



Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?

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Centre on Global Health Security | November 2010 | GH BP 2010/01

Summary points

- Counterfeit, falsified and substandard medicines pose a serious threat to human health, particularly in poorer countries with weak regulatory mechanisms.
- But the relationship between combating counterfeit medicines, addressing safety, quality and efficacy issues and enforcing privately owned intellectual property rights has become controversial.
- There are concerns that a wider definition of 'counterfeit' threatens the trade in generic medicines of assured quality on which many developing countries depend; and about the legitimacy of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), the detention of generic drugs in transit in the European Union, and the negotiation of the Anti-Counterfeiting Trade Agreement (ACTA).
- 'Counterfeit' has a specific meaning in intellectual property, related to wilful trademark violations. But in relation to medicines it is now sometimes used in a much broader sense to do with misrepresentation of identity or source, or even medicines that are simply 'substandard'.
- Some countries use the term 'falsified' to describe medicines that misrepresent their identity or source, but do not necessarily violate intellectual property rights.
- 'Substandard' medicines are those that do not meet quality standards specified for them, but may also be defined specifically to cover products from authorized manufacturers which fail to meet quality standards set for them.
- Failure to reach agreement on the definitions of counterfeit, falsified and substandard medicines hampers the constructive policy debate and collaboration at the international level that are necessary to take effective action against the producers and distributors of these medicines.

Introduction

Counterfeiting – literally copying or imitating – has been practised for millennia. Counterfeiting of money is its oldest form and has been around almost since coins were invented. The United States Secret Service was established in 1865 for the express purpose of suppressing counterfeit currency and this remains one of its major functions. For a long time, money counterfeiting was predominant. However, in the modern age, counterfeiting is most often associated with the imitation of major brand-name consumer goods.

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For many goods, such as clothing or accessories, the effect of counterfeiting is principally financial and economic. Employment and income may be diverted from brand-name manufacturers to counterfeiters, and consumers may benefit from lower prices or lose from poor-quality imitations. Essentially, income is redistributed between brand owners, counterfeiters and consumers. The extent to which the economic losses fall on the brand owner is disputed, because counterfeiting may also expand the market for a brand.

In the case of food, medicines, cosmetics and some other goods, counterfeiting can also pose a serious threat to human health because products are likely to

be either substandard or contain positively dangerous components or ingredients. This kind of counterfeiting is thus qualitatively different from, for example, a fake Rolex watch.

Counterfeit, falsified and substandard medicines pose a considerable threat to health. Although detailed knowledge of their prevalence and impact on human health is limited, they can fail to cure, promote antimicrobial resistance, and ultimately kill. The threat from these medicines is probably growing, particularly in poorer countries with weak regulatory mechanisms and poorly monitored distribution networks. Counterfeiting can be very profitable and counterfeiters are becoming increasingly sophisticated. This makes patients in developing countries particularly vulnerable, since they usually have to buy medicines from their own resources.

The context

The World Health Organization (WHO) has played the major role in highlighting the issue of counterfeit medicines, beginning with a 1985 Nairobi Conference of Experts on the Rational Use of Drugs, which considered that the WHO ‘should study the feasibility of setting up a clearing house to collect data and inform governments about the nature and extent of counterfeiting’.¹

In 1988, a World Health Assembly (WHA) Resolution (41.16) went further and called for the WHO ‘to initiate programmes for the prevention and detection of export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations’.² These activities culminated in the launch in 2006 of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) – see Box 1.

But the issue of counterfeit medicines has now become extremely controversial. The definition of counterfeit medicines first devised by the WHO in 1992 and revised by IMPACT in 2008 has generated

¹ <http://apps.who.int/medicinedocs/documents/s17054e/s17054e.pdf>.

² <http://apps.who.int/medicinedocs/documents/s16244e/s16244e.pdf>.

continuing controversy by combining the concept of counterfeiting – which has a specific meaning in relation to intellectual property – with issues related to the quality, safety and efficacy of medicines.

In particular, concerns have been raised that this definition might lead to threats to the legitimate trade in generic drugs of assured quality. These concerns have been exacerbated by the detention in the European Union in 2008 of generic versions of brand-name drugs in transit from India to other developing-country markets on the grounds that they were infringing European patents (see Box 2); and by suspicions over the possible impact of the Anti-Counterfeiting Trade Agreement (ACTA) being negotiated between developed countries and some emerging economies to establish tougher international standards for intellectual property rights enforcement (see Box 3).

Some countries strongly contend that counterfeiting is principally an issue of intellectual property, and expressed their concern that the WHO, by using the term ‘counterfeit’ and providing the secretariat for IMPACT, was becoming involved in the enforcement of privately owned intellectual property rights without the endorsement of all member states in the WHA. Rather,

they argued that the WHO’s role should be to combat substandard drugs – of whatever origin – as part of its mandate to protect public health.

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Following intensive discussions at the WHA in 2010, WHO member states decided to set up an intergovernmental group to make recommendations by May 2011 on the WHO’s role with regard to counterfeit, falsified and substandard medicines, and its relationship with IMPACT.

Box 1: IMPACT

In February 2006, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce. IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of counterfeit medicines. It is a partnership comprised of all the major anti-counterfeiting players, including international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers’ associations and drug regulatory authorities.

IMPACT includes representatives from the following organizations: Interpol, Organization for Economic Cooperation and Development (OECD), World Customs Organization, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical Manufacturers’ Associations, International Generic Pharmaceuticals Alliance, World Bank, European Commission, Council of Europe, ASEAN Secretariat, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and Pharmaciens sans Frontières.

IMPACT is comprised of five working groups, which address the areas where action is needed to combat the spread of counterfeits: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication.

Box 2: EU detentions

In 2008 and 2009 there were at least 19 detentions by customs authorities of medicines in transit through the EU from the source country to destinations in Latin America and elsewhere. Most of these detentions ('seizures' according to critics) occurred in the Netherlands, and 16 involved medicines manufactured in India. These detentions took place under an EU regulation (1383/2003) introduced in 2003 that permitted action against goods infringing intellectual property rights, including goods in transit. In most of the cases, the detentions appeared to be on the grounds of suspected patent infringements in the Netherlands, even though the products were not patented in India or the destination country.

India, Brazil (the destination of at least one shipment) and NGOs involved with access to medicines expressed concern that the detentions threatened the trade in legitimate generic products, and in particular that they could curtail access to medicines in developing countries, which mainly consume more affordable generic products produced in India or other developing countries.

Brazil, India and other developing countries raised these issues at the WHO Executive Board meeting in January 2009, and subsequently at a meeting of the TRIPS Council of the World Trade Organization (WTO). The TRIPS Council is the member state body established under the WTO for administering the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is part of the agreements made when the WTO was established in 1995. Both Brazil and India argued that the actions by the EU and the Netherlands authorities were contrary to the principles of the General Agreement on Tariffs and Trade (GATT), another part of the WTO agreements to promote free trade and tariff reductions, by restricting the free movement of goods, and contrary to various parts of the TRIPS agreement itself. The EU argued that the regulations in question were compatible with TRIPS, that confiscating (genuinely) counterfeit medicines in transit was beneficial to third countries with less capacity for identifying them, and that whether or not goods in transit infringed patents was a matter of national rather than EU law.

Both India and Brazil submitted to the WTO in May 2010 a 'request for consultations' with the EU and the Netherlands, which is the first step in the WTO's dispute settlement process. These requests elaborate the various ways in which EU and Dutch laws and regulations may be contrary to the WTO GATT and TRIPS agreements. If consultations do not result in agreement between the parties, then the complainants may request a dispute settlement panel, which can take up to a year to report. Meanwhile, the EU has launched a consultation on the relevant EU regulation with a view to making possible amendments, one aspect of which is the treatment of goods in transit.

What are counterfeit medicines?

Policy debates about counterfeit medicines have been bedevilled by a lack of clarity over what exactly they are. Because 'counterfeit' is such a widely used term in common parlance, it is often assumed that there is no need to define its usage in a particular context. But this is an error. The lack of clarity has in fact contributed significantly to current controversies over how best to address the problem of counterfeit medicines.

National definitions of counterfeit, falsified and substandard drugs vary widely (see Annex for a selection of international and national definitions). The WHO is also undertaking a survey of national legislation on 'counterfeit medicines', and the draft results illustrate the extreme diversity of national usage of these terms.³ Nevertheless it remains important to strive for agreement at the international level on the basic concepts and definitions related to these medicines in order to facilitate reasoned policy discussion based on common understandings.

³ http://www.who.int/medicines/services/counterfeit/WHO_ACM_Report.pdf.

Box 3: Anti-Counterfeiting Trade Agreement (ACTA)

The Anti-Counterfeiting Trade Agreement (ACTA) seeks to coordinate international cooperation on intellectual property rights enforcement practices to tackle counterfeit and pirated goods. It is currently being negotiated by Australia, Canada, the European Union, Japan, Mexico, Morocco, New Zealand, the Republic of Korea, Singapore, Switzerland and the United States.

ACTA has three main objectives:

- better coordination of international cooperation;
- establishing best practice in enforcement methods;
- providing a more coherent legal framework.

According to participants, ACTA does not intend to create new intellectual property rights but will focus on better enforcement of already established intellectual property rights, and will be consistent with the WTO's TRIPS Agreement. Rather, the intention is to create improved international standards on how to take action against large-scale infringements of intellectual property rights.

Many of the concerns over ACTA arose from the lack of transparency in the negotiation process, which made some observers suspicious about the nature of the provisions being negotiated. In response to these concerns, a draft text was released in April 2010 that included bracketed text proposals, but omitted attribution to the proposers. In October 2010 a consolidated and largely finalized text of the proposed agreement was published after a final round of negotiations in Tokyo.

In terms of content, critics tended to focus on the provisions relating to copyright and the internet. As regards access to medicines, the concerns very largely coincided with those relating to the EU detentions of medicines, and in this regard the key question on whether ACTA would include the enforcement of patent rights, and more specifically the detention of goods in transit because of patent infringements. This is because the EU wanted to introduce into ACTA provisions contained in EU regulation 1383/2003, in particular to cover goods in transit and to widen the scope beyond piracy (copyright) and counterfeiting (trademark infringement) to all other intellectual property rights. A broader suspicion was that this was part of the strategy of developed countries to ratchet up intellectual property rules in ways that go beyond TRIPS, and that these rules would subsequently be imposed on non-ACTA signatories and ultimately lead to a reduction in the legitimate trade in generic medicines.

In the event, the nearly final agreement does cover patents along with other intellectual property rights covered by the TRIPS agreement, but the parties have agreed that patents are not within the scope of the contentious section on border measures.

Counterfeits in intellectual property

In the world of intellectual property, counterfeiting tends to have a precise meaning related to trademark violation. For instance, the WTO glossary defines it as follows:

Unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods.⁴

⁴ http://www.wto.org/english/thewto_e/glossary_e/counterfeit_e.htm.

This reflects, although not entirely accurately, the definition reached in the WTO TRIPS Agreement, which refers only to ‘counterfeit trademark goods’:

... ‘counterfeit trademark goods’ shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.⁵

Thus counterfeiting in the WTO and the TRIPS Agreement refers specifically to unauthorized use of a trademark. It should be borne in mind that trademarks, like other intellectual property rights, are private rights. It is up to the owner of the trademark to enforce it against infringers. Therefore, counterfeiting, where criminal penalties apply, needs to be distinguished from the normal case of simple trademark infringement, where civil procedures apply and it is for the trademark owner to initiate proceedings. The TRIPS Agreement obliges WTO members to apply criminal penalties for ‘wilful trademark counterfeiting ... on a commercial scale’.⁶ However, under TRIPS and in most national laws, trademark infringement is generally a matter of civil law (for instance where the activity cannot easily be proved to be wilful, or where the trademark is not identical but very similar) and cannot be regarded as counterfeiting. In TRIPS, the owner of a registered trademark has ‘the exclusive right to prevent all third parties not having the owner’s consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion’.⁷ Thus, for

example, use of a non-identical sign could result in a civil case of trademark infringement being successful if it was held by the court that confusion with the original brand was likely.

Even where there is no trademark infringement (or the trademark is not registered), many countries have common-law offences related to ‘passing off’, where brand owners may seek civil remedies. In India, there are many cases where civil proceedings have been launched to prevent the sale of medicines with similar brand names under the Trademark Act, for infringement and/or on the grounds of ‘passing off’. For instance, in 2005 GlaxoSmithKline (GSK) was successful in gaining an injunction against Unitech Pharmaceuticals, preventing it from selling medicines under the brand name FEXIM and with similar packaging to its own registered brand PHEXIN.⁸ Other cases arise specifically in respect of medicines because brand names may be derived from the generic name of the drug.

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Thus counterfeiting is a particular facet of trademark infringement, characterized by the ‘unauthorized’ use of a trademark that not only infringes a trademark

⁵ http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

⁶ TRIPS Agreement, Article 61.

⁷ TRIPS Agreement, Article 16.1.

⁸ <http://www.indianmi.org/legal.htm>.

owner's legitimate rights but does so in such an egregious way as to attract criminal penalties.

Although these understandings of the meanings of counterfeits and trademark violations are common ground in the intellectual property community, various organizations have sought to give counterfeiting a much wider scope, covering almost the whole spectrum of intellectual property rights. For example, according to a recent OECD report,

The types of intellectual property rights most implicated in counterfeit finished pharmaceutical products include patents, trademarks and industrial design. The infringement of patent rights occurs when there is the unauthorised production, use, sale, importation of a patented active ingredient or excipient, or use of a process or method.⁹

The word 'counterfeiting' is commonly used very loosely in policy discussions to include infringement of any intellectual property right. For example, although EU legislation on border controls makes a clear distinction between counterfeiting (trademarks), piracy (copyright) and other forms of intellectual property infringement (including patents), the 2007 European Commission report on its implementation failed to make this distinction, using the title *Report on Community Customs Activities on Counterfeit and Piracy*. The title of the report for 2008, published in July 2009 following the controversy over medicines seizures in the EU under this legislation, was changed to *Report on EU Customs Enforcement of Intellectual Property Rights*.¹⁰ Similarly the EU, along with Switzerland and Japan, sought to include in ACTA provisions covering all intellectual property rights, including patents. Switzerland, however, in its Patent Act specifically excludes from border measures goods in transit that are exclusively infringing a patent in Switzerland but not in the exporting or importing country, thereby ensuring that legitimate generics will not be detained in transit.

‘ For a number of reasons many countries, including the US and the UK, are opposed to extending criminal sanctions to patent infringement ’

A closely related issue is that of the distinction between criminal and civil penalties. The TRIPS Agreement obliges countries to have in place criminal sanctions for trademark counterfeiting, as described above, but envisages the possibility that countries *may* invoke criminal procedures for infringements of other intellectual property rights. For a number of reasons – including the complexity of patent law, the absence of certainty of the legal validity of a patent until tested in a court of law, and the impossibility of law enforcement agencies determining whether or not a patent is being infringed – many countries, including the US and the UK, are opposed to extending criminal sanctions to patent infringement.

It is important to note that counterfeiting laws, or those covering other infringements of intellectual property rights, are generic in application and not specifically or even particularly directed at medicines. These laws are designed to protect and enforce private rights, and the rights holder is generally responsible for pursuing potential infringers in the civil court. The logic behind criminal sanctions for wilful and commercial counterfeiting (or piracy in respect of copyright) derives from analogy with theft of physical property. It is not in any way related to the harm that might be caused by consuming such goods, or concerns about the quality of such goods. It is the tension between the enforcement of private property rights and the threat to public health posed by counterfeit medicines that is at the heart of the controversy about anti-counterfeiting efforts.

⁹ *The Economic Impact of Counterfeiting and Piracy* (Paris: OECD, 2008), p. 347. <http://browse.oecdbookshop.org/oecd/pdfs/browseit/9208041E.PDF>.

¹⁰ http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm.

What are counterfeit medicines?

At a workshop organized by the WHO and the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) in 1992, participants agreed on the following definition of counterfeit medicines:

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 active ingredients or with fake packaging.¹¹

It can be seen that this definition bears little relationship to the rather precise definitions in international and national law relating to counterfeiting. The first sentence bears some resemblance to 'passing off' in the

intellectual property sense. It says nothing about quality, only that a deliberate deception is involved concerning the identity or source of the medicine. It has the effect of defining as counterfeiting a wide range of actions that would not be classified as counterfeiting under most national laws, although they might well attract civil or even criminal penalties on other grounds.

The second sentence is essentially descriptive and adds nothing concrete to the first sentence. But it does introduce the concept of quality by stating that counterfeits may, or may not, contain the right ingredients and – rather as an afterthought – have 'fake packaging'. The afterthought raises another question about the meaning of 'fake', and would appear, in any case, to be covered by the first sentence.

The distinguishing feature of medicines, as compared with almost all other products, is that a condition of their being legitimately marketed is the requirement for a rigorous approval process by a

Box 4: Definition developed by IMPACT

A medical product is counterfeit when there is a false representation [5] in relation to its identity [6] and/or source. [7] This applies to the product, its container or other packaging or labelling information.

Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components [8] or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

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 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.

5. Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purpose of sanctions imposed.

6. This includes any misleading statement with respect to name, composition, strength, or other elements.

7. This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

8. This refers to all components of a medical product.

Source: <http://www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf>

¹¹ <http://www.who.int/medicines/services/counterfeit/overview/en/>.

national medicines regulatory authority, such as the Food and Drug Administration in the United States or the European Medicines Agency in the EU. In practice, in many developing countries the regulatory authority may lack capacity, particularly the ability to control what appears on the market. However, at least in principle, there is a mechanism for controlling medicines quality that should prevent the marketing of substandard drugs, whether counterfeit or not.

This WHO definition, although never formally adopted by WHO member states (i.e. by the World Health Assembly), was broadly accepted by many stakeholders. Subsequently, an IMPACT meeting elaborated the WHO definition in 2007, and then revised it further in 2008, in response to concerns expressed in particular by the generic pharmaceuticals industry (see Box 4).

Essentially this version slightly amends the original WHO definition, widening the scope to cover all medical products, and making three additions that provide examples of what are not considered counterfeit products. The latter are designed to allay the fears of those manufacturers who felt threatened by the earlier IMPACT and WHO definitions; in particular their fears that legitimate generic drugs of assured quality might be regarded as counterfeit.

While this definition was accepted by the European Generic Association (EGA),¹² principally because it clarified that patent status should not be confused with counterfeiting, it failed to satisfy many developing-country delegates to the WHO Executive Board meeting in January 2009, or at the World Health Assembly in May 2010, when it was next discussed. They raised a number of issues concerning the involvement of the WHO in the enforcement of intellectual property rights, their perception of the legitimacy of IMPACT, and the apprehension that customs detentions in the EU of medicines in transit

mainly from India to other developing countries seemed to indicate a concerted threat to the generics industry.

‘ The distinguishing feature of medicines, as compared with almost all other products, is that a condition of their being legitimately marketed is the requirement for a rigorous approval process by a national medicines regulatory authority ’

Most African nations and developed countries support the WHO’s role as the secretariat of IMPACT. On the other hand, most South American and Asian nations are vigorous opponents of its involvement. The key issues as set out by its opponents are broadly as follows:

- Counterfeiting is an intellectual property concept, and should not be confused with issues concerning the safety, quality and efficacy of medicines. Specifically, they support the definition of counterfeiting contained in the TRIPS Agreement, with no amendments.
- The WHO, as a public health agency, should focus on quality, safety and efficacy, and these issues should not be viewed through an intellectual property lens. It is not the WHO’s role to act as an enforcer of intellectual property rights.
- IMPACT, the ‘seizures’ in the EU, and the anti-counterfeiting treaty (ACTA) are all manifestations of a ‘TRIPS-plus’¹³ agenda on the part of

¹² <http://www.egagenerics.com/pr-2008-12-08.htm>.

¹³ ‘TRIPS-plus’ is a commonly used phrase to indicate intellectual property rules or policies that go beyond what is contained in the TRIPS Agreement.

developed countries in league with pharmaceutical companies, aimed at harming sales of legitimate generic drugs.

- IMPACT lacks legitimacy and has no mandate from member states but seeks legitimacy through having WHO as a secretariat. IMPACT is not representative and its decision-making is opaque.

‘It is not at all clear how a ‘public health counterfeit’ differs from any product that contains the wrong ingredients’

The defence of the WHO Secretariat against these claims is as follows:

There is clear consensus among the Taskforce’s partners (i.e. IMPACT) that ‘counterfeit’ medicines should not be confused with issues relating to medicines that are not authorized for marketing in a given country, nor with patents violations or disputes. The word ‘counterfeit’ is also commonly used in relation to goods that infringe trademarks. Falsified or counterfeit medical products may infringe intellectual property rights, but whether a good is considered counterfeit from a public health perspective is independent of whether the product infringes intellectual property rights. According to its mandate, WHO is working on the issue of counterfeit medical products from a public health perspective. The other aspects, including the enforcement of intellectual property rights, come under the mandates of other bodies or international organizations.¹⁴

Although this is an attempt to clarify, in reality it creates further confusion by introducing the concept of a ‘counterfeit from a public health perspective’ that is independent of intellectual property status. But it is then not at all clear how a ‘public health counterfeit’ differs from any product that contains the wrong ingredients.

What are substandard medicines?

Just as ‘counterfeiting’ is often used loosely to refer to infringement of any intellectual property right, it is also commonly used synonymously with other words used to describe medicines whose quality is not assured (in particular substandard, spurious, fake or falsified). In fact, the original 1988 WHO resolution, quoted above, bracketed together ‘falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations’.

Almost universally, investigations of the counterfeit issue in the public health literature proceed by checking a sample of medicines to see to what extent they meet quality specifications. They are therefore assessing whether or not drugs contain the correct ingredients and the correct characteristics (e.g. bioavailability, dissolution). In one article, it is noted that ‘a set of drugs manufactured by Sapphire Lifesciences ... were all counterfeit as this company did not exist at the address mentioned on the packaging’.¹⁵ In fact, this is an attempt to mislead (probably on the part of a developing-country manufacturer) by purporting that the product comes from a certain developed country in order to take advantage of supposed African preferences for drugs produced in developed countries. Such drugs are not counterfeit in the intellectual property sense – there is no attempt to deceive customers into thinking they are buying an established brand – but they would be counterfeit in the WHO sense in terms of

¹⁴ http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_ID3-en.pdf.

¹⁵ Magnus A. Atemnkeng, Katelijne De Cock and Jacqueline Plaizier-Vercammen, ‘Quality Control of Active Ingredients in Artemisinin-derivative Antimalarials within Kenya and DR Congo’, *Tropical Medicine and International Health*, Vol. 12, No. 1 (January 2007), pp. 68–74, <http://www3.interscience.wiley.com/cgi-bin/fulltext/118506856/PDFSTART>.

the deception about their source. On this basis, they could well fall foul of a number of national laws on the grounds that they are deceiving the consumer as to the source of the drugs.

However, the article reveals that, while they were not approved for marketing in the country of sale, two of the three drugs manufactured by Sapphire had the correct active ingredient content, while one had 87.8% of the claimed content. Meanwhile, several of the medicines approved for marketing in other countries failed content tests. Without defining the terms, the authors concluded that ‘substandard compounds have the potential to do as much harm as counterfeit drugs or even more’. Thus here ‘substandard’ is used implicitly to mean a failure to meet specified quality standards.

‘ But it is clearly unsatisfactory to define substandard medicines as “genuine” and to confine their manufacture to only “authorized” manufacturers ’

The literature frequently makes little attempt to define exactly what is meant by counterfeit or substandard, as in the example above. The WHO’s 2003 definition of substandard was:

Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting. Counterfeit medicines are part of the broader

phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source.¹⁶

Under this definition there is no imputation of intent, which implies that marketing of substandard drugs may or may not be deliberate, and may or may not be the consequence of counterfeiting. However, current usage seems to imply that counterfeiting involves an element of deliberate deception whereas a substandard drug somehow involves an inadvertent failure to meet required standards or a result of deterioration or damage in the distribution chain.

Thus the WHO’s updated definition in 2009 is entirely different and specifically excludes counterfeits:

Substandard medicines (also called out of specification (OOS) products) are genuine medicines produced by manufacturers authorized by the NMRA [National Medical Regulatory Authority] which do not meet quality specifications set for them by national standards.¹⁷

The logic of this definition, derived in relation to the WHO definition of ‘counterfeit’, is that because counterfeit medicines are necessarily produced by an illegal manufacturer, then substandard medicines must be ‘genuine’ medicines produced by an ‘authorized’ manufacturer. But it is clearly slightly unsatisfactory to define substandard medicines as ‘genuine’ (presumably what is meant is ‘with the intent of producing genuine medicines’) and to confine their manufacture to only ‘authorized’ manufacturers. Moreover, it is self-contradictory. If the medicines were found by the local NMRA not to meet its quality standards, they should not be on the market (unless deterioration occurred in the distribution

¹⁶ <http://www.who.int/mediacentre/factsheets/2003/fs275/en>.

¹⁷ <http://www.who.int/medicines/services/counterfeit/faqs/06/en>.

chain). Common sense suggests that medicines with incorrect ingredients found in the marketplace may typically not have been submitted to the local NMRA by the manufacturer.

In an attempt to overcome some of these problems, the WHO has now proposed a further definition in May 2010 for consideration by its Expert Committee on Specifications for Pharmaceutical Preparations:

Each pharmaceutical product that a manufacturer produces has to comply with quality standards and specifications at release and throughout the product shelf-life required by the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable National Medicines Regulatory Authority before the product is authorized for marketing.

Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.¹⁸

What are falsified medicines?

In Europe, and in much of Latin America, a further classification has evolved, in part to overcome some of the confusions created by current definitions of counterfeit and substandard medicines. The EU notes the following definition in its proposed new legislation:

There is an alarming increase in the EU of medicinal products which are falsified in relation to their identity, history or source. These products are from the point of view of EU pharmaceutical legislation illegal insofar as they do not comply with the Community rules for medicinal products. Therefore, in the context of this proposal for an amendment of the pharmaceutical legislation these products shall be referred to as ‘falsified medicinal products’.

Falsified medicinal products may contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients. They pose a major threat to European patients and European industry and there are strong concerns in the public and amongst policy makers about the steady increase of these products detected in the EU in the last years.¹⁹

Falsified products include substandard products in the European definition, but the term is adopted specifically to differentiate them from counterfeits – ‘the term “falsified” is used to distinguish the issue from IP violations, so-called “counterfeits”.’²⁰ Meanwhile, in the draft Council of Europe Convention on counterfeiting (called MEDICRIME)²¹ the term ‘counterfeit’ is defined as ‘a false representation as regards identity and/or source’ and it is made clear (rather as in the WHO interpretation) that the Convention concerns ‘medical products whether they are protected under intellectual property rights or not’.

‘Falsified products include substandard products but the term is adopted specifically to differentiate them from counterfeits – the term “falsified” is used to distinguish the issue from IP violations, so-called “counterfeits”’

In Brazil, those who ‘falsify, corrupt, adulterate or alter a product intended for therapeutic or medical use’ face a fine and up to 15 years in prison. On the other hand, while Brazil has no legislation referring to counterfeits in intellectual property law governing industrial

18 www.who.int/medicines/services/expertcommittees/pharmprep/14052010NewDefinitionSubstandardMeds-QAS10-344Rev1.pdf.

19 [www.europarl.europa.eu/meetdocs/2009_2014/documents/com/com_com\(2008\)0668_/com_com\(2008\)0668_en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/com/com_com(2008)0668_/com_com(2008)0668_en.pdf).

20 http://ec.europa.eu/health/human-use/quality/fake-medicines/index_en.htm.

21 http://www.coe.int/t/dghl/standardsetting/medicrime/CDPC%20_2009_15Fin%20E%20Draft%20Convention%2009%2011%2009CM.pdf.

products (including medicines), it has incorporated the TRIPS Agreement into its law and thus follows the definition of ‘counterfeit trademark goods’ outlined in that agreement (see above).

In India, the Drugs and Cosmetics Act focuses on ‘spurious’ drugs, whose manufacture and sale is a criminal offence, but the definition relates only to deceptions concerning source and identity, not shortfalls in quality standards, which form a separate part of the legislation.

Conclusions

The definitional issues relating to counterfeit, falsified and substandard medicines seem necessarily of less practical importance than the actions taken at international, regional and national levels to combat them and their harmful effects. But the failure to reach agreement on these definitions hampers meaningful and constructive policy debate (as notably witnessed by recent events in the WHO), and inhibits the degree of international collaboration necessary to take effective action against the producers and distributors of these medicines. It also has important implications for how national legislation is constructed and the penalties applicable for different kinds of offence.

‘ The failure to reach agreement on these definitions hampers meaningful and constructive policy debate, and inhibits the degree of international collaboration necessary to take effective action ’

The way forward will need to be determined by the principal actors themselves. Key issues will include:

- Whether a different definition or concept of counterfeit goods, applicable to medicines specifically, is necessary or desirable and, if so, what it should be;
- Whether substandard medicines should be defined solely in relation to specified quality standards;
- Whether the adoption of the classification ‘falsified medicine’ could or should be more widely adopted as an alternative to ‘counterfeit medicine’ and what relationship this classification would then have to ‘substandard’ and ‘counterfeit’ medicines.

Annex: Selected definitions

Definitions

Source

COUNTERFEIT (GENERAL)

'... any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.'

TRIPS Agreement, Footnote 14 to Article 51.

'(a) "counterfeit goods"; namely:

(i) goods, including packaging, bearing without authorisation a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder's rights under Community law, as provided for by Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark (4) or the law of the Member State in which the application for action by the customs authorities is made;

COUNCIL REGULATION (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

(ii) any trademark symbol (including a logo, label, sticker, brochure, instructions for use or guarantee document bearing such a symbol), even if presented separately, on the same conditions as the goods referred to in point (i);

(iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i);'

'**counterfeit trademark goods** means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country in which the procedures set out in Section 2, 3, 4 and 5 of Chapter 2 are invoked;'

Draft Anti-Counterfeiting Trade Agreement, October 2010

COUNTERFEIT MEDICINES

'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 active ingredients or with fake packaging.'

WHO/IFPMA Workshop, April 1992

'A medical product is counterfeit when there is a false representation [5] in relation to its identity [6] and/or source. [7] This applies to the product, its container or other packaging or labelling information.

IMPACT Meeting, Tunisia, December 2008

Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components [8] or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

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 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.

5. Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purpose of sanctions imposed.

6. This includes any misleading statement with respect to name, composition, strength, or other elements.

7. This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

8. This refers to all components of a medical product.'

'a false representation as regards identity and/or source'

MEDICRIME Convention, Council of Europe

'The term 'counterfeit drug' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.'

US Food, Drug and Cosmetic Act, 21 U.S.C. 321 Section 201 (g) (2)

Definitions	Source
<p>'a) any drug product which is not what it purports to be; or b) any drug or drug product which is so colored, coated, powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labeled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design, or device which makes a false claim for the drug or which is false or misleading; or c) any drug or drug product whose container is so made, formed or filled as to be misleading; or d) any drug product whose label does not bear adequate directions for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or e) any drug product which is not registered by the Agency in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc.) Decree 1993, as amended.'</p>	Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Decree
<p>'... a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacturer.'</p>	Pakistan Manual of Drug Laws
<p>'... medicinal products with correct ingredients but not in the amounts as provided there under, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to: 1) the drug itself, or the container or labeling thereof or any part of such drug, container or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark, and Technology Transfer in the name of another natural or juridical person; 2) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used; 3) an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records, and 4) a drug which contains no amount of or a different active ingredient, or less than 80% of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration.'</p>	Philippines Republic Act No. 82036
FALSIFIED MEDICINES	
<p>'... falsified in relation to their identity, history or source. These products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients, thus posing an important threat to public health.'</p>	Draft EU Directive, SEC (2008) 2674, SEC (2008) 2675, December 2008
<p>'... a drug shall be deemed to be spurious: (a) if it is imported under a name which belongs to another drug; or (b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product.'</p>	India Drugs and Cosmetics Act, 1940 and as subsequently amended
SUBSTANDARD MEDICINES	
<p>'Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source.'</p>	WHO Fact Sheet No 275, November 2003
<p>'Substandard medicines (also called out of specification (OOS) products) are genuine medicines produced by manufacturers authorized by the NMRA {National Medical Regulatory Authority} which do not meet quality specifications set for them by national standards.'</p>	WHO Frequently Asked Questions, October 2009
<p>'Each pharmaceutical product that a manufacturer produces has to comply with quality standards and specifications at release and throughout the product shelf-life required by the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable National Medicines Regulatory Authority before the product is authorized for marketing.'</p>	Proposal from WHO for new definition of substandard medicines, May 2010
<p>Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.'</p>	

The Chatham House Centre on Global Health Security examines global health issues from an international affairs perspective, focusing on their politically and economically sensitive determinants and implications. It seeks to inform policy by offering evidence-based, politically feasible solutions that help policy-makers, civil society, the private sector and other leaders reach decisions and take actions that improve global health. It does so by providing a neutral forum for debate in order to stimulate discourse between the international affairs and public health communities, and by contributing to knowledge through independent, rigorous analysis, research and new ideas concerning global health challenges and how they manifest themselves as foreign policy problems. Its work is focused on three often interlinked aspects of global health security:

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The author acknowledges helpful comments from Kirk Kashefi, Chan Park, Peter Beyer and Carlos Correa and editorial guidance from Emma Ross. But the responsibility for the paper is his own.

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Registered charity no: 208223

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Designed and typeset by SoapBox, www.soapboxcommunications.co.uk

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