

What's in a word? Falsified/counterfeit/fake medicines – the definitions debate

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ABSTRACT

There is a rising tide of criminal activity to manufacture and distribute falsified, counterfeit, or fake medicines. The exact size of this problem is unknown but estimates vary from US\$75 billion to US\$200 billion per year, and evidence clearly demonstrates it is on the increase. Depending on the world region, infiltration into the legitimate supply chain versus the illegitimate (e.g., the internet) varies greatly. However, what is certain is that the direction of travel by regulatory agents is to develop supply chains that allow access to medicines via the World Wide Web. Within this context, there has been a long-running debate about how to correctly describe the various forms of medicines that are fraudulently or otherwise manufactured and distributed. This article attempts to describe the evolution of the definitions and recommends that a consensus be formed to describe such medicines that reach the public:

- Falsified medicine: This being the term used and defined in the Falsified Medicines Directive and which is primarily concerned with public health.
- Counterfeit medicine: This is closely associated and legally defined within intellectual property legislation and concentrates on trademark protection.
- Fake medicine: This is the term that best serves to communicate with the public to raise awareness about the phenomenon.

Keywords: Counterfeit, Fake medicine, Falsified

Introduction

What's in a word? When it comes to falsified, counterfeit, or fake medicines, their definitions depict a broad landscape – not of rolling hills and beautiful sunsets but of dark depths and raging undercurrents. Why such a dramatic introduction? Criminal activity to produce and distribute such medicines is on the increase and is putting health and lives at risk (1-3). With vast profits to be made and with punitive laws inadequate to cover the seriousness of the crime, this is an evolving area that deserves much attention and action (4).

With the click of a mouse, a potentially illegal medicine can be ordered online (5, 6) – often unwittingly, and yes, sometimes in full knowledge that the medicine might contain too much, too little, or no active substance at all (7). This route of distribution is known as the “illegitimate” supply chain, as opposed to the “legitimate” supply chain, which

is normally subject to a national authorisation system for manufacturers and wholesale distributors, including brokers, to registered pharmacies or hospitals for dispensing. Illegal online medical product sellers, sometimes called rogue online or Internet “pharmacies,” threaten the health, lives, privacy, and security of Internet consumers globally. According to multiple sources (8), which is generally consistent with the findings of the World Health Organization (WHO) and the National Association of Boards of Pharmacy, at any one time there are approximately 40,000-50,000 active online medical product sellers worldwide, and 93%-96% of them are operating illegally. These sellers do not operate in compliance with the laws of the jurisdiction in which they are located, or to where they are selling the products. It has been estimated that these criminals could generate up to US\$35m in one year from a single website (6).

It is an unfortunate fact, for the patient in many developing countries, that the illegitimate supply chain moves seamlessly into the legitimate supply chain, with a myriad of points of entry, from street markets to corner shops, peddling an array of medicines that might or might not contain active medicinal ingredients (9, 10).

The scope of the problem

“The exact size of the counterfeiting problem is not known. Due to the criminal nature of their activities, counterfeiters

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seek to avoid detection, concealing the extent of the crimes committed, which makes data collection and reporting extremely difficult. One measure we have – the number of seizures reported by enforcement authorities around the world – represents only the tip of the iceberg” (11).

This quote by Thomas Kubic of the Pharmaceutical Security Institute (PSI) sums up the difficulty of assessing the true extent of the problem.

The PSI, founded in 2002, is “a not-for-profit, membership organization dedicated to: Protecting the Public Health; Sharing Information on the Counterfeiting of Pharmaceuticals; and Initiating Enforcement Actions through the Appropriate Authorities” (11).

The PSI documented no less than 3,002 incidents of pharmaceutical crime during 2015. This represented a significant increase from 2014 and an all-time annual high. From 2011 to 2015, total incidents increased by 51% (1).

Any incident that involved the seizure of more than 1,000 dosage units was classified as a commercial incident. Those incidents involving less than 1,000 dosage units were classified as noncommercial. In 2015, there were 971 counterfeiting incidents that involved either customs seizures or police/health inspector raids. This represents a 34% increase over the prior year. The “commercial” size of counterfeit medicines seizures made by law enforcement was 33%. Also, the number of noncommercial seizures increased significantly in 2015. The seizure of 1,000 dosage units or less represented 56% of the total.

In 2015, incident data were analyzed with respect to 7 regions of the world. Every region experienced a pharmaceutical crime incident. In total, 128 countries were found to have been impacted by pharmaceutical crime. A country is viewed as being impacted if the suspect medicines originated in that country, transited that country, or were found in that country.

PSI documented a 38% in the worldwide incident total compared to the previous year. Incidents impacting the Asia Pacific region surpassed 1,000 annually for the first time in 2015. Also, incidents in North America increased over 100% from the previous year. Clearly this reveals a developing picture where criminals are seeing a continuing opportunity to increase their illegal and potentially very harmful trade.

A recent European research-based project funded by the German Ministry of Education and Research and carried out by the ALPhA group (12), also revealed that there is a growing criminal market place for the illegal sale of mainly prescription medicines online. The high profit margins and low risk of detection with limited penalties for prosecution have accelerated criminal activity in this lucrative area of crime. A key ALPhA finding has been the comparison of the legal landscape across 28 EU Member States, with particular focus on criminal law and fines. This revealed a very varied landscape indeed, with different safety standards of the distribution of medicines via the internet, and confirmed the consumer’s lack of knowledge as to how to distinguish legal from illegal online sellers of medicines.

A key recommendation was to encourage the implementation of an EU-wide harmonization exercise of the criminalization of pharmaceutical crime and applicable sanctions, and that this should be carried out with urgency. It is worth noting

that the Medicrime Convention is the first international criminal law instrument which provides a framework for national and international co-operation by public and private sectors for the protection of victims and witnesses.

The Pangea operations can be regarded as the cornerstone of concerted global law enforcement activity. Here, again, we see some alarming facts revealed during the Pangea IX 2016 operation (13).

“Targeting the illicit online sale of medicines and medical devices and involving some 193 police, customs and health regulatory authorities from 103 countries, Operation Pangea resulted in 393 arrests worldwide and the seizure of more than US\$53 million worth of potentially dangerous medicines.

Private partners from the Internet and payment industries also supported the operation, which saw the suspension of 4,932 websites selling illicit pharmaceuticals.

The operation also targeted the main areas exploited by organized crime in the illegal online medicine trade: rogue domain name registrars, electronic payment systems and delivery services. A further 700 investigations have now also been launched by national authorities worldwide with at least 40 cases directly linked to organized crime.

As well as raids at addresses linked to the illicit pharmaceutical websites, some 334,000 packages were inspected and 170,340 seized by customs and regulatory authorities during the international week of action (May 30 to June 7, 2016).

Among the 12.2 million fake and illicit medicines seized during the operation were slimming pills, anti-malarial and cholesterol medication, erectile dysfunction pills, hair loss treatments, and nutritional products. More than 270,000 medical devices worth an estimated US\$1.1 million were also recovered.

Police in Hungary seized some 65,000 anxiety medication tablets hidden in the back seat of a car and inside the spare wheel, in the same *modus operandi* often used to smuggle narcotics, and an underground laboratory producing fake medication and steroids was discovered in Austria.

Myanmar authorities seized illicit anti-cancer medication, and in Singapore, anabolic steroids, sleeping pills, pregnancy test kits, and drugs for infertility and weight loss were also recovered during Operation Pangea IX” (13).

With 40,000-plus illegally operating websites (8) aimed in any given day across the World Wide Web, this reinforces the need to combat the ever-increasing level of this lucrative trade that harms people as well as economies.

Given the fact that the term “counterfeit” relates to intellectual property rights (14), it is appropriate to highlight a recent Quantification Infringement Report by the EU Intellectual Property office (EUIPO) entitled “The economic cost of IPR infringement in the pharmaceutical sector” (15). This report estimated that this illegal activity equated to a 4.4% loss in pharmaceutical sales of €10.2 billion with an additional €7.1 billion of lost revenue in related sectors with a total of 90,000 jobs lost annually.

The evolution of the definitions

This article sets out to explain the different definitions of a “fake” medicine. The complexity of meaning, which derives from the different types of “fake” medicines when juxtaposed

against in-country laws and regulations that support the legal system to combat criminal activity, underlines the importance of using the right language.

It is worth noting that the WHO took a great deal of time and intellectual expenditure of energy to agree a term that the majority felt comfortable with.

It was in 1988 that the definition bandwagon got rolling. A WHO expert working group used the word “counterfeit” among a number of terms, and eventually established what is now widely recognized, namely: substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products (16).

It was not until 1992, at a WHO international meeting, that the term “counterfeit” began to gain more acceptance as the key descriptor. The conclusion of the meeting was broad agreement that counterfeit products may include:

- products with the correct ingredients, or
- with the wrong ingredients, or
- without active ingredients, or
- with incorrect quantities of active ingredients, or
- with fake packaging.

This description also stated that it covered branded and generic types of medicines (17).

At this point it is worth cataloguing the significant milestone initiatives that have occurred since this definition was coined on the basis of a presentation by Dr. Sabine Kopp (18) (Tab. I).

The formation of the IMPACT taskforce

One of the most significant initiatives in the quest for the most accurate term for fake medicines, was the formation, under the auspices of the WHO, of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Launched in 2006, its aim was to establish coordinated networks across and between countries to halt the production, trading, and selling of counterfeit medicines. It was in 2008 that the IMPACT body proposed a definition of a “counterfeit medical product” (19) as follows:

“‘COUNTERFEIT MEDICAL PRODUCT’ (2008)

The term counterfeit medical product describes a product with a false representation (i), of its identity (ii), and/or source (iii).

This applies to the product, its container or other packaging or labelling information.

Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components (iv), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

TABLE I - Milestone initiatives

1988, May: resolution WHA 41.16 requesting WHO “to initiate programmes for the prevention and detection of export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations, and to cooperate with the Secretary-General of the UN in case provisions of the international drug treaties are violated” (WHA 41.16, 1988).

1992: first international meeting on “counterfeit drugs” organized by WHO. Outcome: definition of “counterfeit drug” (17).

1994: resolution WHA 47.13 requesting WHO “to assist Member States in their efforts [...] in combating the use of counterfeit drugs” (WHA 47.13, 1994).

1996: WHO Project on Counterfeit Drugs, with the outcome published in 1999:

“WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs” (48)

2000-2005: WHO, IFPMA, IGPA/EGA, Pharmaciens Sans Frontières, WSMI Round Table meetings on counterfeit drugs.

2001: WHA technical briefing on counterfeit drugs.

2004: International Conferences of Drug Regulatory authorities (ICDRA) in Madrid requested WHO to work at a draft international convention on counterfeit medicines.

2005-2006: No consensus among Member States on an international convention on counterfeit medicines.

2006, February: Rome conference recommended the establishment of an international taskforce.

2006, July: ToR and name International Medical Products Anti-Counterfeiting Taskforce (IMPACT) endorsed at a meeting in Rome.

2006, September: Circular Letter announcing the establishment of IMPACT to Member States.

2007, December: IMPACT “Draft Principles and Elements for National Legislation against Counterfeit Medical Products Background” document for a meeting of experts in Lisbon.

2009: Circular Letter C.L.25.2009 asking countries to comment on what descriptions are being used to describe a counterfeit medicine (60 responses received from various countries). The majority of Member States use “counterfeit” (34) in their national legislation. Other terms used are: “falsified” (5 non-English-speaking Member States) “illicit,” “illegal,” “unregistered,” “unauthorized,” 19 “adulterated.”

2016, November 23: Report of the informal technical working group on draft working definitions of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. This WHO working group agreed the following: “Based on the deliberation of the working group it is recommended that the Member State mechanism replace the use of ‘substandard/spurious/falsely-labelled/falsified/counterfeit medical products’ with ‘substandard and falsified medical products,’ as the term to be used in its name and in all future documentation on the subject of medical products of this type” (14).

TABLE II - Classification of medical products to be used by the WHO global surveillance and monitoring system and the Member State mechanism (taken from the World Health Organization, “Report of the informal technical working group on draft working definitions of substandard/spurious/false-labelled/falsified/counterfeit [SSFFC] medical products”) (14)

Substandard	Unregistered/Unlicensed	Falsified
Also called “out of specification,” these are authorized medical products that fail to meet either their quality standards, or their specifications – or both	Medical products that have not undergone evaluation and/or approval by the national/regional regulatory authority for the market in which they are marketed and/or distributed	Medical products that deliberately or fraudulently misrepresent their identity, composition, or source

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

Notes:

- i. Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purposes of sanctions imposed.
- ii. This includes any misleading statement with respect to name, composition, strength, or other elements.
- iii. This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder, or steps of distribution.
- iv. This refers to all components of a medical product” (20).

The issue of counterfeit medicines was again on the agenda at the Sixty-Fourth World Health Assembly (WHA64) which took place in Geneva in May 2011. At the meeting, WHO Member States reached a stalemate with regard to the definition of “counterfeit medicines.” Differences between WHO Member States could not be resolved and, due to these divergent views, the Working Group requested that members consider extending the period set out in WHA63(10) (2010) “in order to allow the Working Group to complete its work.” After engaging in further deliberations, this extension was granted.

Importantly, positions remained polarized with regard to the linking of intellectual property to the issues of quality, safety, and efficacy of medicines.

In May 2012, the item was on the WHA agenda again, and WHO Member States passed Resolution WHA65.19 (2012), creating a new membership-driven mechanism to further discuss the issues (21).

“No universally agreed definition”

As outlined on the WHO’s website, “...there is currently no universally agreed definition amongst Member States.” The WHO continues to use the term “Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical product” (22). However, the recent recommendations by the

WHO working group (14) will have a significant bearing on the terminology to be used, and are described below.

The issues around not having a full consensus is that while SSFFC medicines are substandard, not all substandard medicines are spurious, falsely labeled, falsified or counterfeit. For instance, substandard medicines may include “accidental manufacturing errors or where a medical product has degraded due to poor storage” (22).

However, as they state, the term “counterfeit” is “widely used to include falsified, unlicensed, falsely packaged, stolen, and substandard medical products” (22).

It clearly can be seen that it has been a long road with many discussions and debates from which the definitions have slowly emerged; the term “torturous route” would not be an understatement, and it is a reflection on the challenges that arise from this complicated subject. Therefore, it is important to attempt to separate out the categories, as different strategies are required in each case. In this context, below are the definitions taken from the WHO November 23, 2016 “Report of the informal technical working group on draft working definitions of substandard/spurious/false-labelled/falsified/counterfeit (SSFFC) medical products” (14). Here, the working group recommended that the term “counterfeit” be dropped. This is because “...the terms of reference of the Member State mechanism on SSFFC medical products expressly exclude the protection of intellectual property rights from the mandate of the mechanism and, therefore, the same criteria shall be used in the definitions to be used in its deliberations and work. The term ‘counterfeit’ is now usually defined and associated with the protection of intellectual property rights. For reference purposes, the definitions of ‘trademark counterfeit goods’ and pirated copyright goods are included as defined under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)” (14) (Tab. II).

“Substandard”

“Member States have previously agreed on the terminology for substandard medical products.

Substandard medicines (also called out of specification products) are genuine medicines produced by manufacturers authorized by the National Medicines Regulatory Authority (NMRA) which do not meet quality specifications set for them by national standards” (22).

However, it could be argued that this definition falls under the newer definition as cited by the EU Commission for falsified medicines.

“Counterfeit”

“The term counterfeit is legally defined within intellectual property legislation, which deals with brand and trademark protection. This has been perceived to have reduced the focus from what is first and foremost a public health issue.

Jurisdictions across the world define counterfeit medicines in many different ways. Some Member States have based their national legislation on the previous WHO definition:

‘A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging.’

Other [WHO] Member States use the terms spurious or falsified, and various slightly different definitions exist in the National Legislation.

Whilst a universally WHO agreed definition has been recently established, it is unlikely to alter the position of the WHO Member States who already have legislation, and have relied on their own domestic criminal and regulatory laws to sanction offenders for many years.

In terms of data collection and analysis, it is important to identify and examine the actions, activities, and behaviors specific to each incident together with the characteristics of the suspected SSFFC medical product in order to determine the intentional or accidental aspects of the incident” (22).

The Medicrime Convention

It is important to note that the Medicrime Convention (23) represents another significant measure in combating falsified medicines, and that it does not seek to address issues concerning intellectual property rights. It is the only measure of this nature and it is to be welcomed as it focuses on the risk to public health. It is also the first international criminal law instrument to oblige States Parties to criminalize:

- the manufacturing of counterfeit medical products (note according to the Convention, “the term ‘counterfeit’ shall mean a false representation as regards identity and/or source”);
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents;
- the unauthorized manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements.

The Convention provides a framework for national and international cooperation across the different sectors of the public administration; measures for coordination at the national level; preventive measures for use by the public and private sectors; and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.

The following quote can be found in the Explanatory Report to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. It exemplifies the objective as one that strives to protect the health of individuals from being harmed by counterfeit medicines.

“Counterfeiting of medical products and similar crimes violate the right to life as enshrined in the European Convention on Human Rights and Fundamental Freedoms, as these criminal and dangerous conducts effectively deny patients the necessary medical treatment and may often be harmful to their health, sometimes even leading to the death of the patient or consumer” (24).

Whilst the Convention will continue to use the term “counterfeit,” it is intended that new materials relating to Convention topics will use the term “falsified” in the vast majority of instances.

Falsified medicine – the Falsified Medicines Directive

The Falsified Medicines Directive is probably the single most significant change to the European medicines supply chain in 50 years (25, 26). The Directive, published in 2011, “introduces tougher rules to improve the protection of public health with new harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled. The measures include:

- obligatory safety features on the outer packaging of the medicines which includes a unique serialized data matrix to enable verification of authenticity combined with tamper evidence seals;
- a common, EU-wide logo to identify legal online suppliers [...];
- tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and
- strengthened record-keeping requirements for wholesale distributors” (25).

It is important to note that this Directive states “the term ‘falsified’ does not include IP infringements or inadvertent manufacturing errors,” and that such falsified medicines are “a major threat to public health and safety. [...] Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international levels” (25).

The EU definition of falsified medicines

The European Commission Directorate for Public Health defines falsified medicines as “fake medicines that pass themselves off as real, authorized medicines. Falsified medicines might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose – either too high or too low. As they have not been properly evaluated to check their quality, safety and efficacy – as required by strict EU authorization procedures – this could be detrimental to health. Falsified medicines are a major threat to public health (the term ‘falsified’ refers to all forms of falsification, while the term ‘counterfeit’ specifically refers to an infringement [of

intellectual property rights). As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year” (25).

The Fakeshare projects

There are two major projects being undertaken, notably Fakeshare II and those carried out within the project Fake-share (I). Both projects are cofunded by the European Commission under the “Prevention of and Fight against Crime Programme,” with the aim of developing a structured system of sharing of information on illegal e-pharmacies and pharmacrime in general.

These sequential major projects (Fakeshare I has moved to Fakeshare II) are coordinated by the Italian Medicines Agency (AIFA) and cofunded by the “Prevention of and Fight against Crime Programme” of the EU. These projects have contributed greatly to the language used through the many reports that have been published and the material contained within their website (<http://www.fakeshare.eu/en>).

- The project aims at developing coordinated initiatives (such as investigation, campaigning, training) against the illegal distribution of medicines, with the goal of optimizing the use of resources in activities developed at national and international levels, by:
- ensuring the coordination of investigation activities and police force initiatives;
- targeting the illegal web distribution of medicines;
- sharing information between countries with similar scenarios.

From May 2013 to April 2015 Fakeshare developed and offered a web platform and cooperative web tools for strategic prevention and action against the use of the internet as a support to the distribution of counterfeit medicines and, in general, for counteracting pharmacrime.

In its “Vademecum,” (27) Fakeshare appears to use the term “falsified” as an over-arching term, but for the vast majority of descriptions the word “counterfeit” is used. This can be seen in the opening section on page 2 where the heading is FALSIFIED MEDICINES but within the remainder of the text the term counterfeit is used comprehensively. However, it is equally important to note that under the “Documents” section of the website the leading article clearly prefers the term “falsified” as can be seen here:

“Falsified medicinal products made by manufacturers: a real possibility”

“1. Falsification: the general framework

The first case of a falsified medicinal product occurred in 1937 when an American pharmaceutical company, [to increase] its sale-volumes, used di-ethylenglycol (a toxic solvent) to manufacture a syrup containing sulfanilamide and more than 100 people, including a lot of children, died.

The company was charged [with] ‘misbranding’; this term is usually used to mean ‘inaccurate and false labelling’” (28).

Counterfeit vs. falsified vs. fake?

So we now have a clear segmentation of definition beginning to appear, with the term “counterfeit” gradually becoming more associated with intellectual property rights (notwithstanding the fact that the Medicrime Convention has used the term “counterfeit” in relation to matters pertaining to public health). The second term emerging is “falsified” and this is primarily centered around the threat to public health and, therefore, patient safety. Notably, future material in connection with the Medicrime Convention will use the term falsified in the majority of cases.

But these are hardly user-friendly terms for the lay person. Surely we need a word that is immediately understood and thus enables communication to be optimized. Perhaps the word “fake” is the most appropriate term? The Collins English dictionary describes fake as: “to cause (something inferior or not genuine) to appear more valuable or real by fraud or pretence” (29).

The term “fake” is already becoming more widely used by those seeking to raise public awareness. The Alliance for Safe Online Pharmacy EU recently published a report entitled “Fighting Fakes by Raising Public Awareness” (30). This was an interim report on a powerful Google AdWord campaign. Over 13,500 Google first page results per day were exposing the Italian public to such a term.

The European Directorate for the Quality of Medicines & Healthcare (EDQM) has been very active in coordinating an innovative public-facing campaign entitled “Open Mind, Free Minds: a psycho-pedagogical concept guide for teachers” (31). This project was financed by the EDQM and had 6 consultants: (3 psychologists in Italy, 1 artist in Serbia, 2 information technology experts Italy/Serbia), and 2 coordinators: AIFA (32) and the Medicines and Medical Devices Agency of Serbia (ALIMS) (33). This was a science-based concept to arrive at the key messages. Two age groups, 8-11 and 12-15, were focused on. The communication strategy used an interactive story where the reader could choose different outcomes. The graphics were innovative and were drawn to capture the imagination of the age group concerned. The materials used were print, PDF, and Webcomic versions. The teaching concept was designed by psychologists and the base structure comprised a web tool and teaching tool.

Similarly, the organization “Fight the Fakes,” with over 34 active members, uses this term (34). This organization’s objective is to make fake medicines everybody’s business and these are their reasons:

- because they are deceitful, illegal and dangerous;
- because fake medicines put patients at risk of further illness, disability or even death;
- because fake medicines undermine public trust in health-care professionals and in health systems;
- because fake medicines harm, not heal;
- because fake medicines put the health of whole communities in danger by exposing them to greater drug resistance (34).

Similarly, the International Institute of Research Against Counterfeit Medicines uses the term “fake” when it communicates to the public. They recently launched a campaign to the public entitled “IRACM launch a France-wide awareness campaign about the hidden side of illegal e-pharmacies” (35).

ASOP Global has numerous educational activities and educational materials, and endorses the term “fake” for communicating to the lay person (36).

Member State activity to raise public awareness

The Falsified Medicines Directive (26) Member States contains an important article that will undoubtedly have a bearing on the public's knowledge of falsified or fake medicines in the future. This is because the Directive obliges each Member State to inform the public about falsified medicines and the purpose of the Common Logo:

“Article 85d

Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website” (26).

Already we are seeing useful communication campaigns by a number of Member States, some of which can be found here:

1. The Medicines & Healthcare Products Regulatory Agency (MHRA) in the UK (37-39). The ASOP EU has a 2017 objective to continue to support the “Best Practice” seminar so that Member States and nonprofit patient organizations can combine their skills and experience to further this goal.
2. The Netherlands campaign, Drugs Online de echt of nep quiz – Think Carefully before you do anything (40).
3. The Federal Agency for Medicines and Health Products – Belgian campaign (41-44).
4. The Agency of Spain for Medicines and Health Products (AEMPS) (45).

Conclusion

We now have a growing consensus around 3 key definitions to describe a medicine that is not what it purports to be, namely: falsified, counterfeit, and fake. Each term has its own important place and use. We can state now that the term “falsified” is concerned with public health and “counterfeit” is more connected with intellectual property. Both are equally important and useful terms in their own right and lend themselves to dealing with the “supply side” and help to determine which law enforcement approach is most pertinent. However, for the “demand side” created by the public buying medicines, then it can be argued that the term “fake” has the most resonance with the general public who need to be made aware of the dangers.

It is the role of governments, businesses, and all stakeholders to continually raise public awareness in this area. Surveys clearly show that there is an absolute need for this. In the HappyCurious survey covering 5 European countries – notably France, Spain, Germany, Italy, and the UK – involving 5,010 people, whilst a majority (66%) have heard of fake medicines, respondents seem to have little information about them, and 77% say they have not been adequately informed (46).

This is no more eloquently put by the Fondation Chirac, which calls for “A global and permanent mobilization” and states:

“The scourge of falsified medicines is rarely featured in the media and is little understood by the general public and political authorities. Becoming aware of the problem is the first, essential step to effectively battle the scourge and to better protect Public Health” (47).

It is the duty of us all to support this important educational need as well as continue the good work of all of the agencies involved in eradicating this patient and consumer safety issue. Therefore, a mutual understanding and acceptance of a “common” language is essential.

This article has collected the views of many of the organizations mentioned to provide an authoritative endorsement for the 3 major definitions described, and represents a growing consensus to use the terms: falsified, counterfeit, and fake in the context of medicines and public health.

Glossary

1. **SSFFC:** substandard, spurious, falsely labelled, falsified, and counterfeit. A WHO-created term in wide use in many WHO Member States.
2. **Counterfeit medicine:** a widely used term to include falsified, unlicensed, falsely packaged, stolen, and substandard medical products. This term is more often used to describe a situation that involves an intellectual property crime.
3. **Falsified medicines:** these are fake medicines that pass themselves off as real, authorized medicines. Falsified medicines might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose – either too high or too low. The term “falsified” refers to all forms of falsification, while the term “counterfeit” specifically refers to an infringement of intellectual property rights.
4. **Fake medicine:** a term becoming more popular to use when communicating to the public about a falsified or counterfeit medicine.

Other terms

1. ASOP EU – the Alliance for Safe Online Pharmacy in the EU: a collaboration of stakeholders to combat fake medicines that can be bought on illegally operating websites.
2. ASOP Global – the Alliance for Safe Online Pharmacies (US based): a collaboration of stakeholders to combat fake medicines that can be bought on illegally operating websites.
3. CSIP – The Center for Safe Internet Pharmacy (US based): a collaboration of internet and intermediary stakeholders



to combat fake medicines that can be bought on illegally operating websites.

4. Fight the Fakes: a campaign that gives a voice to those who have been personally impacted, and shares the stories of those working to put a stop to the threat to public health of fake medicines.
5. Fondation Chirac: a foundation supporting all actions aiming to ensure access to certified medicines.
6. EAASM – the European Alliance for Access to Safe Medicines: an alliance dedicated to protecting patient safety by ensuring access to safe and legitimate medicines and safe medical practices.
7. IRACM – International Institute of Research Against Counterfeit Medicines: an independent international organization that is dedicated to the fight against counterfeiting and falsification of drugs, primarily through information, prevention and training.
8. LegitScript: this site supports companies, and Internet users decide which websites are trustworthy, and why.
9. FakeShare: a project coordinated by the Italian Medicines Agency (AIFA), which is aimed at developing coordinated initiatives (such as investigation, campaigning, and training) against the illegal distribution of medicines.

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References

1. Pharmaceutical Security Institute. Incident Trends. <http://www.psi-inc.org/incidentTrends.cfm>. Accessed November 25, 2016.
2. 20 Shocking Counterfeit Drugs Statistics. Health Research Funding.org. <http://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/>. Published December 19, 2014. Accessed November 28, 2016.
3. WHO. IMPACT, Counterfeit Drugs Kill! https://www.gphf.org/images/downloads/library/whoimpact2008_counterfeit_drugs_kill.pdf. Updated May 2008. Accessed November 25, 2016.
4. Interpol. Pharmaceutical crime – the dangers. <https://www.interpol.int/Crime-areas/Pharmaceutical-crime/The-dangers>. Accessed November 30, 2016.
5. European Alliance for Access to Safe Medicines. The counterfeiting superhighway: the growing threat of online pharmacies. <http://www.eaasm.eu/index.php?cID=21&cType=document&download=1>. Accessed December 12, 2016.
6. European Alliance for Access to Safe Medicines. Counterfeiting the counterfeiter. <http://www.eaasm.eu/cache/downloads/av3r9187z4wg4ocs8w84gogs0/CtC%20report%202012.pdf>. Accessed December 12, 2016.
7. Fight the Fakes. Same Packaging But Fakes. [Infographic] <https://www.flickr.com/photos/fightthefakes/24990576862/>. Accessed December 8, 2016.
8. LegitScript. Confident compliance. <https://www.legitscript.com/>. Accessed November 25, 2016.
9. Akhras K. Economic burden of counterfeit medicine in Africa: situation analysis and proposed solution. Presented at ISPOR Annual European Meeting – Africa Network Forum; October 31, 2016; Vienna, Austria. <http://www.ispor.org/Event/GetReleasedPresentation/874>. Accessed November 28, 2016.
10. Mages R, Kubic TT. Counterfeit medicines: Threat to patient health and safety. *Pharmaceuticals Policy and Law*. 2016;18:163-177. <http://www.ifpma.org/wp-content/uploads/2016/11/15.-Counterfeit-Medicines-Threat-to-Patient-Health-Safety.pdf>. Published October 9, 2016. Accessed November 25, 2016.
11. Pharmaceutical Security Institute. <http://www.psi-inc.org/index.cfm>. Accessed November 25, 2016.
12. ALPhA, Auswirkungen der Liberalisierung des Internethandels in Europa auf den Phänomenbereich der Arzneimittelkriminalität. [Effects of the liberalization of the Internet trade in Europe on the phenomenon of pharmaceutical crime.] Universität Osnabrück. <https://www.alpha.uni-osnabrueck.de/en/final-conference.html>. Accessed December 8, 2016.
13. Interpol. Online sale of fake medicines and products targeted in INTERPOL operation. <https://www.interpol.int/News-and-media/News/2016/N2016-076>. Published June 9, 2016. Accessed November 25, 2016.
14. World Health Organization. Report of the informal technical working group on draft working definitions of standard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. http://apps.who.int/gb/ssffc/pdf_files/MSM5/A_MSM5_7-en.pdf. Published November 23, 2016. Accessed December 6, 2016.
15. European Union Intellectual Property Office. The economic cost of IPR infringement in the pharmaceutical sector. https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/resources/research-and-studies/ip_infringement/study9/pharmaceutical_sector_en.pdf. Accessed November 25, 2016.
16. WHO. Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products [fact sheet]. <http://www.who.int/mediacentre/factsheets/fs275/en/>. Accessed November 25, 2016.
17. WHO Division of Drug Management & Policies. Counterfeit drugs report of a WHO/IFPMA Workshop 1-3 April 1992. <http://apps.who.int/medicinedocs/documents/s16244e/s16244e.pdf>. Accessed November 30, 2016.
18. Kopp S. WHO presentation: Counterfeiting: An overview of problems and dangers. http://www.google.co.uk/url?sa=t&ct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwipq6y7wMTSAhWhJ5oKHcopDbIQFgghMAA&url=http%3A%2F%2Fwww.whcaonline.org%2Fuploads%2FWHEN%2520WHA%25202009%2F07SKopp%2FSabine%2520Kopp.ppt&usq=AFQjCNH2QwYT-C16p78dKj191DIHACPvug&sig2=X-Mb8kyc6_Mq5nQdrpXDGG. Accessed February 27, 2017.
19. Interpol. Tunisia hosts international taskforce meeting supported by INTERPOL in drive against fake medicines. <https://www.interpol.int/News-and-media/News/2008/PRO75>. Accessed February 9, 2017.
20. Forzley M. The Nomenclature and Definition of Counterfeit Medical Products. On global forum on law justice and development. <http://www.globalforumljd.org/sites/default/files/docs/library/WHO-Evolution%20of%20Definitions%20Definition.pdf>. Accessed February 9, 2017.



21. GHD-NET. Substandard, spurious, falsely-labelled, falsified, or counterfeit (SSFFC) medicines. <http://www.ghd-net.org/negotiations/substandard-spurious-falsely-labelled-falsified-or-counterfeit-ssffc-medicines>. Accessed November 25, 2016.
22. WHO. Definitions of SSFFC medical products. <http://www.who.int/medicines/regulation/ssffc/definitions/en/>. Accessed November 25, 2016.
23. Council of Europe. The MEDICRIME convention. <http://www.coe.int/en/web/medicrime/the-medicrime-convention>. Accessed February 9, 2017.
24. Council of Europe. Explanatory report to the Council of Europe convention on the counterfeiting of medical products and similar crimes involving threats to public health. <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016800d383b>. Accessed February 9, 2017.
25. European Commission on Public Health. Medicinal products for human use – falsified medicines. http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm. Accessed November 25, 2016.
26. European Commission on Public Health. Falsified Medicines Directive. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf. Accessed February 14, 2017.
27. Fakeshare.eu. Vademecum. <http://www.fakeshare.eu/sites/default/files/downloads/Vademecum.pdf>. Accessed February 9, 2017.
28. Fakeshare.eu. Falsified medicinal products made by manufacturers: a real possibility. <http://www.fakeshare.eu/en/docs/528>. Accessed February 9, 2017.
29. Collins Dictionary. Definition of fake. <http://www.collinsdictionary.com/dictionary/english/fake>. Accessed November 25, 2016.
30. European Alliance for Access to Safe Medicines. The Alliance for Safe Online Pharmacy in the EU. Fighting fakes by raising public awareness. <http://asop.eu/cache/downloads/8h23cbi9xo8w4o0k8o0gwo04w/Fighting%20Fakes%20by%20Raising%20Public%20Awareness%20-%20ASOP%20EU%20and%20EAASM%20report%20May%2019%202016.pdf>. Accessed November 25, 2016.
31. Council of Europe. Counterfeit medicines & similar crimes publications. <https://www.edqm.eu/en/Counterfeit-medicines-and-similar-crimes-1625.html>. Accessed February 14, 2017.
32. Agenzia Italiana del Farmaco. Italy and Serbia have signed an agreement for the exchange of information on medicines. <http://www.aifa.gov.it/en/content/italy-and-serbia-have-signed-agreement-exchange-information-medicines>. Accessed February 14, 2017.
33. ALIMs. Medicines and Medical Devices Agency of Serbia. <http://www.alims.gov.rs/eng/>. Accessed February 14, 2017.
34. Fight the Fakes. <http://fightthefakes.org/>. Accessed November 25, 2016.
35. International Institute of Research Against Counterfeit Medicines. IRACM launch a France-wide awareness campaign about the hidden side of illegal e-pharmacies. <http://www.iracm.com/en/2016/11/iracm-launch-france-wide-awareness-campaign-hidden-side-illegal-e-pharmacies/>. Accessed November 25, 2016.
36. Alliance for Safe Online Pharmacies. Public awareness materials. <http://safeonlineRx.com/public-awareness/>. Accessed November 25, 2016.
37. Medicines and Healthcare products Regulatory Agency. Dodgy diet pills: dying to lose weight? <https://www.gov.uk/government/news/dodgy-diet-pills-dying-to-lose-weight>. Accessed February 14, 2017.
38. Medicines and Healthcare products Regulatory Agency. Count down to Christmas with the FakeMeds advent calendar. <https://www.gov.uk/government/news/count-down-to-christmas-with-the-fakemedes-advent-calendar>. Accessed February 14, 2017.
39. Medicines and Healthcare products Regulatory Agency. Slimming pills Dying to lose weight? <https://fakemedes.campaign.gov.uk>. Accessed February 14, 2017.
40. Ministerie van Volksgezondheid Welzijn en Sport. De Echt of Nep? Quiz: the real or fake? <http://www.echt-of-nep.nl>. [In Dutch] Accessed February 14, 2017.
41. Federal Agency for Medicines and Health Products. Medicines over the internet? Do not surf with your health! http://www.geneesmiddelen-via-internet.be/nl/pdf/AFMPS_Leaflet_NL.pdf. [Leaflet in Dutch] Accessed February 14, 2017.
42. Federal Agency for Medicines and Health Products. Medicines over the internet? Do not surf with your health! http://www.medicaments-par-internet.be/fr/pdf/AFMPS_Leaflet_FR.pdf. [Leaflet in French] Accessed February 14, 2017.
43. Federal Agency for Medicines and Health Products. <http://www.geneesmiddelen-via-internet.be/nl/>. [In Dutch] Accessed February 14, 2017.
44. Federal Agency for Medicines and Health Products. <http://www.medicaments-par-internet.be/fr/>. [In French] Accessed February 14, 2017.
45. Logotipo común europeo, European common logo on Agencia española de medicamentos u productos sanitarios. <https://distafarma.aemps.es/farmacom/faces/templates/estaticas/logotipoEuropeo.xhtml>. [In Spanish]. Accessed February 14, 2017.
46. HappyCurious for Sanofi. Europeans and counterfeit medicines. http://www.happycurious.fr/wp-content/uploads/2016/07/36553_2014-05-15_Counterfeit_medicines_EN.pdf. Accessed November 25, 2016.
47. Fondation Chirac. A global and permanent mobilization. <http://www.fondationchirac.eu/en/conflicts-prevention/access-to-medicine/learn-more-about-fake-medicines/global-and-permanent-mobilization/>. Accessed November 25, 2016.
48. World Health Organization. Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. http://apps.who.int/iris/bitstream/10665/65892/1/WHO_EDM_QSM_99.1.pdf. Accessed November 25, 2016.