Falsified medicines

Introduction

Since 2011, the European Parliament has declared an alarming increase in medicinal products containing poor quality or falsified ingredients, no ingredients or in the wrong dose – either too high or too low – that pose a major threat to public health and patient safety. According to the EMA definition, a falsified medicine is:

> *'A fake medicine that passes itself off as a real, authorised medicine.'* (1)

The introduction of a definition for falsified medicine was necessary to differentiate it from other illegal medicinal products known as **counterfeit medicines** (those that do not comply with intellectual-property rights or that infringe trademark law), and to facilitate the identification of strategies to address each issue.

Falsified medicines have not undergone the normal quality, safety and efficacy assessments by regulatory authorities that are required for EU authorisation procedures. Because of this, the consequences of taking falsified medicines can be serious, and can include:

- Untreated diseases, or failure of medical treatments.
- Unexpected and dangerous interactions with the medicines that the patient is already taking regularly.
- Severe side effects.

Types of falsified medicines

Falsified medicines are not limited to a single type of medicines, targeted population or region. For example:

- In developing countries, there is evidence of falsified **‘vital’** (potentially life-saving or crucial to providing basic health services) and **‘first necessity’** medicines (those that satisfy the priority health care needs of the population) such as antibiotics, tuberculosis, malarial and anti-retroviral medicines used against HIV. Other products like analgesics, anti-inflammatory medicines, and blood products may also be falsified.
- In wealthy countries in Europe, as well as in the United States, the presence of falsified medicines has increased considerably, especially online.

Products that are not reimbursed by health systems are a prime targets for falsification, such as medicinal products against sexual dysfunction or those that promote weight loss.

European regulation on falsified medicines

Several global organisations and associations are involved in tackling the threat caused by falsified medicines. Some of the key players are the World Health Organisation (WHO), Interpol, the World Customs organisation and the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA/WGEO). They all coordinate operations and share information to stop the supply of falsified medicines.

Directive 2011/62/EU (3) on falsified medicines for human use s provides a framework for the distribution of medicines, so that they are offered for sale only through licensed pharmacies and approved retailers, including approved internet providers.

This directive introduced safety features aiming to prevent falsified medicines entering the legal medicine supply chain (from manufacturers to distributors, pharmacies and hospitals) and reaching patients with four main types of measures across

Europe:

1. **Safety features of medicines**

Two safety features are to be placed on the packaging of most medicines: a 2-dimension barcode or **unique identifier** and an **anti-tampering device**. This regulation was published in February 2016 by the European Commission (4) for the Marketing Authorisation (MA) holder to place these features on the packaging of most prescription medicines and certain non-prescription medicines no later than February 2019. These safety features aim to guarantee the authenticity of medicines for the benefit of patients and businesses, and strengthen the security of the medicine supply chain.

2. **Supply chain and good distribution practice**

The Directive introduces new responsibilities for wholesalers that includes regulations in quality system, personnel training and hygiene, premises and equipment, documentation, and others.

3. **Substances manufactured outside the EU**

From July 2013, all active substances manufactured outside the EU have to be accompanied by a written confirmation from the regulatory authority of the exporting country when imported into the EU, many countries have committed to doing this. These statements are issued per manufacturing site and per active substance and ensure that Good Manufacturing Practice (GMP) is observed and is equivalent to that of the EU.

4. **Internet sales**

The Directive has introduced an **obligatory logo** that will appear on the websites of legally operating online pharmacies and approved retailers in the EU (5).

Risks of falsified medicines

The WHO estimates that over half the medicines sold via the Internet are falsified. In Europe, 97% of online pharmacies are illegal. Online purchasing of medicinal products has increased over the years, since it may seem attractive to the consumer for different reasons:

- Time saved in the purchase.
- Cheaper medicine.
- Avoiding previous medical consultation to obtain prescription medicine.

Risks of falsified medicines to patients are multiple:

- Falsified medicines could include fake or wrong ingredients, inactive pharmaceutical ingredients. Falsified medicines can even contain dangerous substances. They may contain ingredients in the wrong amount, and the active components might be too weak or too strong, or might have expired.
- Falsified medicines fail to treat the patient’s illness and can worsen the condition, or cause disability or even death. They can also increase resistance to legitimate treatments (antibiotics or anti-parasites) and pose an increased risk of adverse drug reactions/side effects.
- Falsified medicines might not be safe when used with other medicinal products.
- Falsified medicines might not be labelled correctly, and might have been stored or shipped at incorrect temperatures or humidity conditions, causing the deterioration of the components.

It is important to enable patients to recognise trustworthy sources and to be aware of the risk of illegal Internet sales. They should be aware of the risks from falsified medicines through information about the common logo, in websites and

campaigns. Patient organisations can raise awareness by informing patients and promoting safety of their medicine to support public awareness campaigns.

A strong patient-health professional relationship should be established in order to support the doctors and other medical personnel in raising awareness about the problems and risks associated with falsified medicines.

Buying medicine online safely

In some EU countries, it is possible to buy medicines online. Purchasing medicines over the Internet can be easy and convenient. However, it has to be safe.

Patients should buy medicines only from online vendors that have registered with the national competent authorities in the EU member states.



EU online pharmacy logo (UK version) that should appear on the websites of all online medicine vendors in the EU.

Figure 1: Obligatory logo (UK version) that should appear in the websites of all online medicine vendors in the EU (6).

[glossary_exclude]A logo is intended to allow patients and consumers to be able to identify online pharmacies and retailers that have been approved and that provide authorised medicines. It is important to check these online pharmacies and retailers in the online registries available for each EU country. A list of these registries can be found on the European Medicines Agency website:https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview/buying-medicines-online#ema-inpage-item-10478 (4 July 2021)[/glossary_exclude]

The patient should not continue with the purchase if the retailer is not on the list.

Patients as well as healthcare professionals have a very important role in detecting and reporting falsified medicines. Providing patients with accessible and accurate information is crucial to avoid confusion.

[glossary_exclude]References

1. https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview/buying-medicines-online#ema-inpage-item-10478 (4 July 2021)
2. https://www.interpol.int/News-and-Events/News/2013/INTERPOL-and-pharmaceutical-industry-launch-global-initiative-to-combat-fake-medicines (4 July 2021)
3. Directive 2011/62/EU on falsified medicines https://eur-lex.europa.eu/eli/dir/2011/62/oj (4 July 2021)
4. European Commission Delegated Regulation 2016/161 https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf (4 July

2021)
5. Buying medicines online (4 July 2021)
6. Technical guidance in using the obligatory logo https://ec.europa.eu/health/human-use/eu-logo and https://ec.europa.eu/health/sites/default/files/files/eu-logo/logosancointernet_charte_v2.pdf (4 July 2021)[/glossary_exclude]

[glossary_exclude]Further resources

- Medicines verification in Europe. What to expect in 2019 https://ec.europa.eu/health/sites/default/files/files/falsified_medicines/201602_stakeholders_workshop_final.pdf (4 July 2021)
- 5 myths about fake medicines: http://fightthefakes.org/resources/5myths/ (4 July 2021)[/glossary_exclude]