



**International Pharmaceutical Federation
Fédération internationale pharmaceutique**

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FIP STATEMENT OF POLICY ON COUNTERFEIT MEDICINES

Introduction

The FIP is seriously concerned about the continuing, even increasing, risk to public health represented by counterfeiting of medicines, particularly in countries where legislation governing the manufacture and distribution of medicines, or the enforcement of legislation, is ineffective. The massive circulation of poor quality, harmful and counterfeit active ingredients and finished products in international commerce can seriously reduce the quality of patient care.

All counterfeiting is to be deplored. For some goods such as designer clothing, the purchaser is usually aware that the product is not genuine. This is not the case for medicines when all purchasers are vulnerable and are likely to assume that the product is genuine and do not have the ability to decide otherwise. The patient is then at risk.

New global trade arrangements, free trade arrangements and deregulation measures and unregulated internet sales of life-style medicines are dramatically changing the pharmaceutical market world-wide resulting in a proliferation of medicines. This has established an environment that favours an increase in counterfeiting activities.

Counterfeit medicines are difficult to detect. They can escape all controls especially as a result of the increasing globalisation and cross-border trading as more and more countries manufacture and export medicines, active ingredients and excipients. In addition, readily accessible modern technology makes it easy to produce copies of packaging that are virtually identical with the genuine articles. The same applies in many cases to the medicinal products themselves.

The precise extent of the occurrence and distribution of counterfeit medicines is unknown, even though estimates derived from country studies are widely cited. Since 1982, WHO has been collecting data on counterfeit medicines. The majority of cases involved tablet and capsule dosage forms. However, there is a shortage of validated information and thus the acquisition of accurate data is a priority.

Counterfeiting is attractive because relatively small quantities of counterfeit medicines can provide huge profits to the counterfeiter; and trading in them is seen to carry less risk than trafficking in the field of addictive drugs. Counterfeiting is undertaken for both long established and recently marketed medicines, both branded and generic, and both domestically manufactured and imported.

In some countries, limited access to affordable medicines creates an environment that is conducive to the distribution of counterfeit products, which perpetuates inequity in the quality of health care among the world's population.

The key to the reduction in the availability of counterfeit medicines is the maintenance of the integrity of the quality controls at all stages in the manufacturing and distribution channel for medicines. Counterfeiting completely undermines the long established controls of quality, safety and efficacy of medicines that are designed to protect the public.

A separate joint FIP/IFPMA statement entitled "Ensuring the quality and safety of medicinal products to protect the patient" was adopted at the 1998 FIP Congress. That statement emphasises the need for effective regulatory safeguards to ensure that the patient is protected from the hazards of poor quality, substandard and counterfeit medicines.

This statement is complementary and follows several resolutions of the World Health Assembly in the field of counterfeiting and the access to safe and affordable essential medicines (WHA 39.27, WHA 41.16, WHA 47.13, WHA 47.17, WHA 54.11 and WHA 54.13).

Definition

In this statement, counterfeiting in relation to medicinal products means the deliberate and fraudulent mislabelling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product. Counterfeiting can apply to both branded and generic products and to traditional remedies. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with false or misleading packing; they may also contain different, or different quantities of, impurities both harmless and toxic.

It is therefore the policy of FIP

- to express its firm support for, and co-operation in, initiatives by international bodies including United Nations' organisations like WHO and UNICEF, as well as the World Trade Organisation and Interpol, professional non-governmental organisations like the WMA and the IFPMA and national regulatory and pharmacopoeial authorities, to promote co-ordinated activities to detect and eliminate the manufacturing of and trading in counterfeit medicines,
- to support the Global Alliance for the Quality of Pharmaceuticals formed by WHO and to collaborate with the other partners to make its work more effective,
- to raise understanding of the urgent need to increase awareness of the importance of quality, safety and efficacy of medicines through advocacy and promotion; and to promote the policy

that, when necessary, countries receive assistance in improving access to good quality medicines, with special focus on those used in life-threatening conditions like HIV, TB and malaria, which will diminish the market for the manufacture, distribution and sale of poor quality and counterfeit medicines,

- to express its willingness to assist developing countries, on request, to identify a source of expert advice on the implementation of an effective system for the detection and elimination of counterfeit medicines,
- to urge national governments
 - to recognise the serious risk to public health represented by counterfeit medicines and to ensure that the public are made aware of these risks through information in the media,
 - to enact comprehensive medicines legislation, including provisions prohibiting the manufacture, import and sale of counterfeit medicines, and to enforce this legislation rigorously,
 - to recommend surveillance mechanisms to control and check the menace of counterfeit medicines and evaluate the extent of the problem.
 - to recognise and maintain the safeguards, designed to protect public health, that are provided by the established and normally licensed supply channel for medicinal products (from manufacturer to pharmaceutical wholesaler to pharmacy to patient) and minimise risk and maintain public confidence, by promoting the use of this supply channel,
 - to require documentation at all points in the distribution chain of all parties that have held custody of medicinal products from the original source to the pharmacy, and to impose severe penalties for forgery of such documentation.
 - to require labelling of the actual origin of medicinal products,
 - to recognise the serious risk of increased infiltration of counterfeit medicines through distance-selling, especially cross-border,
 - to put in place, with adequate funding, within the overall national quality assurance system for medicines, effective measures to detect and prevent the circulation of counterfeit medicines including the development of appropriate analytical methods and training programmes for pharmacists on detection of counterfeits,
 - to ensure that medicines made for export are regulated and controlled to the same standards as those produced for domestic use,
 - to maintain reasonable margins for pharmacists and wholesalers in order to ensure professional and reliable practice,
 - to recognise that corruption and conflicts of interest may adversely affect the integrity of personnel undertaking regulatory and law enforcement functions in relation to medicines, and
 - to adopt and implement WHO guidelines for the development of measures to combat counterfeit medicines (WHO/EDM QSM/99.1).

- to urge charitable organisations to ensure that effective quality assurance checks are carried out before any medicinal product is purchased or used for humanitarian purposes.
- to urge national organisations representing pharmacists
- to convince national governments to use maximum efforts to enforce all appropriate measures to prevent or minimise the manufacturing and distribution of counterfeit medicines,
 - to develop, implement and monitor effectively Good Pharmacy Practice, in accordance with WHO/FIP guidelines or national guidelines if available,
 - to report to national regulatory authorities any instances where counterfeit medicines have been offered or supplied in their country and request that the information be widely disseminated, and
 - to include in their Code of Ethics and Standards of Professional Practice for pharmacists, a requirement for co-operation with governmental and other regulatory authorities as well as with pharmaceutical manufacturers in the detection of the circulation of counterfeit medicines and in measures designed to prevent such circulation.
- to urge wholesalers of medicines and their national and international trade organisations to institute purchasing policies and procedures that will prevent counterfeit medicines from entering the normal supply system. And, further, to urge wholesalers of medicines to provide pharmacists with assurances of the integrity of the system so that they in turn can assure their patients of the integrity of the medicinal product.
- to urge pharmacists in all fields of practice
- to implement WHO/FIP, or national, Good Pharmacy Practice guidelines
- to purchase medicinal products only from reputable sources, paying regard to the storage conditions before purchase and subsequent chain of supply of the medicines concerned,
 - to be alert to differences in quality of packaging, labelling or leaflets and in physical appearance of medicinal products,
 - to report to the state regulatory authority for medicines and the appropriate pharmaceutical organisation any instance where it is suspected, because of absence of expected therapeutic effect or for any other reason, that counterfeit medicines have been offered or supplied, and
 - to isolate and withhold from supply any suspected counterfeit medicinal product and co-operate in investigations to detect the source.
- to collect information concerning the implementation of this statement.

This FIP Statement of Policy on Counterfeit Medicines replaces that adopted in 1999 in Barcelona.