Roche Position[1] on Counterfeit and Falsified Pharmaceutical & Diagnostic Products

Background

Counterfeiting and falsification of pharmaceutical and diagnostic products is a criminal act that poses a significant global public health problem. Counterfeit and falsified medicines and diagnostic products are mostly offered for sale by unlicensed sources. As the negative implications for public health and safety of the patients are high, Roche takes this issue extremely seriously. Counterfeiting is a crime that, in addition to infringing intellectual property rights,

- endangers the lives and the well-being of patients;
- undermines confidence in healthcare systems and health professionals;
- damages public confidence in authentic pharmaceutical and diagnostic products and their manufacturers and distributors;
- is a threat to the reputation of the legitimate healthcare business;
- creates a financial burden on governments because of the money wasted on counterfeits and related enforcement measures.

Stakeholders' Expectations and Concerns

Roche's primary task is to research and develop medicines and diagnostic tools for tangible improvements in the health, quality of life and survival of patients. However, the company has no official power to intervene directly and will not assume liability for damage claims related to counterfeit and falsified products. National authorities and agencies, such as health authorities, customs, police, intergovernmental agencies, and international organizations (e.g. WHO), take the primary responsibility for the prevention and control of counterfeiting and falsification.

Roche Position

To date, Roche's exposure has been low; only a few cases of counterfeiting involving Roche products have been reported. Roche fully supports governmental efforts and is committed to cooperate with the authorities whenever a Roche product is concerned. Roche's policy ensures an action plan for rapid information, possible detection, coordination, analysis of suspect products, reporting and timely interaction with authorities.

Based on its corporate principles and recognizing the potential impact of this public health issue, Roche has even further developed its policy in order to ensure the company's contribution to the fight against counterfeiting and falsification and to respond to counterfeit products within its

[1] Pertains to SDGs 3 and 16

sphere of influence such as continuously monitoring and improving product security using technology to quickly identify counterfeited and falsified medical products. As appropriate, Roche follows relevant national and international standards, guidelines and regulations aimed at combating falsified active pharmaceutical ingredients (APIs), medicines and diagnostics. Further, Roche participates in national and international industry and governmental efforts to develop stronger laws and improve enforcement, educate the public and train local officials.

Counterfeit and falsified medicines are mostly offered for sale by unlicensed sources. Roche's medicines are only available on prescription and often require appropriate infrastructure for administration; the company recommends buying prescription only medicines exclusively from trusted sources such as doctors or authorized pharmacies.

Outlook/Status/Current engagement and initiatives

Roche has implemented numerous technical anti-counterfeiting measures, however, such measures cannot completely prevent counterfeits: savvy counterfeiters could still detect and replicate them. To perpuate the effectiveness of the anti-counterfeiting measures implemented, Roche does not disclose them to the public. The company is pursuing and coordinating anti-counterfeiting measures relating to the design, including packaging and labelling, of all its products. Roche is involved in industry and governmental efforts to contain counterfeit and falsified medical products on national and international level and is also implementing requirements from authorities. Despite these measures, consumers may not recognize a counterfeit of legitimate product, even with sophisticated anti-counterfeit measures.

Roche actively contributes to national and international industry and governmental efforts to develop stronger laws and improve enforcement, educate the public and train local officials.

This updated position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on May 14, 2018 and entered into force the same day. It was reviewed in April 2020.

Frequently Asked Questions

Frequently asked questions on Counterfeit Medicinal products

1. What are counterfeit and falsified 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.

To fill this gap, a working definition of "falsified medical products" was proposed and approved at the World Health Assembly 2017: *"Medical products that deliberately/fraudulently misrepresent their identity, composition or source."* Such deliberately/fraudulently misrepresentation refers to any substitution, adulteration, or reproduction of an authorised medical product or the manufacture of a medical product that is not an authorised product.

Roche supports efforts to harmonize definitions of falsified medicines as a mechanism to facilitate coordination amongst different countries and international organizations. Reference to "counterfeiting" will continue being used in the context of "*products deliberately and fraudulently mislabeled with respect to identity, source or history, with Trademark infringement implications*".Falsified and counterfeit medicines having correct quantities of active ingredients but with fake packaging or simply copies of an original product are exceptions rather than the rule. In most cases, counterfeits and falsified products 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 active ingredient, no active ingredient at all or even an entirely wrong active ingredient. Whatever the case, a counterfeit and falsified medicine can harm patients, even cause death.

2. What risks are associated with counterfeit and falsified medicinal products?

By not having the therapeutic benefit patients are expecting from the product, counterfeits and falsified medicinal and diagnostic products pose not only a danger to patients, but also globally a significant public health threat. In most severe cases, using a counterfeit and falsified 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 ineffectiveness[2]. For instance, a patient suffering from cancer, may be deprived of proper treatment because the counterfeit and falsified medicinal product contains none, or too little, of the active ingredient. Conversely, patients may also be harmed by products containing too much

[2] http://www.who.int/mediacentre/factsheets/fs275/en/index.html

of the active ingredient, or other potentially harmful ingredients. In addition, counterfeit and falsified medical devices and diagnostics present an obvious danger to human health. Furthermore, counterfeit and falsified 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.

3. What are the causes of counterfeiting and falsification?

Counterfeiting and falsification is an increasingly common crime and affects all regions over the world. Globalization and the ever increasing significance of the internet are contributing factors which also readily provide access to numerous distribution channels. Insufficient regulations governing the medicines distribution system exacerbates the discovery of counterfeiters and, thus, to apply penalties. Unfortunately, technological achievements do not yet stop at counterfeiting and falsifying medicinal and diagnostic 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 to engage in counterfeiting activities.

4. What are the consequences of counterfeiting and falsification?

Counterfeiting and falsification 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, are potentially put at serious risk. As they may not meet the strict quality standards imposed by regulatory authorities and legitimate manufacturers, counterfeit and falsified medicinal products pose a number of risks by being ineffective, containing harmful ingredients, or both. Possible consequences of counterfeits and falsified diagnostics and medical devices could be wrong results or compromised sterility. As a consequence, counterfeiting and falsification 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 and falsification is a lose-lose situation for consumers, the government, and legitimate manufacturers.

5. Where are counterfeit and falsified medicinal products found?

Counterfeiting and falsification is a growing problem in all regions of the world, due to large and quick profits they allow for, 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

and falsification. The problem affects not only developing countries, but developed countries as well. Whereas counterfeiting and falsification is more widespread in regions with ineffective regulations and sanctions, no country is immune of counterfeiting.

6. What types of medicinal products are counterfeited and falsified 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 and falsified. Whereas, some years ago mostly "lifestyle" pharmaceutical products have been counterfeited and falsified, 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.

7. Have Roche products been counterfeited and falsified?

Like every other healthcare company, Roche is exposed to counterfeiting and falsification. Worldwide, any kind of product can be and has been counterfeited and falsified: 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. Therefore, Roche is actively working to prevent the counterfeiting and falsification of its products by collaborating with anti-counterfeiting organizations, cooperating with local authorities and taking concrete measures inside the company.

8. What can be done globally to address the problem?

There is no easy solution to the counterfeiting and falsification problem, and the consequences affect not only patients at the end of the supply chain, but also involve governments and healthcare companies. Counterfeits and falsified 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 and falsification. 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 newest technology that has been proven to be more effective against counterfeiting.

9. What is Roche in particular doing to combat counterfeit and falsified 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 and falsification:

- 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 differentiate from genuine products.
- 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 and falsification.
- Roche aims to improve security in supply and distribution chains to make it easier to track our medical products, and to prevent counterfeit and falsified products entering the supply chain. Roche includes security features on packs to allow for distinction between legitimate products and counterfeits. Roche has been working with other pharmaceutical manufacturers to promote a serialisation solution in Europe[3] and many other countries, which enables pharmacists to compare a unique number on each pack of medicines against a central database to confirm its legitimacy. These techniques are already quite versatile from a technical standpoint and only unfold their full effect in regions with a high standard in pharmacy regulation and digitization.
- 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 Global 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.

10. How can the patient avoid getting counterfeit and falsified medicinal products?

The best way to avoid counterfeit and falsified 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 are not licensed in their 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

[3] European Medicines Verification System: https://emvo-medicines.eu/
[4] https://www.psi-inc.org/
[5] http://www.ifpma.org/subtopics/counterfeit-medicines/?parentid=268
[6] https://www.efpia.eu/

criminal act of counterfeiting and falsification by third parties, the company has undertaken steps to increase the likelihood that counterfeit and falsified products can be identified.

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

A fact is that the internet has facilitated the increasing globalization of counterfeiting and falsification. 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 and falsified 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.

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

Patients may not know that they have received a counterfeit or falsified 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 were later identified as being counterfeit and falsified, or they may have had an unusual reaction to the counterfeit and falsified product. Typical abnormalities associated with the use of counterfeit and falsified 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 and falsified then please contact your local Roche office.

13. What steps does Roche take if it identifies counterfeit and falsified medicinal product?

Roche acts immediately when counterfeits and falsified products are suspected by analysing suspected counterfeit and falsified samples and convening a global expert team to coordinate Roche's response. Roche vigorously pursues anyone who makes, distributes or sells counterfeits and falsified versions of the company's products and seeks prosecution of offenders. If counterfeit and falsified 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 and falsified products from reaching patients. Because of the health risks associated with taking a counterfeit and falsified 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/dam/jcr:d1fed4b2-1d2d-4f40-98ff-c5fae6be0ba1/en/roche_position_on_counterfeiting.pdf
- World Health Organization's (WHO) Information-platform on Counterfeiting: http://www.who.int/medicines/regulation/ssffc/en/
- WHO's Fact Sheet on Counterfeiting: http://www.who.int/mediacentre/factsheets/fs275/en/
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Information Platform on Falsified Medicines: http://www.ifpma.org/subtopics/counterfeit-medicines/?parentid=268
- IFMPA's 10 Principles on Counterfeit Medicines: https://www.ifpma.org/resource-centre/ifpmas-10-principles-on-counterfeit-medicines/
- Fight the Fakes Campaign: http://fightthefakes.org/