The safety of medicines between European harmonisation and international anti-falsification measures

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Substandard, spurious, falsely labelled, falsified and counterfeit drugs (SSFFC)

SSFFC drugs are medical products that:

- do not contain any specific active substances, irrespective of the indication on the label
- contain substances other than those indicated on the label
- contain an exact quantity of the active substance, but its source differs from the declared one
- contain the active substances in an amount different from that specified; they may also contain impurities or different amounts of the same substance
- are genuine drugs but the packaging label is forged
There is no universal definition of SSFFC drugs

- **Substandard**: drugs that do not meet quality and safety standards, with the exclusion of genuine medicines affected by manufacturing errors, including errors caused by negligence, willful misconduct or recklessness.

- **Spurious**: terminology used in South Asia to indicate false or counterfeit labeling.

- **Falsely labeled**: includes genuine products with falsified packaging.

- **Falsified**: European terminology which involves fraudulent activity.

- **Counterfeited or pirated**: underlines the deliberate intention to imitate the genuine product in violation of intellectual property rights.
SSFFC medicines are not equivalent to their genuine counterparts in terms of quality, safety and efficacy.

They pose a threat to global public health because the phenomenon has an international dimension.

They are distributed throughout the world and online sale allows to obtain falsified medicines without control and outside the legal distribution chain.
Extent of the problem

- Information on the real extent of the phenomenon is inadequate
- The problem affects both developed and developing countries, being more evident in countries where import, manufacture, distribution, administration and sale of drugs are less regulated
- The problem concerns both generic and brand drugs
- Falsification techniques have become more and more sophisticated
According to the WHO, 7–10% of medicines circulating around the world are counterfeit, with rates that vary between 25 and 50% in developing countries.

Falsification and counterfeiting are more prevalent in regions where regulation and control are lower:

- Most industrialized countries with efficient market surveillance and regulatory systems (eg, the United States, most EU countries, Australia, Canada, Japan, New Zealand) report a low percentage of counterfeit drugs, for less than 1% of the value of the pharmaceutical market.

- In many African countries, and partly in Asia and Latin America, there are areas where more than 30% of the drugs for sale can be counterfeited, while in other developing markets the percentage comes to 10%; In general it is a percentage between 10 and 30%.

- In many former Soviet republics the percentage is of more than 20% of the market value.
Medicines bought on the Internet from websites that hide their physical location are falsified in more than 50% of cases.
Examples of falsification/counterfeiting

- Imitation of original products
- Concealment of manufacturing site
- Altering the expiration date
- Falsification of documents
- Deception concerning licence status
- Imitation of security features
The most common causes and factors

- absence of *ad hoc* legislation
- too mild penalties
- national regulatory authorities that are lacking or inefficient
- lack of, or incorrect application of, drug legislation
- low / irregular drug administration
- absence of controls on drugs for export
- marketing through various intermediaries and free trade areas
- corruption and conflicts of interest
Public health: regular use of substandard or falsified medicines can lead to ineffective treatment or drug resistance. In some cases, it can be fatal.

Economy: the margin of profit on the sale of falsified medicines could reach 20%, so the illicit drug industry is 25 times more profitable than drug sales: **200 billion USD**

Organized crime: this type of organized crime presents less risk and less negative social value as compared to other illicit trafficking

Intellectual property rights: counterfeiting damages pharmaceutical companies and patent holders
Other relevant aspects

- Violation of fundamental rights: life, health, property, security

- Judicial impact: in terms of increased civil, criminal and administrative litigation

- Social impact: poverty, ignorance, fear of stigmatization

- Ethics: in the practice of the medical profession, in the management of healthcare establishments, for enterprises
Specific measures of contrast

- Adoption of effective laws

- Establishment of regulatory authorities to ensure that manufacture, importation, distribution, administration and sale are licensed or carried out in licensed premises and under the control of authorized persons, and also to ensure monitoring and successive controls
A shared responsibility between state authorities, pharmaceutical manufacturers, distributors, medical personnel, consumers and the general public

Exchange of information with other countries and with WHO, particularly where the consumption of adulterated medicines can have serious health consequences, a situation in which information must circulate rapidly and widely
In 2006, WHO launched a series of state support measures and established the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

IMPACT includes representatives from WHO, WIPO, WTO, OECD, World Bank, Interpol and the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), consumer associations and patient representatives

IMPACT's objective is to operate at several levels: regulatory legislation and regimes, compliance with the law, technology and communication
The Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Moscow, 2011) is the first international treaty on counterfeiting of medicines and other pharmaceutical products promoted by the Council of Europe to criminalize the manufacture, marketing and administration of counterfeit medicines and the falsification of relevant documents

Since counterfeiting of medical products and related offenses constitute a global threat, the treaty is open for signature by CoE member states and by third countries: at present 27 countries have signed the Convention (including 4 that are not members: Burkina Faso, Morocco, Guinea and Israel), ten of which have also ratified it. The Convention entered into force on 1 January 2016.
Offenses that State Parties have the obligation to criminalise

- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents;
- the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements.
MEDICRIME Convention

- It represents an effective tool for establishing common minimum standards in the field of criminal law and procedure.

- Counterfeiting of drugs is conceived as a violation of the right to life.

- It provides prevention, punishment of criminals and protection of victims and witnesses.

- It establishes a useful framework for the development of national and international cooperation between the police and the health and customs authorities.
International judicial cooperation
(in addition to the procedures established by MEDICRIME)

- At the European regional level: European arrest warrant: membership of a criminal organization, violation of industrial property rights and product falsification (Article 2 of Framework Decision 2002/584/JHA)

- At bilateral and multilateral levels: extradition procedures → condition of double criminality

- At the international level: United Nations Convention against Transnational Organized Crime → Proposal by the UN Committee to include counterfeit medicines among transnational crimes punishable under the Palermo Convention
DIRECTIVE 2011/62/EU
of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

OJ L 174, 1.7.2011, p. 74-87

(adopted under articles 114 and 168, paragraph 4, al. c, TFEU)
The main new features of Directive 2011/62 are three:

- Prescription drugs must have on the outer packaging an identification number and an anti-burglary system to allow the pharmacist to verify the authenticity of the product and the integrity of the container prior to sale. This helps prevent falsified medicines from reaching patients.
The active ingredients of medicinal products must be manufactured in accordance with the appropriate quality standards (‘good manufacturing practice for active substances’) regardless of whether they are manufactured or imported into the EU. In the case of imports, the country of origin must certify that the active ingredient has been manufactured according to standards equivalent to those of the Union. These provisions ensure that medicines sold in the EU use only safe and high-quality ingredients.
Falsified Medicines Directive

- Pharmacies authorized to sell medicines online must be identified with the same logo throughout the EU. By clicking on the logo it is possible to check the legality of the pharmacy. This helps EU citizens to make an informed choice when buying medicines on the Internet.
European logo that "certifies" the sites of pharmacies and other exercises authorized by the Member States to sell medicines online, approved by Regulation 699/2014 of 24 June 2014, pursuant to Directive 2011/62.

In order to avoid falsification, the Commission has also provided an encryption system which should prevent 'theft' and replication of the image by pirates, but it is up to the Member States to decide to use electronic protection.

Logo mandatory from 1 July 2015.
Unique identifier for packaging


- The unique identifier (i.e., a two-dimensional barcode Data Matrix) is used to verify the authenticity of the drugs and identify the individual boxes.

- The anti-tampering device verifies the integrity of the packaging and indicates whether it has been opened or tampered with since leaving the manufacturer, thus ensuring that the contents of the box are genuine.

- It shall apply from 9 February 2019 and holders of marketing authorization in all Member States are required to adopt the necessary changes for its implementation.