders. Therefore, for the purpose of this document both terms will be used in the same context.[2]
   In 1992, the World Health Organization (WHO) defined counterfeit medicines as “medicines that have been 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.” The term “counterfeit” and its associated definition was widely accepted by both governments and industry for many years.

   In 2006, member states began to debate over use of the terms “counterfeit” vs. “falsified” as there were implications that the former was associated more with intellectual property and trademark protection while the latter was primarily concerned with public health.

   Prompted by the need for clarity and simplification of terminology as well as an end to the decade-long debate, WHO officially adopted “Falsified” in 2017, providing the following definition: “Falsified medicines are medical products that deliberately/fraudulently misrepresent their identity, composition or source.” Of particular note was that the newly published definition for “falsified” was clearly a derivative of the original definition for “counterfeit”.

2. National Association of Boards of Pharmacy (NABP) Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators, June 2018.
3. The WHO Member State Mechanism on Substandard and Falsified Medical Products, April 2019.