

The Nomenclature and Definition of Counterfeit Medical Products

The beginning of all wisdom is to call things by their right name. Chinese proverb
By Michele Forzley

INTRODUCTION

Medicines and medical products are essential to health systems. Their quality, efficacy and safety are fundamental. Ensuring these fundamental features is the primary role of drug regulators. Evaluation, analytical control, validation, standards, good practices and pharmacovigilance were developed for this purpose and converge to assure the efficacy, quality and safety of medicines. These technical measures, combined with the enforcement of applicable laws and regulations, aim to reduce unregulated, substandard and counterfeit medical products from entering the pharmaceutical and medical product supply chain. Notwithstanding these efforts, the problem of substandard, unregulated, and the focus of this paper - counterfeit medicines continues to plague drug regulators and consumers.

Early on in the history of the WHO, in 1985, attention was focused on the problem of counterfeit medical products. Despite the work of more than two decades there remains substantial variation in the nomenclature of and in the features in national and international legal definitions of counterfeit medical products. The WHO and many other stakeholders have acknowledged "the absence of a universally accepted definition" and how its absence "not only makes information exchange between countries very difficult ... it also limits the ability to understand the true extent of the problem at [the] global level....In some countries the issue is more complex and there is no distinction between counterfeit and substandard drugs."¹ This gap in the nomenclature and definition also has consequences for domestic and international law enforcement and cooperation between and within law enforcement agencies and courts.

There is moreover international debate on the term counterfeit itself, a debate that reflects a principle issue in the entire discussion on what to do about counterfeit medical products. The issue revolves around adopting a nomenclature and definition that reflect the WHO mission to protect health as compared to intellectual property rights. The IMPACT initiative has made some progress towards agreement on the definition, but not enough to support an enduring legal solution that may be formally adopted by the WHA as the WHO definition. Some regions and countries have found possible solutions, and some are comfortable with the first WHO definition and now the latest one adopted by the IMPACT in 2008. But as these are not universally adopted, desired global data collection and cooperative law enforcement will remain elusive and problematic. Thus, with a view to finding a universally accepted solution, this paper will describe, compare and analyze the current and proposed nomenclature and features of national and international definitions of counterfeit medical products and Member views on the proposed IMPACT 2008 definition. Suggestions for what considerations may be useful to finding a definition and nomenclature that serves the goal to protect public health are also presented.

RESULTS OF MEMBER SUBMISSIONS AND RESEARCH

In November 2009, Director General Chan issued Circular Letter 25.2009 requesting Member States to supply their definitions of counterfeit medicines (or equivalents) in national legislation. This information, in addition to research by staff and consultant Michele Forzley, informs this report. As of February 1, 2010 a total of 65 definitions were collected.ⁱⁱ

Member state definitions were assessed to determine the nomenclature used by Members and which category of law best characterized the definition. In the cases when a country identified the name of the law in which the definition was found no assessment was needed. Categories were added for countries in which the WHO definition was adopted (See the “WHO Definition” herein), those having no definition and those in which legislation is pending to add or change the legal definition. See Chart 1 which lists the data.

There are three main categories of substantive law in which a definition of counterfeit medical product may be found. These include the health and safety law including the drug law and identified in Chart 1 and this paper as the “DRA”, intellectual property law “IP” and criminal law. Not surprisingly out of a total of 65 country definitions, the majority of definitions (42/65) fall within the DRA. Some (5) of the DRA definitions were based the “WHO definition” discussed later and the balance were unique with a variety of elements described later. The next largest counts (14) had no definition and (10) had an IP based definition. A total of (4) countries two have two definitions; one based on IP law and a second within the DRA. Six (6) international governmental organizations including the EU were included (4) of which had no definition and (2) fell within IP. Seven countries and the EU are in process to amend the legal definition and several are awaiting the final outcome of a new WHO definition. Further information on the definitions is discussed in a later section.

HISTORY AT THE WHO

World Health Assembly and Executive Board

One of the earliest WHO conferences on counterfeit medicines was held in 1985 in Nairobi on the rational use of medicines. The conference recommended:

WHO, with other international and nongovernmental organizations should study the feasibility of setting up a clearing-house to collect data and inform governments about the nature and extent of counterfeiting.²

Based on this request, the World Health Assembly (WHA) adopted the first resolution on this subject during the 1988 session. Resolution 41.16 requested "the Director-General to initiate programs for the prevention and detection of the export, import and smuggling of falsely labelled,

ⁱ I suggest in whatever final version of this report this is included - or something like it somewhere. Michele Forzley is a lawyer, public health professional and law professor at Widener School of Law. She holds a JD degree from New England Law and a MPH from Johns Hopkins School of Public Health. She declares that she has no conflict of interest with regards to this work or others. I do not now nor have I ever worked for members of the pharmaceutical industry.

ⁱⁱ For many countries it is impossible to find any information on the definition. This is because health related legal information is not in the WHO International Digest of Health Legislation nor in any one of a number of other sources of legal information, such as GLIN.gov, the Ministry of Health or other Ministry web sites, the large repositories of international legal materials law libraries, such as the U.S. Library of Congress, or in commercial legal information databases such as Lexis-Nexis.

counterfeited or substandard pharmaceutical preparations and to cooperate with the Secretary General of the United Nations in such cases when the provisions of the international drug treaties are violated." ³ iii

Numerous WHA resolutions on counterfeit drugs have been adopted since resulting in various requests to the Director General: to assist Member States in combating the use of counterfeit drugs;⁴ to continue to develop and disseminate information on instances of counterfeit drugs;^{5,6} and to support Member States in their efforts to combat the manufacture, trade and use of counterfeit medical products.⁷ Discussions on reports WHA A62/13 and WHA62/14 were postponed to the 63rd WHA due to the Swine Flu crisis.⁸

The “WHO Definition”

Since 1992, a so-called WHO definition has circulated and has been used by various stakeholders, the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and the WHO staff. This definition resulted from an April 1992 meeting organized by the WHO and IFPMA on counterfeit drugs in Geneva. The text reads:

A counterfeit medicine is one which is deliberately and fraudulently mislabelled 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, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.

For the purpose of this report the terms drug, medicine and pharmaceutical product are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use.

Though there does not appear to be a WHA or Executive Board resolution adopting or endorsing this text as the “WHO definition,” the following examples demonstrate its wide use and adoption within the WHO community and among stakeholders. Moreover, Member States typically refer to this text – and did so in their responses to CL 25.2009 – as the “WHO definition.” Some have even adopted it as their national definition. For these reasons, in Chart 1 a column has been included for countries that rely on this definition.

The Expert Committee on Specification for Pharmaceutical Preparations (Expert Committee) is the technical board for WHO in *all* pharmaceutical areas. Its reports are adopted by WHO through an official process. On the subject of counterfeit medicines, many observations and recommendations were adopted by the Expert Committee during sessions from 1992 to 2009. The Expert Committee also noted the importance of a legally sound definition of "counterfeit drug" to hinder penetration of counterfeit drugs,⁹ to assess the real extent of the problem and improve the clarity of case reporting.¹⁰ Furthermore, it expressed concerns that U.N. agencies could risk sourcing sub-standard, counterfeit and/or contaminated medicines, leading to product complaints and product recalls, waste of money, and most seriously, health risks to patients.¹¹ In its 1996 Report 863, the Expert Committee provided examples of counterfeit medicines suggested by the “WHO definition.”¹²

• fake packaging + correct quantity of correct ingredient = counterfeit

- fake packaging + wrong ingredient = counterfeit
- fake packaging + no active ingredient = counterfeit
- fake packaging + incorrect quantity of correct ingredient = counterfeit
- genuine packaging + wrong ingredient (deliberate) = counterfeit
- genuine packaging + no ingredient (deliberate) = counterfeit
- genuine packaging + incorrect quantity of ingredient (deliberate) = counterfeit
- genuine packaging + incorrect quantity of ingredient (not deliberate) = substandard
- genuine packaging + correct quantity of ingredient = genuine

The Expert Committee also used the WHO definition in the Glossary to the 1996 Guidelines on import procedures for pharmaceutical products. These guidelines list the key steps in controlling pharmaceutical products. (*See Text Box A*). These are important as they are the guidance on what steps should be taken by DRA to control pharmaceutical products and are listed in an order that suggest that at first a visual inspection is to be taken. In considering the elements of the definition of a counterfeit medical product it may be useful to reflect on these steps resulting from expert consultations.

Key Steps in Controlling Pharmaceutical Products

- ~Visual exam
- ~Physical exam
- ~Routine sampling
- ~Analysis
- ~Quarantine of consignments
- ~Forensic investigations of suspected counterfeits
- ~Notifications to consignees
- ~Forfeiture and destruction
- ~Notification to other authorities

Text Box A

In 1999, the Expert Committee published the *Guidelines for the development of measures to combat counterfeit drugs*. In these the 1992 “WHO definition” is adopted as is a definition of a drug found in the glossary. It is noteworthy that the Expert Committee found the term “drug” to be synonymous with medicine, pharmaceutical product and

pharmaceutical and that a drug is:

Any substance or mixture of substances that is manufactured for sale or distribution, offered for sale, sold, supplied or presented for use in:

- (i) *the treatment, mitigation, cure, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof in humans or animals*
- (ii) *normal physiological conditions in humans or animals: or*
- (iii) *the restoration, correction or modification of organic functions in humans or animals, or any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.*¹³

One major difference in how member states name and define counterfeit medical product is that some limit the definition to just pharmaceuticals, some include all medical products and some do

not distinguish the kind of product. This raises the question later discussed as to what to call counterfeit medical products. Is the focus on medicines alone enough when the Expert Committee included items to be used for treatment, mitigation, cure, prevention or diagnosis for humans and animals and when all medical products can be and are counterfeited?

The most recent notation by the Expert Committee, in the glossary of 2006 Technical Series 937, the “WHO definition” again appears, although this time a comment indicates that in other contexts the term counterfeit may have other meanings. TS 937 is important as it is the publication in which *Good Distribution Practices (GDP)* and *Guidelines for implementation of the WHO Certification Scheme on Quality of Pharmaceutical Products Moving in International Commerce* are found.¹⁴ These are essential to the process of quality assurance in pharmaceuticals a primary goal of all efforts to combat counterfeit medical products.

Finally in 2006, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was formed as a voluntary coalition of stakeholders. To keep the focus on the public health implications of counterfeiting rather than on the intellectual property related aspects the WHO serves as its Secretariat. Its outputs such as recommendations and policy advice reflect the agreement reached among IMPACT stakeholders. Among these have been attempts to identify a definition and nomenclature on which consensus can be reached.

IMPACT initially relied on but then built on the 1992 “WHO definition”. During the 2008 Third General IMPACT Meeting in Hammamet in 2008, a new definition of counterfeit medical products was agreed upon by participants.¹⁵ Though the IMPACT stakeholders have agreed to the definition it has not been presented to or adopted by the WHA. Even though there had been agreement on the text there remains open debate over its content and the nomenclature of counterfeit medical products. To inform the EB and WHA on the nature and scope of the debate the DG issued Circular 25.2009 so that this report could be drafted. The text reads:

The term counterfeit medical product describes a product with a false representation (1) of its identity (2) and/or source (3). This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components (4), with wrong ingredients/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 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:

- (1) *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.*
- (2) *This includes any misleading statement with respect to name, composition, strength, or other elements*
- (3) *This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution*
- (4) *This refers to all components of a medical product.*

NOMENCLATURE AND DEFINITIONS FROM INTERNATIONAL GOVERNMENTAL ORGANIZATIONS OTHER THAN THE WHO

Definitions of counterfeit products are found within the governance documents of several international governmental organizations. Although these definitions are not specific to medicinal or health products, a medical product may be considered counterfeit under these definitions if the manner in which it is counterfeiting fits within these definitions. These organizations include the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), and the World Custom Organization (WCO).ⁱⁱⁱ

The most well-known of these is the WTO Agreement on Trade Related Intellectual Property Rights (TRIPS). It provides WTO Members mandatory minimum legislative standards for recognition and enforcement of intellectual property rights. The TRIPS establishes definitions for trademark counterfeiting and copyright piracy only. Under TRIPS, a patent is *infringed*, not counterfeited.

With reference to trademarks, the WTO Glossary defines *counterfeit* as the:

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.^{iv}

Clearly the legal definition of a counterfeit includes two key elements under international trade law. These are first an unauthorized representation of a trademark and second a view to deceive the buyer. TRIPS on the other hand provides two definitions of *counterfeit* in Part 111 “Enforcement of Intellectual Property Rights,” Note 14. In these there can be a counterfeit of both trademarks and copyrights. The text retains the concept of an unauthorized representation of either a counterfeit or a copyright but does not require a “view to deceive”.

The text of the definitions is:

For the purpose of this Agreement:

ⁱⁱⁱ The UN Office on Drug Control (UNODC) is the secretariat for a number of conventions, none of which define or mention or counterfeit drug.

^{iv} WTO web site – <http://...>

- (a) "*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;
- (b) "*pirated copyright goods*" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

The Enforcement text adds the additional requirement that the counterfeited product must infringe the under the laws of the country of *importation*. Thus if a product is not trademarked or copyrighted in the country of importation then any definition of counterfeit medical product that referred to brand or trademark could not be enforced under intellectual property laws including Customs border seizure procedures. The remaining grounds for enforcing under brand or trademark will have to derive from other types of laws including the drug regulatory, customs or consumer protection law. For non-WTO member states now totaling around 40 which are also WHO members *only* the definition within the health and drug law will stand to protect citizens and be the basis for the work of regulators.

Moreover, TRIPS sets out the requirements for mandatory civil, administrative and criminal law procedures for actions against any intellectual property rights (IPR) infringements.^v However it is only mandatory for Members to provide national legislation on criminal procedures and penalties in cases of trademark counterfeiting or copyright piracy if such actions are *willfully committed on a commercial scale*. Thus there is no impediment to criminal sanctions in cases of counterfeit medical products – in fact WTO members (153 in number) must create a specific crime for such cases.

The World Intellectual Property Organization (WIPO) administers 27 treaties, protocols, agreements and conventions on intellectual property and related topics on behalf of its 184 Member States. The WIPO does not have its own definition of counterfeit; rather it adopts the TRIPS definitions. Its function is to promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field among other specific roles as outlined in Article 4 of the WIPO convention.¹⁶ Ultimately WIPO is an organization whose focus is recognition and enforcement of IP rights, which are defined by several conventions on intellectual property including among them TRIPS.

WIPO has widely recognized that counterfeit medical products deserve special attention. It recommends the collection and updating of data to assess the full extent of health and safety risks

^v Article 41(1).

for consumers from counterfeiting and this information is given to policy-makers, law enforcement agencies, and the public. Moreover, it proposes that the training of law enforcement authorities, especially customs administrations, that focus on counterfeit products posing health and safety risks should be intensified.¹⁷

World Customs Organization (WCO)

The World Customs Organization administers about 20 conventions and agreements on customs with a view to harmonize customs procedures; it manages the harmonized code on nomenclature and other aspects of trade facilitation.¹⁸ Like the WIPO, the WCO does not maintain its own definition of a counterfeit. Instead it relies on those of TRIPS and its Member States.

The Group of Eight (G8): Anti-Counterfeit Trade Agreement (ACTA)

At the G8 Leaders 2006 Summit in St. Petersburg, member States announced the launch of a comprehensive intellectual property rights and anti-counterfeiting enforcement strategy based on a previous strategy adopted in 2005.¹⁹ As a result, the Anti-Counterfeiting Trade Agreement (ACTA) of 23 October 2007 was proposed. ACTA provisions are still under negotiation, but participants aim to reach agreement in three main areas: international cooperation, enforcement practices and a legal framework with potential provisions on criminal enforcement, border measures, civil enforcement, optical disc piracy and IPR enforcement issues relating to Internet distribution.²⁰ The countries involved as of the end of 2009 include the United States, Australia, Canada, the European Union and its 27 member states, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, and Switzerland.²¹ At present there is no proposal for any definition of a counterfeit under ACTA other than what is in TRIPS.

REGIONAL DEFINITIONS

EUROPEAN UNION, COMMISSION, PARLIAMENT AND COUNCIL

The European Commission defines *counterfeit good* under Article 2(1a) of Directive 1383/2003, a customs regulation on the entry of products into the legal supply chain. It provides a definition of counterfeit in terms of trademarks and copyrights.^{vi} To distinguish infringements of intellectual property rights from medical products in customs legislation, the Commission introduced the phrase “falsified medical product” in a 10 December 2008 Proposal to amend Directive 2001/83/EC, which lays the regulatory framework for pharmaceutical regulation.²² This proposal defines counterfeit medical product as one that has “a false representation of its identity and/or source.” Adopted in December 2008 the proposal will be presented to the European Parliament during its session of 2009-2010.²³ Falsified medical products are further described in an explanatory report relating to a Draft Convention on counterfeiting of medical products and similar crimes involving threats to public health proposed in the Council of Europe. The explanatory report continues that a medical product would not be considered as counterfeit for the sole reason that it is not authorized and/or legally marketed in a particular State. Moreover, substandard products, products a subpart of which is substandard and adulterated

^{vi} EC Council Regulation 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. (See Article 2 (1) a and b).

products are excluded from the definition when these quality defects are not the result of an intentional action or omission on the part of the manufacturer.²⁴

ASSOCIATION OF SOUTHEAST ASIAN NATIONS (ASEAN)

Member Countries of this regional group are: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. During the WHO regional meeting of SEARO in New Delhi (September 2008), a draft definition of counterfeit medical products was proposed by ASEAN.²⁵

A medicine or a medical product (medicine, vaccine, diagnostic or medical device) is counterfeit when it is deliberately and fraudulently mislabeled with respect to its identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/ [components], with wrong ingredients/ [components], without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

The following situations should not be confused with counterfeiting:

- (a) quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate, authorized medical products;*
- (b) patent disputes or violations arising from the international trade of products that are legitimate and authorized for marketing in their country of origin or destination.*

CIVIL SOCIETY AND TRADE ASSOCIATIONS

The World Self Medication Industry has no definition but works with the “WHO definition”. The International Pharmaceutical Federation (FIP), the International Alliance of Patients Organizations (IAPO) and the International Council of Nurses coordinate on the issue of counterfeit medicines and have adopted the “WHO definition” in their efforts to increase patient safety.²⁶

The European Generics Association (EGA) also favors the “WHO definition”. It holds the position that counterfeiting is not a reason to increase intellectual property protection and that to do so would be ineffective and unjustified. The organization proposes that measures to tackle counterfeiting should be taken in criminal enforcement and penal sanctions, reinforce and improve drug regulation particularly as it relates to good manufacturing and distribution practices and enforcement by regulatory and law enforcement authorities.²⁷

DISCUSSION

The Nomenclature of Counterfeit Medical Products

The assessment of definitions and nomenclature indicated there are variations in the terms and phrases used to describe counterfeit medical products and the features of the definitions. Thus two sections follow: the first on nomenclature and the second on the features of definitions. A third section discusses comments on the IMPACT 2008 definition followed by a discussion on pending national legislation. The most differences are found in the features of definitions in the DRA. If a country follows an IP definition its definition is basically the same as all others. However even in DRA definitions elements of IP are found as are other features.

NOMENCLATURE

This section is presented according to the words used to describe counterfeit medical products. Of all the 65 names, 37 use the term counterfeit and 10 use fake, spurious, falsified, or misbranded. The next term or *the what* that is counterfeited is most often (27) medicine, medical, medicinal, drug or pharmaceutical. Outlier names included illicit, and unregistered. Further discussion of nomenclature follows.

PRODUCTS, GOODS, SUBSTANCES

The last term in phrases used to describe counterfeit medical products is perhaps the most illustrative of how nations have already legislated on this issue. Sixteen members chose non-descript terms of products, goods, and substances and did so when the classifier term drug, medicine or the like was not used in the phrase. This approach was not limited to definitions in the IP law; rather it is used in the DRA. Those nations that rely on an IP definition and had no definition within the drug law used the term *good* which would be applicable to any good in finished or raw or partially finished form. The term *product* can also be applicable to any kind of item as compared to substances generally interpreted to exclude finished or partially finished items. IMPACT Principles and Elements for National Legislation (IMPACT Principles) has adopted the term product and has indicated *medical product* include medicines, devices, diagnostics, accessories, API and excipients.²⁸ Medicines according to the Expert Committee include any substance or mixture of substances used in the treatment, mitigation, cure, prevention or diagnosis of disease in humans and animals.²⁹

Thought in the balance of this report the nomenclature *counterfeit medical products* will be used, these differences in nomenclature and meaning of the terms suggests that to settle the question of how to define a counterfeit medical product may require a decision on *the what* that can be counterfeited. If the WHO adopts the term *product* this will reflect the widest range of possible items relevant to health that may be counterfeited and that may be the subject of regulation and law enforcement for the purpose of protecting health. Product will include everything that is not a fixture in the legal sense – in other words immovable. With this approach at the WHO level, members are free to limit *the what* to medicines alone or include devices or other items but need not in order to allow for data collection and law enforcement cooperation as long as the other elements of the definition are not in conflict with the WHO features. Or of course the WHO may determine that it will limit its efforts to medicines or a subset to include for example, vaccines, biologics, and pharmaceuticals. This will be a key decision.

THERAPEUTIC, HEALTH, MEDICAL, DRUG, PHARMACEUTICAL, TRADITIONAL MEDICINES

The second term in nomenclatures - the adjective consist of *therapeutic, health, medical, medicines, pharmaceutical, drugs* and *traditional medicines*. The terms most widely used by Members are *medical* and *medicine*, which to some extent can be attributed to the term used in Circular Letter 25.2009, which requested information on definitions of counterfeit *medicines*. Several Members used *drug*, a few used *health* and a couple referred to *traditional medicines*. Members did not submit their definition for *medicines* or *medical* as they were not asked to do so and unless the definition was included in the law, it was not available to compare it to the Expert

Committee or IMPACT definitions. There is variation in these terms as well, and their use may be worth considering. The common definition of medical refers to medicinal or therapeutic, but does not include all the functions included in the way in which the 1999 *Guidelines for the development of measures to combat counterfeit drugs* defined *drug* as “treatment, mitigation, cure, prevention or diagnosis of disease... in humans and animals...”³⁰

IMPACT Principles uses the term *medical* product, or medicines, devices, diagnostics, accessories, API and excipients. The term *medical* does not necessarily allow for traditional medicines, or vitamins or other items that may be within the jurisdiction of the health or drug agency. On the other hand an agency may choose to limit its scope of counterfeit efforts to drugs as the US FDA has done.

The term *health* is used by some countries and is one that encompasses the most products, even those not regulated per se by the drug regulatory agency. The term *health* reflects the WHO mission and purpose as per Article 1 of its Constitution, maintains the health-related focus of anti-counterfeit efforts and provides for the widest range of products that may be within the scope of national health laws or products that may injure the health of humans and animals.

COUNTERFEIT, FALSIFIED, FAKE, SPURIOUS, FRAUD, ILLEGAL

The term counterfeit seems to be the focus of the most debate as reflected by member comments on the IMPACT definition. Most nations use the term *counterfeit*, no matter whether the definition is found in the DRA or IP law. It is also found in the customs and criminal law. Synonymous terms such as *fake*, *spurious* and *fraudulent* are also used, though less often. A few states refer to *misbranded* or *illegal* products. The term *counterfeit* is used in TRIPS and national intellectual property legislation in WTO Member States, by the EU, the WIPO and the WCO. While this study did not consider non-WTO Member States, the term *counterfeit* is likely used by these as well and this term has been a part of legal terminology in other realms of law and in relation to non-medical products such as those that are applicable to documents, currency, art, consumer goods (such as toothpaste), and more.

Even if the term *counterfeit* is found in the DRA, concepts familiar to the idea of brand and trademark are also found including falsified information on brand identity, packaging, labeling and other external indicia of identity and/or source, When the adjective *medicines or the like is used*, the features of related definitions reflect the composition of the product, mainly with reference to the quality and content of API. Thus, there are two main differences in how countries treat the adjective of counterfeit – that of identity or brand and that of content. How countries use the term *counterfeit* is more fully understood by the features of the full definition discussed later. Finally some countries rely on the broader concept of “illegal”. The term *illegal* denotes the widest range of activity that can include counterfeiting, but also lack of registration or other authority such as to import or manufacture. Some countries use the term *fraudulent*.

THE TERM COUNTERFEIT: AMBIGUOUS OR INADEQUATE?

Historically the word *counterfeit*, used as an adjective, noun and verb and from the French words *contrefait*, *contrefaçon*, *contrefaire*, has been employed for many years in discussions of medicine, art, and other items without any reference whatsoever to the intellectual property issues. *Counterfeit* as an adjective or noun is synonymous with *fake*, *spurious*, *copy*, *imitation*,

forgery, phony, and bogus. As a verb it means to make a fake in order to deceive. No matter the form of the word, counterfeit always means deception, misrepresentation and misleading. On this point there seems to be consensus.

There are objections to the use of the nomenclature “counterfeit”. Critics’ main concern is that the use of *counterfeit* could block or hinder legitimate generic medicines in transit between or within countries because the term is also used in intellectual property law. Some believe that the term places the problem of counterfeit medical products within the realm of intellectual property and not that of health. There is no support for the WHO to be involved in the enforcement of IP rights, and there is caution against confusing cases of suspected patent infringement, parallel imports, and generics with counterfeit medical products. To change what has been a long standing practice to use the term counterfeit will not be without consequences that are worthy of consideration and which will call into question other issues. There may be other ways besides nomenclature to address the concerns.

To more fully explore the grounds for opposition to the term counterfeit and the relative utility of the term *counterfeit*, it is necessary to look at the term *generic* and the concept of patent infringement. In IP legal practice when a patent is violated it is not said the patent has been counterfeited – it is said the patent is infringed. Patents are granted in general for a formula or a process which are not in general naked to the eye. On the other hand, national definitions of counterfeit medical products contain the elements such as mislabeled, false identity and other indicia of origin and source. A key aspect of the deception is that the consumer is unable to determine the authenticity by visual cues. This manner of determining if a patent is violated in general does not apply.

The term generic has a mixed meaning. First, in general, the term *generic* connotes “not specific, common, general or having no particularly distinctive quality or having no trademark.”³¹ A second meaning is that the item is “off patent” or a replica for which the patent period has expired. In health and especially for drugs, generic medicine is understood in both of these ways – off patent and not branded, and this conception of the meaning of generic is common around the world. Moreover a generic medicine may be legal in the IP sense but not so in the DRA due to a lack of registration, or other authorization such as for marketing, manufacturing or importing. A product without authorization from the DRA would be illegal.

Further a generic product of any type including medicine can be and many are trademarked or branded. Trademarks and copyrights can be created with or without registration at the IP office. Many countries recognize a non-statutory trademark or copyright generally recognized after use by its claimant. In addition countries provide a formal process and WTO Member countries must do so, for the registration of trademarks. Once registered proof is established as to ownership and in some cases additional enforcement mechanisms are available. Moreover, as the generic industry grows and matures, competition within it will defy national borders, its supply chains will establish roots in many countries and surely its products will become (and in some cases, have already been) the subject of counterfeiting. Consider the studies on malaria product counterfeiting in Southeast Asia. These were not patented products. Thus it is not surprising that the EGA supports the 1992 WHO definition, which incorporates the brand and trademark concepts.

Even when a manufacturer does formally trademark a product its name and other identification information that establishes identity and source must be provided a DRA for marketing authorization and other information. The name of a manufacturer is often associated with a brand a word used to sometimes mean a trademark but also a class of goods used to identify a firm or producer. Thus while a company like Cipla may not have registered its name as a trademark its name is already a brand which can be counterfeited.

Thus the terms generic, brand, identity and trademark are interlinked in a manner the complexity of which may not be capable of simplification by not using the term counterfeit. Moreover, taking the term *counterfeit* out of circulation may also require a name other than *generic* given its intimate association. To accomplish the demise of the term counterfeit will require the term significant legislative alignment a process that may resource intensive without a corresponding benefit. Alignment will require removal, replacement and cross referencing in domestic law in concert with consideration of international legal obligations. It is doubtful that such extensive legal exercises will result ant benefit to public health.

OTHER CONSIDERATIONS

First responders: The perspective of law enforcement, judicial proceedings and administrative procedures are other factors to consider regarding the utility of the term *counterfeit*. The key actors in discovering suspicious counterfeits are law enforcement officers – namely drug inspectors, police and customs or border officials. These officers must be armed with field ready tools to make determinations if an item is worthy of suspicion. The fastest tools are visual, external and standardized and these are indicia associated with trademark, brand or identity, and authorization. Indeed the first key steps in controlling pharmaceutical products as stated by the Expert Committee are visual and physical exam followed by routine sampling as noted above in Text Box A. If the tool of visual indicia is not maintained for officers, the first line of defense is effectively weakened.

A question for deliberations on this point is the matter of relative risks – do the risks of officers occasionally seizing generic medicines because they are suspected of being counterfeit outweigh the goal of reducing the incidence of counterfeit medical products? The concern that using the term *counterfeit* may impede legitimate trade in generics is appreciated, but procedures on fragile or perishable goods exist and provide expedited time frames in which to determine if medical products are counterfeit or not. In this process if a medical product is a genuine generic medical product this fact will be determined. Given the rapid telecommunications of today, no more than a few days or hours need pass to make such a determination. In such as short time little harm can come to pass. The matter of whether a product is the subject of a patent dispute is not determined by an officer at the first interaction. This factor is a determination made later along with the steps subsequent to visual inspection as identified by the Expert Committee.

The real problem may not be the nomenclature of counterfeit medical products at all. The experience of medical products procurement whether donor or national budget funded demonstrates that trade facilitation is a major problem. Now shipments remain on the docks too many days due to customs and port clearance failures.³² These trade facilitation failures can be remedied; expedited procedures for medical products and trainings for inspectors can reduce the

potential for occasional incorrect tagging of generics as suspected counterfeits. To improve these capabilities will improve the overall port and customs procedures that may slow entry of medical products for reasons other than suspicion of counterfeits and thus enhance access to medicines. The view that the customs and border control capacity should be strengthened is shared by WIPO, WCO, and USAID and has been supported by the evidence.

Legal coherence and alignment: Perhaps the most compelling reason for a universally accepted nomenclature and definition is coherence and alignment within and between national and international laws. Within countries there are definitions within two bodies of law enforced by the same officers both customs and DRA inspectors. These same officers will from time to time interact with officers from outside their domestic jurisdiction. The nomenclature must not only be consistent between different sources of law, the name and definition must also be applied to all actors in the supply chain. One is hard pressed to think of one medical products and it matters not whether it is *legal or counterfeit* – that has a single source of origin. Instead, the components might be made in different countries and the final product distributed through a multitude of distributors, public and private procurement agencies and central stores, public and private pharmacies and ultimately dispensed or sold by public and private sector pharmacies, doctors, or medicine sellers. All of these actors must be subject to legal enforcement of laws against counterfeit medical products. To do so it is essential laws are coherent and aligned so as to avoid legal disputes as to meaning.

Features of the definitions in national law

The features of the definition of counterfeit medical product vary, but can be grouped by types. The text box below lists the types and notes the key features of each. Annex A contains the actual language of the legal information supplied by Member States or discovered by research, the name in use and features of each definition. Annex B charts the features by type and includes the features of the IMPACT definition for comparison. The IMPACT definition is the only one to rely on a negative definition, or a statement as to what a counterfeit is not.

MAIN DEFINITION TYPES

- A. API: References to the API, their amounts, quality, and relationship to national standards.
- B. Authority: Whether there is or is not authority to market, distribute, manufacture, or sell.
- C. Quality: Measures of expiration, adulteration, contamination or otherwise substandard in relation to national standards or those of relevant pharmacopeia.
- D. Intent and knowledge: To mislead, deceive, defraud, think it is other, more than what it is or it is the authentic product of another when this is not true.
- E. Recklessness, negligence, should have known
- F. Unusual definitions: Misrepresented international unpatented name, or deviated from recognized principles.
- G. Intellectual property right infringement: Generally a trademark or trade name or other visible feature that distinguishes the product.
- H. Exterior Markers: Reference to visible markers such as labeling, packaging, trademarks, *as these relate to the name and location of the manufacturer and which are deceptive or misleading. Here intent is not always a requirement.*

National definitions vary widely but some observations can be made that indicate some degree of pattern and standard approach. DRA definitions tend to be of type API, Quality and Authority, although some include a mix brand identity that does not reflect status of a registered trademark. Some refer to falsified as to origin or identity which are most comparable to the idea of brand short of IP. This approach is also similar to the those that used *illicit* or *legal product* to refer to whether a product is registered and/or authorized for marketing and the range of other activities that may apply, including but not limited to import, packing, filling, something related to the supply chain, and use beyond indications. Some are solely the Authority type and others just Quality with reference to standards such as API or other national pharmacopeia standard or that of what was indicated when a product was registered. Several rely on the IP definition only and some rely on a criminal law definition, in which elements of intent, recklessness and potential and actual harm are requisite.

Given that some definitions are such that other substantive laws in effect manage counterfeit medical products, it may be useful to consider any final definition in regards to these. The most obvious example is when the definition is in the criminal law, has features of intent and severe penal sanctions such as prison. In these cases, the definition must serve different kinds of officers and be capable of legal proof under what ever standard of legal proof is required under local law. Another example is the Authority type in which a status is the issue. Here for example if a status is current registration then what if a product is one late on registration? Is it counterfeit or late? Another issue is the degree to which the concept of substandard might or might not best be mixed with any final concept of counterfeit. Clearly many definitions are totally based on what might be considered issues relating to Authority and in the absence of some deception counterfeit may not be the best categorization.

There are many features that are grouped under External Markers, many of which are also the subject of some other kind of regulation such as labeling requirements. For these to be counterfeit in the sense of the term, a deception should be a part of the definition otherwise there is no way to discern a counterfeit from a printing error or other error that is not a result of a

counterfeit intent or view to mislead patients, consumers, officers and regulators into believing that a product is something other than what it is. External markers can be easily noted by officers and inspectors who can be equipped with access to regulatory files in which the status of a product or manufacturer can be determined. In comparison, quality features or those that must be corroborated by analysis are more complex to detect and confirm. This is not to say that adulterated products should not be considered counterfeit. It may be more useful to agree that adulterated products or those lacking requisite quality features such as API or other are not counterfeit at all but are substandard. Thus counterfeit would be limited to those medical products that are deceptive in some manner without any need to determine quality.

Definitions in criminal law

Several countries, including the EU, Brazil, Egypt and Switzerland, placed the definition of counterfeit within the criminal law. These include a different nomenclature – that of falsified medicines –illegal product and - those that do not satisfy legal requirements, instead of counterfeit. However the term *counterfeit* remains a part of the IP law of all, and it is found in other parts of the law as well such as the Customs law. In these approaches, the criminal law is used to prohibit and punish placing such products on the market. This approach does not distinguish counterfeit and substandard products. Some countries, according to the initial results of the study of criminal law by the Max Planck Institute, have counterfeiting offenses that require causation of (at least) palpable dangers to life and/or health.³³ Under the criminal approach, a counterfeiter can be subjected to severe sanctions such as prison.

The key feature of the criminal law that differs from civil law definitions found within the substantive laws on health and safety and IP is that of the requirement of intent. Common definitions of counterfeit include the concepts of deceit, fraud and misrepresentation, but only those found in criminal laws include the element of actual intent. Some definitions used the concept of intent when referring to an activity such as intent to sell a product which is counterfeit – whether the seller knows or not. Intent has been noted by IMPACT as a fact to be considered for the purpose of the sanctions and the degree of their severity. However, the matter of establishing intent is an evidentiary challenge especially when considering all the actors in the supply chain, some of which have only moved boxes. It is difficult to prove a state of mind – that a defendant knowingly intended to deceive. Circumstantial evidence such as a seller offering products or warehousing products is easier to demonstrate in court. Thus many countries that incorporate the element of intent do so in terms of an action rather than a state of mind. Intent can also be demonstrated in terms of the result of the deceptive behavior – did it (or would it) deceive the buyer, consumer or regulator? Was he or she deceived or misled into believing an item was something other than what it is?

CRIMINAL LAW UNDER TRIPS

Under TRIPS, the national law of WTO Members must provide for a substantive crime of counterfeiting in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. The remedies must be sufficient to provide a deterrent and penalties are to be consistent with crimes of corresponding gravity. Thus, if a counterfeited trademarked product caused death, then the punishment must correspond to that of murder. Also Members may provide for crimes for other cases of intellectual property infringement which could include crimes for patent infringement.³⁴ Thus there is no legal impediment to adding crimes under the IP law for IP

infringements that cause harm to the health of humans, animals or the health of the public such as when a counterfeit medicines results in drug resistance or deaths.³⁵ Specifically, Article 61 states:

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture, and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.

The import of this requirement is that those members of the WHO which are also WTO members are required to legislate and enforce crimes regarding willful trademark or copyright counterfeiting. In this regard, there is no requirement that the crime is called counterfeiting. Brazil and others chose to call this the crime of medicines falsification. There is every good reason to broaden the kinds of products that can cause harm or death to the health if persons or the public – there should be no need to recite here the numerous horrific cases where innocents have suffered. To limit a crime to medicines may be insufficient.

Having an IP crime in the arsenal of tools to capture and punish a counterfeit medicine perpetrator with the potential for sanctions corresponding in severity to those for murder may well be the kind of deterrent that is essential to gaining on the criminals that counterfeit. The only caution is to consider the use of different nomenclature and the effect on enforcement. Variations in terminology may allow violators to escape prosecution or delay justice due to debates over name and definition.

PROSECUTORIAL TOOLS

In many legal systems the jurisdiction of the drug regulatory authority is limited to administrative and/or other non-judicial procedures such as citations. For example, in the United States when U.S. Food and Drug Administration (FDA) inspector have determined that medicines are counterfeit, his or her authority and responsibility is to refer the matter to the Justice Department. The Justice Department determines what violations to prosecute and then does so under the drug, criminal and/or IP laws. If there is also an IP infringement, the Justice Department can also coordinate with a private right of action by the rights holder but is not required to do so. If there is cooperation the private right holder must prove the IP infringement which saves the public expenditure of resources because the prosecutor may use the fact finding. In the end it makes no sense to reduce the legal theories under which a prosecution may proceed... Of course legal systems vary, but all nations use a system by which civil and criminal offenses are prosecuted by private parties and the government. The definition of counterfeit medicines should be viewed in light of enlarging the offenses capable of prosecution and enhancing the prospects for successful prosecutions.

The European Union is considering a treaty to establish counterfeiting as a criminal offense as a preventive and repressive measure. Their view on the importance of a criminal law:

There is accordingly an urgent need to take decisive repressive and preventive measures against counterfeiting and illicit manufacturing and illicit supplying of medical products in order to protect public health interests. Though counterfeiting and illicit manufacturing and supplying of medical products have already been outlawed at national level in many States, the absence of a dedicated international legal instrument establishing these activities as criminal offences carrying effective, proportionate and dissuasive penal sanctions and providing the basis for efficient international co-operation to combat them has facilitated the cross-border operation of criminals in this field. The purpose of this Convention is to address these shortcomings.³⁶

Member Comments on IMPACT Definition and proposed legislation

There were a total of 21 comments on the proposed text on the definition. Of these 14 favored it and 7 were opposed. No categorization was attributed to the submissions in which no comment was made. Three of those favorable comments included additional information. The US proposed a shorter definition that also merged the earlier versions with the current and provided the following text:

”A medical product is counterfeit when there is a false representation with respect to its identity and/or source. This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct components or with the wrong components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. “

Nicaragua mentioned its support as long as it does apply to generic and branded medicines. Switzerland urged that a comprehensive approach to combating counterfeits would include a definition that differentiated between the various aspects of counterfeits including the IP aspects and those of enforcement. The other countries that support the IMPACT proposed definition are the EU, Botswana, Mexico, Russia, Ukraine, Moldova, New Zealand, Poland, Czech Republic, Latvia, and Maldives.

Opponents mentioned the identification of the term or nomenclature counterfeit as too closely identified with breaches of IP. Belgium, Chile, France, Peru, Thailand, Suriname and Brazil raised this issue. Belgium, Suriname and Brazil propose the concept of falsified medical product in terms of identity or origin. It appears there is consensus among opponents as to the nomenclature rather than the content of the definition. Thailand recommends that the standards and quality of medicines with no reference to IP should be emphasized. Suriname proposed the definition adopted at the 5th PANDRH conference:

Un producto médico (medicamento, vacuna, materia prima farmacéutica o dispositivo médico) es falsificado cuando ha sido deliberadamente elaborado de manera fraudulenta, presentando información incorrecta en relación a su identidad u origen

Proposed legislation

The country of Austria is intending to adopt the definition and name of counterfeit medical products in the draft of the Convention of the Council of Europe “on counterfeiting of medical products and similar crimes involving threats to public health“ which defines “counterfeit” to mean a false representation as regards identity and/or source. The EU is also considering in its Customs legislation the phrase falsified medicinal products as mentioned earlier.

Conclusions

Submissions and Research

1. As of February 1, 2010 total of 65 definitions were collected as the result of Member State submissions were received in response to CL 25.2009 or by desk top research. It is important to note that for many countries it is impossible to find any health legal information. This is because not all health related legal information is in the WHO International Digest of Health Legislation nor in any one of a number of other sources of legal information, such as GLIN.gov, the Ministry of Health or other Ministry web sites, the large repositories of international legal materials law libraries, such as the U.S. Library of Congress, or in commercial legal information databases such as Lexis-Nexis.

Source of the law

2. There are three main categories of substantive law in which a definition of counterfeit medical product may be found. These include the health and safety law including the drug law and identified in Chart 1 and this paper as the “DRA”, intellectual property law “IP” and criminal law. Not surprisingly out of a total of 65 country definitions, the majority of definitions (42/65) fall within the DRA. Some (5) of the DRA definitions were based on the “WHO definition” and the balance were unique. The next largest counts (14) had no definition and (10) had an IP based definition. A total of (4) countries two have two definitions; one based on IP law and a second within the DRA. Six (6) international governmental organizations including the EU were included (4) of which had no definition and (2) fell within IP. Several countries are awaiting resolution of this issue before finalizing pending legislation.

3. Each choice of the substantive law where a definition will be placed will have consequences for enforcement and implementation and training of officers and inspectors.

4. The most comprehensive integration of any final into all aspects of the legal system and substantive laws will enhance the prospects for successful enforcement and cooperation between and within countries.

5. If new nomenclature other than counterfeit is adopted, it will be necessary to engage in substantial legal reform and textual alignment of national and international laws. This will be important for all countries but especially those in which there is no definition, those not yet members of the WTO and those currently undergoing reform of the health and/or drug sectors so as to avoid unintended consequences of piece meal legislation and technical errors.

Nomenclature

6. Based on submissions and research, Members use a varied nomenclature to designate counterfeit medical products including counterfeit medical products, counterfeit goods, counterfeit medicines, counterfeit pharmaceuticals, illegal products, falsified medicines, and others.

7. It may be more effective to focus attention on the terms *medical* and *product* than the term *counterfeit* because of its wide use and the question of whether it is preferable to direct anti-

counterfeiting efforts to all health products or a limited set of items. All names will carry baggage which can be managed by appropriate enforcement measures.

8. Opponents to the IMPACT definition seem to be more in agreement in opposition to the nomenclature rather than the content of the definition. There seems a preference for the phrase *falsified as to identity or source/origin* among IMPACT definition opponents. This approach is consistent with the EU proposed changes to its customs regulation 2001/83.

Types and Features in national and international definitions

9. Main Types and Features

A. API: References to the API, their amounts, quality, and relationship to national standards.

B. Authority: Whether there is or is not authority to market, distribute, manufacture, or sell.

C. Quality: Measures of expiration, adulteration, contamination or otherwise substandard in relation to national standards or those of relevant pharmacopeia.

D. Intent and knowledge: To mislead, deceive, defraud, think it is other, more than what it is or it is the authentic product of another when this is not true.

E. Recklessness, negligence, should have known

F. Unusual definitions: Misrepresented international unpatented name, or deviated from recognized principles.

G. Intellectual property right infringement: Generally a trademark or trade name or other visible feature that distinguishes the product.

H. Exterior Markers: Reference to visible markers such as labeling, packaging, trademarks, *as these relate to the name and location of the manufacturer and which are deceptive or misleading. Here intent is not always a requirement.*

Multilateral and civil society perspectives

10. From the multi-lateral perspective TRIPS defines counterfeit trademarks and pirated copyrights and these definitions are the basis for work at the WCO, WIPO, UNODC and the proposed ACTA.

11. The ASEAN region relies on a WHO definition with slight modifications.

12. Civil society groups such as the WSMI, FIP, IAPO and EGA find the WHO definition acceptable.

13. Public health activists are concerned about the term counterfeit as it can be incorrectly applied to issues that have nothing to do with counterfeits. The concept of intentional misrepresentation as to contents or origins is acceptable but the definition may be improved by outlining concretely acts not covered by the definition.³⁷ Activists urge that trade in legitimate medicines is fundamental, thus parallel trade, generics, products on which there is a patent infringement claim and gray market goods among others should not be treated as counterfeit.³⁸

Comments in IMPACT Definition

14. There were a total of 21 comments on the proposed text on the definition. Of these 14 favored it and 7 were opposed. No categorization was attributed to the submissions in which no

comment was made. Three of those favorable comments included caveats as to final content, but in the main were supportive. The US proposed a shorter definition.

15. Opponents remain firm in opposition to the term counterfeit although the majority has no concern over the term and it is in wide use in DRA laws.

Reform in some countries

16. A number of Members are awaiting the outcome of the question of definition. Some have already considered a proposal of their own most notably the EU which has identified the nomenclature of falsified *medicines in relation to their identity, and/or source* as their solution.

Discussion and points to consider

17. The broader the nomenclature and definition the easier it will be for Members to adapt it to the national context.

18. The more different the final nomenclature and definition are relative to those currently in use and those in international agreements the more time consuming and complicated it will be for national customization and implementation. Moreover, these changes will provide legal loop holes for criminals who will take advantage of any legal confusion caused by such changes.

19. If the IP law is strong and includes provisions for IP rights that are not registered then the drug law need not include IP related features, however their removal also removes the cooperative law enforcement capacity that such features bring.

20. To reduce the risk of honest generics from being mistaken as counterfeits, border and other law enforcement procedures can be amended to provide expedited procedures in the case of medical products especially those with a short shelf life or requiring particular storage conditions.

21. To change the term counterfeit may necessitate a change in the term generic.

22. Whatever terms and phrases are used in the drug law should not be inconsistent with or create confusion with IP law as many medical products are subject to IP rights and if these are counterfeited the IP law enforcement process will be available to work with the DRA to stop those involved and provide a second set of legal theories on which to prosecute.

The role and authority of the WHO

23. The World Health Assembly may consider establishing an expert committee to resolve the issue of the nomenclature and definition of a counterfeit medical product. Its authority is found in the WHO Constitution;

Article 2.3

The World Health Assembly and the Executive Board have authority under Articles 18(e) and 38 of the Constitution of the Organization to establish and dissolve expert committees.³⁹

24. Moreover, a globally applicable definition elaborated in consultation with member states and endorsed by the World Health Assembly as a regulation within its Article 21 (d) and (e) powers.⁴⁰

Article 21 The Health Assembly shall have authority to adopt regulations concerning:

(d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;

(e) advertising and labeling of biological, pharmaceutical and similar products moving in international commerce.

25. Given the debate on the nomenclature and definitional features, an approach such as that taken when the International Health Regulations (IHR) were most recently revised could be useful. The earlier version of the IHR only addressed three diseases. Now its scope includes *public health event of international concern* (PHEIC). To assist in the determination of whether an event is a PHEIC, a one page decision algorithm (found at Annex 2) was developed and is part of the revised regulations adopted by the Assembly in 2005.⁴¹ This kind of tool can be useful in harmonizing and unifying national and international legal definitions and civil society concerns.

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