

Frequently Asked Questions

Frequently asked questions on Counterfeit Medicinal products

1. *What are counterfeit medicinal products?*

As counterfeits come in many forms, also the definition of a counterfeit medicinal product differs in various countries and sectors. To date, no internationally harmonized definition of counterfeit medicines exists, and that contributes to hindering the global fight against counterfeiting. The World Health Organization (WHO) defines counterfeit medicines as “*medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.*”¹ Counterfeit medicines having correct quantities of active ingredients but with fake packaging or being just copies of an original product are exceptions rather than the rule. In most cases, counterfeits can severely endanger the lives and the well-being of patients by causing serious illness or even death or depriving patients of proper treatment. They may have high levels of impurities or contaminants, contain insufficient quantities of active ingredients, too much of the active ingredient, no active ingredient at all or even an entirely wrong active ingredient. Whatever the case, a counterfeit medicine can harm patients, even cause death.

2. *What risks are associated with counterfeit medicinal products?*

By not having the therapeutic benefit patients expecting from the product, counterfeits pose not only a danger to patients, but also globally a significant public health threat. In most severe cases, using a counterfeit medicinal product can be life-threatening. The WHO has identified counterfeiting as a growing, often underestimated danger, citing, in particular, the problems of product toxicity, instability and ineffectiveness². For instance, a patient suffering from cancer, may be deprived of proper treatment because the counterfeit contains none, or too little, of the active ingredient. Conversely, patients may also be harmed by products containing too much of the active ingredient, or other potentially harmful ingredients. Also counterfeit medical devices and diagnostics present an obvious danger to human health. Furthermore, counterfeit products may be contaminated because they are often made in substandard, unregulated and/or unsanitary environments with no concern for safety. In any mentioned scenario, patient's life can be at stake.

¹ <http://www.who.int/medicines/services/counterfeit/overview/en/>

² <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>

3. What are the causes of counterfeiting?

Counterfeiting is an increasingly common crime and affects all regions over the world. Several factors, such as globalization or the internet make it an easy target for counterfeiters, by providing ready access and attractive distribution channels. Insufficient regulations governing the medicines distribution system exacerbates the discovery of counterfeiters and, thus, to apply penalties. Unfortunately, technological achievements do not stop at counterfeiting medicinal products and make it nearly impossible for consumers to distinguish between authentic products and their counterfeits. All these developments make it increasingly profitable for organized crime.

What are the consequences of counterfeiting?

Counterfeiting has significant social and economic ramifications, the most important negative consequence above all is the threat it poses to public health. Consumers are victims of fraud by not getting safe and effective products they paid for and, instead, may be put at serious risk. As they may not meet the strict quality standards imposed by regulatory authorities and legitimate manufacturers counterfeit medicinal products pose a number of risks by being ineffective, containing harmful ingredients, or both. Possible consequences of counterfeit diagnostics and medical devices could be wrong results or compromised sterility. As a consequence, counterfeiting not only undermines confidence in healthcare systems and health professionals, but also damages public confidence in authentic pharmaceutical and diagnostic products, their manufacturers and distributors, resulting in a threat to the reputation of the legitimate healthcare business. In addition to infringing intellectual property rights, counterfeits create a financial burden on governments because of the money wasted on counterfeits and related enforcement measures. Overall, counterfeiting is a lose-lose situation for consumers, the government, and legitimate manufacturers.

4. Where are counterfeit medicinal products found?

Counterfeiting is a growing problem in all regions of the world, due to large and quick profits that can be made, a lack of anti-counterfeiting regulations, and the relatively lenient penalties currently enforced against convicted counterfeiters in many countries. Many organised crime networks, narcotics gangs and even terrorist organisations are involved in counterfeiting. The problem affects not only developing countries, but developed countries as well. Whereas counterfeiting is more widespread in regions with ineffective regulations and sanctions, no country is immune of counterfeiting.

5. What types of medicinal products are counterfeited most?

Counterfeiters target all types of medicines, medical devices and diagnostic tools, including branded and generic products. The most widely used and profitable products

are among those most likely to be counterfeited. Whereas, some years ago mostly “lifestyle” pharmaceutical products have been counterfeited, nowadays increasingly therapies for chronic and / or life-threatening conditions are targets for counterfeiters. However, any kind of medicinal product including medical devices and diagnostics can be a target for counterfeiters.

6. *Have Roche products been counterfeited?*

Like every other healthcare company, Roche is exposed to counterfeiting. Worldwide, any kind of product can be and has been counterfeited: lifestyle medicines as well as medicines for the treatment of life-threatening conditions and all kind of diagnostic products. Roche is aware of the fact that counterfeiters have tried to forge Roche’s entire portfolio as Roche is actively working to prevent the counterfeiting of its products by collaborating with anti-counterfeiting organizations, cooperating with local authorities and taking concrete measures inside the company.

7. *What can be done globally to address the problem?*

There is no easy solution to the counterfeiting problem, and the consequences affect not only patients at the end of the supply chain, but also involve governments and healthcare companies. Counterfeit products normally enter the market at some point in the distribution channel or via purchase from unauthorized sources. The main aim should be patient’s health by ensuring the integrity of the whole supply chain. National authorities and agencies as well as international organizations take the primary responsibility for the prevention and control of counterfeiting. Roche aims to guarantee the safety within the medicinal products distribution system by working cooperatively with all stakeholders. Measures focus on strengthening the accountability within the whole distribution system through tougher enforcement and stricter sanctions, as well as employing new technology that has been proven to be effective against counterfeiting.

8. *What is Roche in particular doing to combat counterfeit medicinal products?*

Roche believes that there is no higher priority than ensuring that patients have safe and effective medicinal products. Therefore, Roche has implemented different approaches to fight counterfeiting:

- Continue to explore and implement new technologies, such as special packaging and printing techniques, that make counterfeits both more difficult to make and easier to spot.
- Work with all relevant stakeholders to determine how to best keep the distribution system safe for patients. Roche has also established business practices designed to further secure the distribution system; increased cooperation with law enforcement

agencies to successfully prosecute counterfeiters; and promotes proactive public policy that will help eliminate counterfeiting.

- Roche aims to improve security in supply and distribution chains to make it easier to track our medical products, and to prevent counterfeit products entering the supply chain. Roche includes security features on packs to enable to distinguish legitimate products from counterfeits. Roche is working with other pharmaceutical manufacturers to promote development of a serialisation solution in Europe³, which enables pharmacists to compare a unique number on each pack of medicines against a central database to confirm its legitimacy. These techniques work less well in emerging markets where pharmacies are often not regulated.
- Support anti-counterfeit organizations such as the Pharmaceutical Security Institute (PSI)⁴, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)⁵ as well as the European Federation of Pharmaceutical Industry Associations (EFPIA)⁶ and cooperate with other companies.
- Awareness raising and training: police, customs, healthcare professionals, lawmakers, public at large.
- Draw on a number of departments and skills to fight counterfeiting. Roche has established an internal Roche Anti-Counterfeiting Commission, which consists of members of all affected departments, and which is heavily involved in the coordination of many anti-counterfeiting activities.

9. *How can the patient avoid getting counterfeit medicinal products?*

The best way to avoid counterfeit medicine is to purchase prescription medicines or diagnostic tools from a reputable pharmacy or from your physician. One should not buy medicinal products from online pharmacies that aren't licensed in his or her country or that offer to write prescriptions or sell medicinal products without prescriptions. Where available, the patient should ask for the product in the manufacturer's original package. One should closely scrutinize the appearance of the medicinal product and its packaging. While Roche cannot prevent the criminal act of counterfeiting by third parties, the company has undertaken steps to increase the likelihood that counterfeit products can be identified. Similarly, there are a number of steps patients can take to protect themselves from the threats posed by counterfeit medicinal products. Roche offers among other things practical guidelines to help people ensure they receive only authentic medication (see also the Tamiflu-Guideline with instructions on how to check packaging and label of

³ EFPIA's Coding and Serialisation Project: <http://www.efpia.eu/documents/36/85/Coding-amp-Identification-of-Products-towards-safer-medicines-supply>

⁴ <http://www.psi-inc.org/index.cfm>

⁵ <http://www.ifpma.org/global-health/counterfeits.html>

⁶ <http://www.efpia.eu/topics/industry-economy/falsified-medicines>

Roche's antiviral product Tamiflu:

http://www.roche.com/identifying_counterfeit_product.pdf).

10. Is it safe to buy medicinal products over the internet?

A fact is that the internet has facilitated the increasing globalization of counterfeiting. Current lack of legal regulations makes online sales of prescription medicinal products an easy target for counterfeiters. With respect to online pharmacies, as there exist diverse cultures in different regions and due to a much higher risk buying a counterfeit medicinal product with an online pharmacy than in a traditional pharmacy, Roche therefore cannot give advice or suggestions applicable to all countries. However, every patient should consider some basic rules when purchasing medicinal products via the internet, such as checking accreditations of the pharmacy by addressing the health authorities in his or her home country or being suspicious if the online pharmacy does not demand a prescription.

11. How can somebody tell if he/she has received a counterfeit medicinal product?

Patients may not know that they have received a counterfeit medicinal product due to increasing technological developments, which makes it possible for counterfeiters to mimic the authentic product. For this reason, it is important to purchase products from a credible source. In some cases, patients have noticed a different taste, consistency, or appearance of products that are later identified as being counterfeit, or they may have an unusual reaction to the counterfeit product. Typical abnormalities associated with the use of counterfeit diagnostics or medical devices could be performance issues, like suspicious results, or application issues. Roche advises patients when having any doubts about a product they have purchased to save the medicinal product and contact their physician or pharmacist immediately. Further, if you suspect a Roche product you have purchased maybe counterfeit then please contact your local Roche office.

12. What steps does Roche take if it identifies counterfeit medicinal product?

Roche acts immediately when counterfeit products are suspected by analyzing suspected counterfeit samples and convening a global expert team to coordinate Roche's response. Roche vigorously pursues anyone who makes, distributes or sells counterfeit versions of the company's products and seeks prosecution of offenders. If counterfeit medicinal products are found to have entered the market, Roche, in close cooperation with the respective Health Authority may alert physicians, pharmacists or wholesalers via letters or other channels and cooperates with them to stop counterfeit products from reaching patients. Because of the health risks associated with taking a counterfeit medicinal product, Roche encourages patients to first report any concerns to their physician or pharmacist.

For further information:

- Roche Position on Counterfeiting:
http://www.roche.com/responsibility/business_ethics/counterfeiting.htm
- World Health Organization's (WHO) Information-platform on Counterfeiting:
<http://www.who.int/medicines/services/counterfeit/overview/en/>
- WHO's Fact Sheet on Counterfeiting:
<http://www.who.int/mediacentre/factsheets/fs275/en/index.html>
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
Position on Counterfeit Medicines:
<http://www.ifpma.org/global-health/counterfeits.html>
- European Federation of Pharmaceutical Industry Associations (EFPIA):
<http://www.efpia.org/Content/Default.asp?PageID=537>
EFPIA's Coding and Serialisation Project:
<http://www.efpia.eu/documents/36/85/Coding-amp-Identification-of-Products-towards-safer-medicines-supply>
<http://www.esm-system.eu/home.html>
Fight the Fakes Campaign:
<http://fightthefakes.org/>