What are falsified medicines?

DEFINING FALSIFIED MEDICINES TO DRIVE ACTION

A clear, widely accepted definition of "falsified medicines" is crucial for efficient and coordinated responses to this threat. However, the current lack of a globally approved definition impedes strong, coordinated national and international measures[1], as the meaning of "falsified" varies between countries and international organizations.

To fill this gap, a working definition of "falsified medical products" is proposed for adoption at the World Health Assembly 2017: "Medical products that deliberately/fraudulently misrepresent their identity, composition or source." Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product. Any consideration related to intellectual property rights (IP) does not fall within this definition.

IFPMA welcomes this approach to use the term "falsified" for the purposes of the work within the Member State mechanism. Reaching this consensus is an important step forward. This proposal is in line with IFPMA's position: as stated in our Ten Principles, patents have nothing to do with falsified medicines.

Falsified medicines are not an IP issue but a public health threat. Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the production of falsified versions of genuine approved medicines. In order to detect a product with a false representation of its identity, some intellectual property tools such as trademark could be used. However, they will not be a determining factor to declare a medicine falsified. Other criteria such as the intention to deceive are key.

As the WHO does not intend to "propose, or affect in any way, national and/or regional legislation either in existence or that may be drafted in the future", the IFPMA and its members will continue to adapt their terminology to their interlocutor.

IFPMA and its members have demonstrated a robust, enduring commitment to medicines' safety – based on ten principles published in 2010. Together, these principles state the need for common approaches that engage all stakeholders, across the supply chain, to pursue a long-term, sustainable strategy to fight this global threat to public health.

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THE DIFFERENCE BETWEEN SUBSTANDARD AND FALSIFIED MEDICINES

It's important to understand the difference between substandard and falsified medicines. The WHO Expert Committee on Specifications for Pharmaceutical Preparations defines substandard medicines as "pharmaceutical products that do not meet their quality standards and specifications". On the other hand, as defined by the WHO Member States Mechanism, the term falsified can be used "when the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source (...)."

The intention to deceive is the key distinction between substandard and falsified medicines.

A substandard medicine is approved and legally manufactured, but does not meet all quality criteria. Even though it may pose a significant health risk, it should not be regarded as falsified. However, falsified medicines are produced with the deliberate intention to mislead patients. And these falsified medicines are also, by definition, likely to be substandard.