# Counterfeit medicines

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**Educational aims**

- To increase awareness regarding counterfeit medicines
- To highlight the threat to patient safety
- To dispel common misconceptions
- To encourage health care professionals to participate in medicines regulation

**Key words**
counterfeit medicines, patient safety, burden of counterfeit medicines

**The issue of counterfeit medicines was mainly associated with developing countries, however it has now become of significant concern world-wide. While the exact extent of the problem is still unknown, the prevalence of counterfeit medicines is increasing, with a shift in focus from life style medicines to life saving medicines. As compared to 2005 the EU registered an increase of 380% of counterfeit medicines seized at EU borders in 2007.[1]**

## Introduction

Within the European Union counterfeiting of medicines has been identified as a significant concern for patient safety, for industry and for policy makers both at EU level and at national level.[2] While counterfeit medicines have been around for some time, the original approach to dealing with this problem was to do so in a subtle manner so as not to undermine the patient's confidence in medicines and not to cause any unnecessary harm to legitimate business.[3] The approach has now changed and all stake holders are urged to become involved and give their contribution to managing and containing this global problem. Consumers and public interest groups are encouraged to participate in medicine regulation.[4]

## Defining the problem

Counterfeit medicines have been defined as '*medicines which are deliberately and fraudulently mislabelled with respect to their identity and/or source. Counterfeiting can apply both to branded and generic products and counterfeit products may include products with the correct ingredients or the wrong ingredients, without active ingredients or with insufficient active ingredient or with fake packaging*.'[5]

Counterfeit medicines are not just substandard medicines, where in the latter case there are problems with the manufacturing process by a known manufacturer. Counterfeit medicines are made by (unknown) people with the intention to deceive and who have no regard whatsoever for patient health and safety. Engaging in the counterfeiting of medicines has the potential for making enormous profits and counterfeiters have the possibility of quickly adapting and adjusting to different situations and products to maximise their profits.[6]

Over recent years there has been a sharp increase in counterfeit medicines seized by customs at EU borders. It is estimated that in industrialised countries counterfeit medicines have a market share of 1%.[7] As evidenced by reports from various national drug agencies, initially counterfeiters targeted lifestyle medicines such as erectile dysfunction and anti-obesity drugs, however they have now shifted their focus to lifesaving drugs such as those used in the treatment of cardiovascular disease, infections and cancers to mention a few.[8, 9]

Apart from using the internet, counterfeiters are also now targeting the licensed distribution chain including wholesalers and pharmacies as this gives them the ability to deal in large volumes of distribution of medicine.

The legitimate distribution chain is a rather complex one and offers counterfeiters a good opportunity to infiltrate the system. Once a counterfeit product has entered the legitimate system, it becomes rather difficult to detect. When considering the EU, counterfeit medicines are usually produced outside the EU and then 'imported for export', i.e. when these products are allegedly not placed on the market in the EU but enter customs territory under transit rules and undergo further minor processing. While they should not be made available within the EU, these medicines can be redirected and enter the legal distribution chain. As in the case with Malta, where to date no cases of counterfeits were found and reported in the legal supply chain, counterfeit drugs are often detected in T1 transit, such as in customs territory where non-EU goods are stored and handled.[1]

**Table 1. What encourages counterfeiting of medicines?[4]**

- Medicines attractive for counterfeiting
- Lack of political will and commitment to establish a strong national medicines authority
- Lack of appropriate medicine legislation
- Absence of, or weak national medicines regulatory agency
- Weak enforcement including corruption and conflict of interest
- Shortage or erratic supply of medicines
- Inappropriate use of medicines
- Price differentials
- Inefficient co-operation between stake holders
- Lack of control over export medicines
- Trade through several intermediaries
- Trade through free-trade zones/free ports

**Misconceptions a regarding counterfeit medicines**

One of the main misconceptions is that counterfeiting of medicines is a problem which only affects developing countries. While the areas which are the most affected are indeed developing countries, Europe and the rest of the industrialised world is increasingly being targeted as can be seen in Table 2. In developing countries antibiotics and anti-protozoals such as anti-malarial medicines are commonly counterfeited while in developed countries hormones and steroids account for the majority of the cases reported.[7]

**Table 2. Reported cases of counterfeit medicines[7,8,10]**

**UK**
Cialis 20mg
Reductil 15mg
Lipitor 20mg
Zyprexia 10mg
Plavix 75mg
Casodex 50mg
Seretide 250
Evohaler 8ml pressurised inhalers
Sensodyne original
Sensodyne Mint 50ml tubes

**USA**
Xenical
Alli

**United Republic of Tanzania**
Metakelfin (anti-malarial)

**China**
Anti-diabetic traditional medicine

It is commonly thought that these are harmless copies or concern issues not affecting the health of the patient but just intellectual property since it is erroneously assumed that only branded products are targeted. As can be seen from the definition, this is not the case as both generics and branded products may be targeted for counterfeiting. Counterfeiters target medicines that can provide them with the largest profit and lucrative markets i.e. high consumption and expensive medicines are main targets.

Another misconception is that it is easy to tell the difference between a counterfeit medicine and an authentic medicine. This is not the case at all. With the technology currently available counterfeiters are able to make their product nearly identical to the original both in the case of the appearance of the medicine itself as well as the packaging. It often requires laboratory analysis to determine if a product is counterfeit.

**Threat to patient safety**

The threat to patient safety is significant. Counterfeit medicines could possibly not contain the correct active ingredient or contain the correct active ingredient in sub-therapeutic quantities alternatively they may contain toxic materials which result in the patient being poisoned.

In 2009 during the Influenza A (H1N1) pandemic significantly more reports were registered regarding the increased occurrence of counterfeit medicines. Counterfeiters identified this as a window of opportunity to sell fraudulent, adulterated or unauthorized antiviral medication or vaccines, via the Internet. [11]

Currently the over-the-counter anti-obesity drug, Alli®, has been targeted by counterfeiters and is available over the internet. The FDA has warned that instead of the registered active ingredient orlistat, the preparation contains sibutramine, with patients taking up to twice the recommended maximum dose of the latter drug if they are following dosing instructions for Alli®. When taken in excess, sibutramine can lead to elevated blood pressure, stroke and cardiac arrest in persons with a history of cardiovascular disease and healthy individuals can experience anxiety, nausea, palpitations, insomnia and slight increase in blood pressure.[10]

The case of counterfeit anti-diabetic traditional medicine reported in China found the preparations to contain six times the normal dose of glibenclamide which leads to the death of two individuals and hospitalization of nine people.[7]

A number of cases have been documented within EU member states. A document published in 2008 provides examples of cases reported during 2006/2007. A seizure of counterfeit heparin (Belgium/Germany) was found to contain a heparin like contaminant which was added to heparin resulting in allergic reactions and possibly caused deaths in 81 cases and side-effects in hundreds of patients.[1]

This document also lists Malta as having 'various' counterfeit cases of hundreds of packs relating to several diseases.[1]

As clearly demonstrated, the use of counterfeit medicines may result in therapeutic failure leading to increased morbidity and possibly mortality, which not only translates into a negative effect on the patient's health and quality of life but also leads to additional medical interventions, prolonged hospital stays, additional costs for treatment translating into an increased burden on the national health care service, on the patient and carers.

Unless an effective means of addressing this problem is found, once counterfeit medicines enter the legal supply chain, estimates indicate that they will be a significant burden to the EU as indicated by the following estimates: [1]

*Main costs - direct costs*

- Costs of hospitalisations as a consequence of treatment using counterfeit medicines:
  Projected base line until 2020 of avoidable hospital admissions is

estimated to cost the EU between 1.8bn EUR-22bn EUR

- Costs occurring in an ambulatory setting for treating the consequences of a treatment involving counterfeit medicines:
  Projected base line until 2020 of avoidable medical treatment at community level by primary health care doctors is estimated to cost the EU between 93m EUR and 1.1bn EUR

*Main costs - indirect costs*

Using Quality Adjusted Life Years (QUALYs), which combine effects on life expectancy and quality of life within a single measure, with 1 QUALY being equal to one year of life expectancy in full health, the projected base line cost until 2020 is expected to lay between 7.65bn EUR and 93bn EUR.

**Combating counterfeit medicines**

All stake holders are encouraged to actively participate in combating counterfeit medicines. Patients, who are usually the first to notice something wrong with their medicine e.g. different taste, unusual colour, novel side-effects when compared to their regular medicines, are encouraged to make a report. Pharmacists are expected to be aware and vigilant, purchasing their medicines only from a reputable source. The publication entitled '*Counterfeit medicines: Advice for health care professionals*' provides an excellent guide for pharmacists.[12] Medical doctors are strongly advised not to encourage patients to obtain their medicines outside the legitimate supply chain, which in Malta, are only licensed pharmacies.

At a global level The World Health Organisation set up the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which is comprised of international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities. Its aim is to halt the production, trading and selling of fake medicines around the globe.[13]

At a national level Malta is actively participating in the Council of Europe Working group on the Pharma package where one of its' pillars is the topic of counterfeit medicines. This group's aim in the Pharma-package pillar is to submit a proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC with regards to the prevention of entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source. Once approved by the EU parliament this directive amending directive 2001/83 will be transposed into national legislation leading to all EU member states having harmonised legislation with regards to counterfeit medicines.[14]

**Key points**

- Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source
- Use of counterfeit medicines can result in treatment failure or even death
- Erosion of public confidence in health-delivery systems may result following use and/or detection of counterfeit medicines
- Both branded and generic products are subject to counterfeiting
- Patients should never be encouraged to obtain medicines outside the legitimate supply chain

**Conclusion**

It is essential that healthcare professional be well informed regarding the significant threats posed by the availability of counterfeit medicines. In their practice they should seek to educate the general public about the matter and in addition should never encourage patients to obtain their medicines in a way which could jeopardise their health and well being.

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