Counterfeit Medicines

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Introduction : WHO Counterfeit Definition

WHO defines Counterfeits medicines as:

Products that are deliberately and fraudulently mislabelled with regard to source and/or identity.

Counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

WHO Activities

In 2006, WHO helped to create the International Medical Products Anti-Counterfeiting Taskforce, or IMPACT. The aim is to involve a range of stakeholders in collaborative efforts to protect people from buying and taking counterfeit medicines. To prevent the manufacture and distribution of counterfeit medicines, IMPACT's areas of focus are:

- Legislative
- Regulatory implementation
- Enforcement
- Communication

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Why do counterfeits pose a public health risk?

Counterfeit medicines pose a public health risk because:

- their content can be dangerous (no, reduced, excess or inferior/contaminated API);

- their quality is unknown, as are the conditions in which they are prepared given that they come from unregulated sources.

- The quality, safety, and efficacy of counterfeit medicines are not known.

- Their use can result in treatment failure or even death.

- Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, counterfeit medicines are made by people with the intent to mislead.

Counterfeits supply

Counterfeit medicine is often sold illegally over the Internet or by illegal operators posing as licensed pharmacies or operators/traders, especially in third countries where regulatory frameworks are either non existent or very weak. In fact in the late 1990's and early 2000's counterfeits were considered a phenomenon to affect only developing countries.

However nowadays due to the ever increasing complexity of the supply chain, counterfeit products managed to penetrate the legal supply chains of countries like the USA and in the EU where medicines regulation is considered to be quite tough and robust.

This can happen due to criminal conduct and especially if whoever is responsible in the legal supply chain does not carry out his duties and obligations diligently.

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Examples of Counterfeit medicines cases

Counterfeit medicine	Country/Year	Report
Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide (two people died, nine people hospitalized)
Metakelfin (antimalarial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies: lacked sufficient active ingredient
Viagra & Cialis (for erectile dysfunction)	Thailand, 2008	Smuggled into Thailand from an unknown source in an unknown country
Xenical (for fighting obesity)	United States of America, 2007	Contained no active ingredient and sold via Internet sites operated outside the USA
Zyprexa (for treating bipolar disorder and schizophrenia)	United Kingdom, 2007	Detected in the legal supply chain: lacked sufficient active ingredient
Lipitor (for lowering cholesterol)	United Kingdom, 2006	Detected in the legal supply chain: lacked sufficient active ingredient

Fight against Counterfeits

To fight counterfeit medicines effectively, a range of stakeholders – not just health professionals – is needed.

To this effect the Commission made a Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

Voted and approved on 16th February 2011 by the EU Parliament

Counterfeit vs Falsified

Counterfeits: A copy presenting itself as the branded product thus deliberately fraudulent and infringing as well IPR (API molecule; formulation; trade name; tablet shape, colour& signs/logos; presentation; etc).

IPR infringement: Generics not presenting themselves as the branded product, and maybe not concealing their identity or source but copying the branded product whilst it is still under patent.

Falsified Medicines

Falsified vs Counterfeits

So the EU Commission used the term falsified and not counterfeit to include a wider scope i.e. even adulteration or falsification of documents, records etc. which show the source, history, purity etc. of a product.

This also distinguishes from those items which infringe the IPR, referred to sometimes as counterfeits also.

Falsified medicinal products in the new proposed directive are defined as:

Any medicinal product with a false representation of:

a) its identity, including its packaging and labelling, name, composition in respect of any of its components and strength and/or

b) its source, including the manufacturer, country of manufacturing, country of origin, marketing authorization holder and/or

c) its history, including the records and documents relating to distribution channels.

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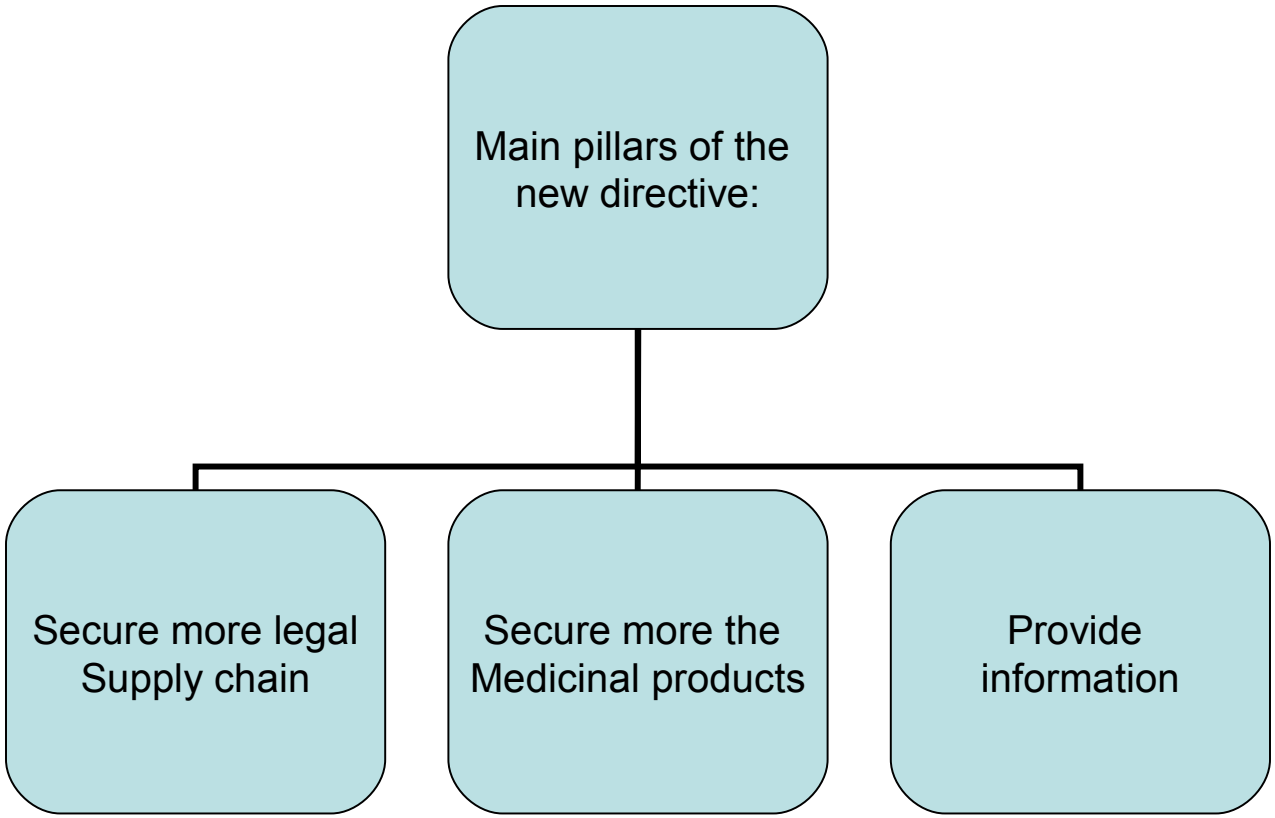
Main three pillars of the new directive

Main changes / proposals coming into force with the new proposed directive which will help in the combat of counterfeits/falsified medicines.



Pillar 1. Secure more the legal supply chain by:

- Mandatory inspections for GMP compliance of all API manufacturers and importers in the EU;
- Set up a list of approved API manufacturers outside the EU (Third Countries approved list);
- A system of good practice, basic GMP for some manufacturers of excipients which are considered to be high risk;
- Regulate also through inspections and licensing all players involved in the distribution chain including traders and brokers involved in transactions and deals of medicinal products;
- Obligation on wholesalers, traders and brokers to report to competent authorities cases of suspected counterfeits;

Pillar 1. Secure more the legal supply chain (continued):

- Warehouses used in customs zones to store temporarily medicinal products must also be inspected and licensed;

- Imports for exports (introduced into the EU) must be carried out under an importation (MIA) licence and not a wholesale dealers licence;

- Operators in Free Trade Zones must at least hold a wholesale dealing licence;

- Re-packagers and relabelers / parallel importers are responsible for products which they source and which they repackage / relabel , even in terms of counterfeits; if any safety features are removed during repackaging / relabeling operations these have to be replaced with similar ones offering same level of protection;

1. Secure more the legal supply chain (continued): Internet Pharmacies.

A). It is up to each individual member state to decide whether to allow operators to operate internet pharmacies in their territory or not;

B). If yes, it is up to member state to list the requirements, but Internet pharmacies set up in the EU must at least :

- notify their activity to the competent authority who can inspect and authorise them,
- operate from the notified physical space,

1. Secure more the legal supply chain (continued): Internet Pharmacies.

- have a logo as approved by the EU Commission shown on their website which will be connected to the competent authority website;
- provide contact details;
- if allowed dispense POMs against prescriptions;
- dispense only medicinal products which are authorised in country of destination;
- operate in line with national legalisation.

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Pillar 2. Secure more the products by:

- Certain medicinal products, initially POMs and later on some OTCS listed by the EU Commission as high risk, will have obligatory safety features such as seals and holograms amongst others, incorporated in their primary and secondary packaging. (Generics are exempt from such an obligatory requirement however whoever wants to introduce safety features through own initiative can do so);

- Introduction of a serialisation number for these high risk products which should be readable at point of sale through an internet connection to databases maintained by Manufacturing Authorisation Holders;

Pillar 3. Provide information by:

- EMA and Member States Competent Authorities must provide information regarding counterfeiting of medicinal products on their websites;

- The EU Commission, EMA and Member States Competent Authorities must carry out information campaigns on counterfeiting of medicinal products to the general public;

- Introduce harsh penalties including imprisonment in the national legislative framework for Counterfeiters;

Local Scenario

Presently the closest definition we have is article 98 in Medicines Act 2003 which speaks about adulteration. However when we transpose the new EU directive we will have harmonised definitions and provisions across the EU.

To date we did not have cases of Counterfeits in the legal supply chain, though there were cases of counterfeit medicines found in the illegal supply chain.

Main risk to our patients remains the internet.

Pharmacists as first line health care professionals are ideally situated to educate their patients on this phenomenon and its risks.

Internet Pharmacies: How to help patients identify reliable internet pharmacies.

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Patients can buy medicines for personal use – E-Commerce Directive (though MS can ban marketing and sale by distance selling on their territory on exceptions such as for health risks) and The Doc Morris case.

- Buy from trusted sources – regulated supply chain more secure;
- Whether the physical address is concealed;
- Whether the name and website of its regulator is listed;
- Only from countries which regulate internet pharmacies;

Internet Pharmacies: How to help patients identify reliable internet pharmacies.

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- Check the regulator's website of the internet pharmacy in which it is established to check whether that internet pharmacy is licensed or not;
- Whether it supplies POMs without a prescription;
- Excessively cheap prices – beware, a red flag;
- If in doubt, don't take chances with your health (give an example of a car).

Initiatives for now taken by the Medicines Authority

The Medicines Authority is tackling this issue of counterfeit medicines mainly through 4 pillars of actions:

1. Availability of more medicines and especially of generic medicines for better competition. The Medicines Authority launched its campaign of Know Your Medicines where public is made aware of what generic medicines are to increase the trust of the general public in generics;

2. Legislation: Implementation of the new EU directive and participating in international fora and conventions such as the WHO, HMA WGEO and the International Convention on Counterfeits;

Initiatives for now taken by the Medicines Authority (continued)

3. Stricter regulation and enforcement where necessary – we have been doing this and will continue to do it in a vigilant way. Established closer contacts and collaboration with the Customs Department and the Police Force;

4. Currently going on through an education campaign at large using various media, such as:

Education campaigns by the Medicines Authority

- Its' website: (http://www.medicinesauthority.gov.mt/knowyourmedicines.htm)
- Distribution of leaflets,
- Participation in national fora and activities e.g. science week,
- Press releases and interviews,
- Articles in local newspapers and magazines,
- Participating in local TV and Radio programmes to educate and increase awareness,
- Provision of a consumer helpline.

Conclusion – Key Points:

- Counterfeit / falsified medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or content and/or source and/or history .
- Use of counterfeit / falsified medicines can result in treatment failure or even death.
- Public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit / falsified medicines.
- Both branded and generic products are subject to counterfeiting and falsification.

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Conclusion – Key Points (continued):

- All kinds of medicines have been counterfeited or falsified, from medicines used for the treatment of life-threatening conditions to lifestyle drugs, and sometimes even inexpensive generic versions of painkillers and antihistamines.

- Some Internet pharmacies are legal operations, established to offer clients convenience and savings. They deliver medications from licensed facilities through regulated means and should operate in line with the legislation. New directive will try to impose minimum safety requirements at EU level.

Thank You

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Any Questions ?