

4. COUNTERFEIT MEDICINES AND ENFORCEMENT IN EGYPT

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ABSTRACT

In this world, there are many counterfeit products. Among these products are counterfeit medicines. Counterfeit medicines are different from other counterfeit products, as they directly affect the human life and health. It is very important to clearly define counterfeit medicines so that the definition does not include other types of medicines. This paper discusses the different ways to address the issue of counterfeit medicines. Several options for overcoming the problem are discussed, including the notion of using TRIPS plus standards, which may only exacerbate the issue rather than resolve it. This is mainly because counterfeit medicines are mainly a public health problem, and not an IP issue. There are many other solutions to fight the introduction of counterfeit medicines such as using technological measures, effective functioning of drug-regulatory authorities (DRAs) and initiatives by some international organizations like INTERPOL. It is strongly recommended that international organizations cooperate to overcome this problem.

Keywords: counterfeit medicine, IP enforcement, WHO, substandard medicines, DRA, customs IMPACT, INTERPOL, falsified medicines.

1. INTRODUCTION

In intellectual property (IP), counterfeiting is usually associated with trademark violation. For instance, the WTO glossary defines counterfeiting as:

"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."¹

For many goods, such as clothing or accessories, counterfeiting causes many problems. However, those problems are mainly financial in nature. In cases where

counterfeit goods are available, consumers may benefit from the low prices of counterfeit goods or lose from the poor-quality imitations.

In the case of food, medicines, and cosmetics, however, counterfeiting is considered a serious danger to human health, as many of these products contain dangerous components or ingredients. This kind of counterfeiting is thus qualitatively different from, for example, a fake Rolex watch.

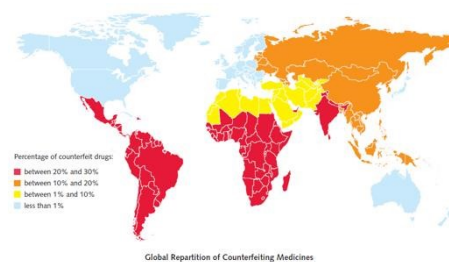
The definition of counterfeit medicines was first devised by the WHO in 1992: "a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."²

This definition has since been modified on 29 May 2017, at the Seventieth World Health Assembly (discussed further below).

A. WHERE CAN YOU FIND THE COUNTERFEIT MEDICINES?

The following figure shows that counterfeit medicines are found all around the world, but found with higher percentages in developing countries.³

This could be because of the high price of medicines, weak role of law, and instances of corruption. It is really a tragedy that people in both developing countries and least developed countries (LDCs), many of whom make a considerable effort to earn money in order to buy necessary medicines, may face a situation where they receive counterfeit medicine.



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¹ WTO Glossary, 'counterfeit' <http://www.wto.org/english/thewto_e/glossary_e/counterfeit_e.htm> Accessed 12 July 2018.

² WHO, 'Substandard and Falsified Medical Products' (31 January 2018) <<http://www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>> accessed 5 May 2018.

³ Sanofi Aventis, 'Drug Counterfeiting: Sanofi-Aventis takes action against counterfeiting', <http://ec.europa.eu/internal_market/indprop/docs/conf2008/wilfried_roge_en.pdf>, accessed 5 May 2018

B. CASE STUDIES

It is obvious that counterfeit medicines are very dangerous to human health. There are many stories to be told of tragedies caused by counterfeiting medicines, especially in developing countries and LDCs. The following examples illustrate the danger of counterfeit medicines categorized by the consequences of using these medicines:

(i) POISONING

Some counterfeit medicines may contain toxic doses or dangerous ingredients that cause poisoning. For example, 84 Nigerian children died from acute kidney failure when they ingested the industrial solvent di-ethylene glycol in teething syrup.

A similar case arose in Panama, when a Chinese chemical company sold di-ethylene glycol as glycerin to a European company. The poison caused acute kidney failure in the people who ingested it as the solvent in cough syrup.⁴

(ii) UNTREATED DISEASE, DISEASE PROGRESSION, AND DEATH

Usually, doctors prescribe medicines in order to treat a disease, or at least relieve symptoms or slow progress of the disease. But, this is not the case with counterfeit medicines. For example, during the outbreak of meningitis in 1995, the government of Niger gave 60,000 individuals a vaccine which was nothing but salt water, resulting in 2,500 deaths.⁵

(iii) MASK THE ILLNESS

This effect of the counterfeit medicines is the most dangerous one. For example, some patients died from taking counterfeit anti-malaria medicine. This counterfeit medicine contained Paracetamol to reduce the fever. Paracetamol reduced the fever so the patients thought that they were treated from the disease while they were not. They ultimately died as the disease was never treated.⁶

2. CAN YOU DIFFERENTIATE BETWEEN COUNTERFEIT AND AUTHENTIC MEDICINES?

It is not easy to differentiate between counterfeit and authentic medicines even for persons working in the field. Some believe that it is easy to distinguish

counterfeit from authentic medicines. This is because they think that counterfeit medicines have poor packaging. The reality, however, is often that counterfeit medicines have the same high quality or even better packaging than authentic medicines. Counterfeit medicines and authentic medicines may have:

A. SAME/SIMILAR PACKAGING

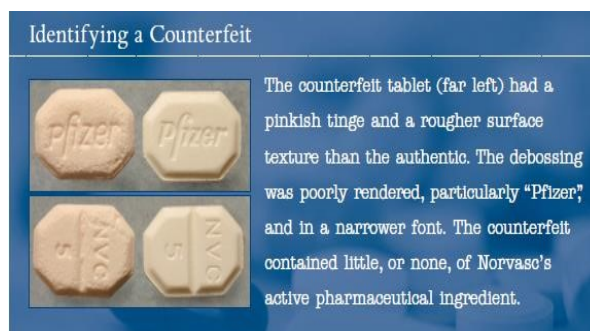
The following photo shows packaged Serostim (a medicine used for AIDS patients), and the packaged counterfeit. The counterfeit medicine is very similar to the authentic one, but with no active ingredients.⁷



B. SAME/SIMILAR TABLETS⁸

In this case, people cannot differentiate the counterfeit medicines from the authentic based on packaging alone as they may be identical. The main difference is in the tablets themselves.

As illustrated below, sometimes one cannot differentiate between the counterfeit and authentic medicines from the package or the tablet, as the only difference concerns the active ingredient. There is no visible difference in the pills—the authentic medicine treats while the counterfeit one could kill.



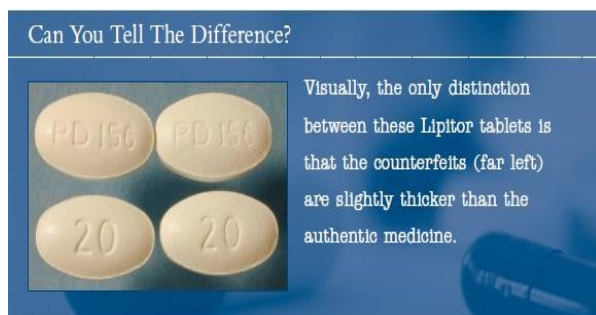
⁴ Gillian J. Buckley and Lawrence O. Gostin, *Countering the Problem of Falsified and Substandard Drugs- Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products- Board on Global Health*, (THE NATIONAL ACADEMIES PRESS 2013) 80-86.

⁵ Wyatt Yankus, *Counterfeit drugs: coming to a pharmacy near you: with update of 2009*, (American Council on Science and Health January 2009) 2.

⁶ Buckley and Gostin (n 5)

⁷ US Food and Drug Administration, 'Counterfeit Drugs' <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingmedicinesafely/counterfeitmedicine/default.htm>, accessed 5 May 2018

⁸ Pfizer, 'A Serious Threat to Patient Safety – Counterfeit Pharmaceuticals', (2007), <www.pfizer.com/files/products/CounterfeitBrochure.pdf> accessed 12 July 2018.



3. IMPORTANT PRINCIPLES AND TERMINOLOGY

It is very important to understand the different terminologies that may cause confusion. These terminologies are explained here.

A. COUNTERFEIT MEDICINE DEFINITION

The definition by WHO in 1992 indicates that counterfeit medicines are those which are:

- Mislabelled in respect to identity and/or source
- Include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients
- Or with fake packaging.⁹

This definition was revised by the International Medical Products Anti-Counterfeiting Taskforce¹⁰ (IMPACT) during the meeting in December 2008. The new definition states that:

"A medical product is counterfeit when there is a false representation in relation to its identity and/or source. 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 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."¹¹

The old definitions of counterfeit medicines by WHO in 1992 and IMPACT in 2008 use the term "counterfeit"¹² which is usually used for violation of intellectual property rights.

Thus, on 29 May 2017 at the Seventieth World Health Assembly¹³ a decision was made to adopt "Substandard and Falsified (SF) medical products" as the term to be used instead of "counterfeit medicines" in order to move away from the confusion which may arise from the old definitions.

The definition adopted in 2017 states that "Falsified medical products are:

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Any consideration related to intellectual property rights does not fall within this definition.

Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

⁹ WHO (n 3).

¹⁰ IMPACT was launched by WHO in 2006 and aims to build coordinated networks across and between countries in order to halt the production, trading and selling of counterfeit medicines. IMPACT includes representatives from the following organizations: Interpol, Organization for Economic Cooperation and Development (OECD), World Customs Organization, WIPO, WTO, 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. It 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.

¹¹ Charles Clift, 'Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?' (2010) Centre on Global Health Security <https://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/1110bp_counterfeit.pdf>. accessed 25 July 2018.

¹² It is noted that some countries use terms other than counterfeit medicines to distinguish the issue from IP violation or counterfeit. For example, Europe uses the term falsified medicine, while other countries like India use the term spurious medicines for this purpose.

¹³ Definitions of Substandard and Falsified (SF) Medical Products <<http://www.who.int/medicines/regulation/ssffc/definitions/en/>>. Accessed 21 November 2018.

“Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

“Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRRA.

“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.”

The term “falsified” which was used in the new definition by WHO appears to be more clear and adequately includes all the various types of deliberate misrepresentation of a medical product in such a way which enables the specific exclusion of intellectual property rights.¹⁴

B. SUBSTANDARD MEDICINE¹⁵

Substandard medicines were first defined by WHO in 2003 as:

“(…) 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 mislabelled with respect to identity and/or source”.¹⁶

WHO updated this definition in 2009 to state that:

“Substandard medicines 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.”

This definition was updated again in 2017 to state that:

“substandard medical products are authorized medical products that fail to meet either their quality standards or their specifications, or both.”

As it is noticed from the old definitions, substandard medicines are those that are approved and legally manufactured, but do not meet all quality criteria by national standards (not by WHO standards). The first definition in 2003 was very broad, including counterfeit medicines as part of substandard medicines, while the definition in 2009 clearly indicates that substandard medicines are genuine medicines and not counterfeit. The last updated definition in 2017 also clearly indicates that substandard medical products are authorized products, but in the footnote of the definition mentions that when the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered “falsified”.

The following examples show that substandard medicines are not less dangerous than counterfeit medicines as they may also cause serious consequences for example:¹⁷

(i) MAY CAUSE ANTIMICROBIAL RESISTANCE:

One example is the malaria resistance to Artemisinin.¹⁸ Artemisinin is a very effective medicine which is proven to decrease the mortality rate of malaria. Unfortunately, there is substandard medicine from Artemisinin, which results in creating malaria resistance to Artemisinin. The resistance appears in Southeast Asia and sub-Saharan Africa, as about 35 percent of the antimalarial medicines in those regions are substandard.

(ii) UNTREATED DISEASE, DISEASE PROGRESSION, AND DEATH:

Substandard medicines could also lead to Untreated Disease, Disease Progression or even death. For example, in 2009 a southwest Chinese newspaper reported a substandard version of the diabetes medicines Glibenclamide (also called glyburide), which contains six times the standard dose. The medicine was tested only after killing two people and injuring nine.

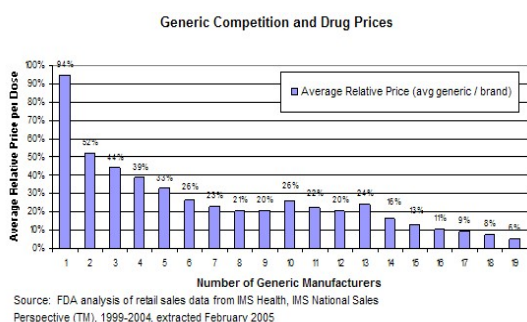
¹⁴ WHO member state mechanism on substandard/spurious/falsely labelled/falsified/counterfeit (ssffc) medical products <http://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1> accessed 22 November 2018.

¹⁵ Also called non-compliant drug and ‘out-of-specification’ products (OOS)

¹⁶ Clift (n 12).

¹⁷ Buckley and Gostin (n 5)

¹⁸ Artemisinin combination treatments are effective in treating falciparum Malaria. In areas where these drugs are available and appropriately used, malaria deaths have dropped dramatically. But, drug resistance could undo the success that artemisinin therapies.



C. GENERIC MEDICINES

Generic medicines are the medicines which contain the same active ingredients and pharmaceutical properties as patented medicines. The following figure represents results of a study made by the FDA to explain the effect of the entry of generic medicines manufacturers on the average relative price of medicine sold in the U.S. from 1999 through 2004.¹⁹

Generic medicines may help in fighting the introduction of counterfeit medicines, as they offer a cheaper alternative to branded medicines. Patients who cannot afford the price of the branded medicine can therefore buy generic medicines, instead of buying medicines from untrusted sources, e.g. from an open market or internet seller, simply because they may sell medicines at lower prices.

D. MEDICINES WHICH ARE INFRINGING PATENT RIGHTS

Medicines that infringe patent rights must not be considered as counterfeit medicines. Any confusion between these two different terminologies may harm the patients and lead to undesired consequences. A case which clearly demonstrates those undesired consequences occurred in Kenya.

In 2008, Kenya enacted the 'Anti-Counterfeit Act', with the encouragement and under the influence of a variety of TRIPS-plus IP enforcement supporters. The law defines "counterfeiting" as "taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods [...]."

This definition was very broad, and considered medicines that infringe patent rights, in Kenya or anywhere in the world, as counterfeit medicines. As a result, generic medicines that are legally available in Kenya and do not infringe any IP rules in Kenya can be targeted as counterfeit products, because they infringe IP rights held by someone anywhere in the world.

Patients with AIDS challenged the Kenyan Counterfeit Law in July 2009. The complainants argued that this law decreases their access to affordable generic medicines and conflicts with the right to life enshrined in Sections 70 and 71 of Kenya's Constitution. The Court agreed with the complainants, finding that the application of this law will harm the access to affordable generic medicines and will have negative consequences, including loss of life.²⁰

3. STRENGTHENING THE ENFORCEMENT OF IP RIGHTS USING TRIPS PLUS STANDARDS AND ITS CONSEQUENCES ON FIGHTING COUNTERFEIT MEDICINES

A. TRADEMARK ENFORCEMENT AND TRIPS PLUS STANDARDS

Academia, IP professionals and policy makers continue to debate whether strengthening the enforcement of trademarks using TRIPS plus standards assists in fighting the issue of counterfeit medicines.

The TRIPS Agreement states two types of trademark infringement:

- 1- Criminal infringement: includes wilful trademark counterfeiting on a commercial scale.
- 2- Civil trademark infringement: includes any product with a name, trademark, size, shape, or color that is confusingly similar to a branded product.

The pharmaceutical field is an exception however, as similar names and packaging are often desirable to demonstrate medical equivalency. Similar names in pharmaceuticals occur frequently because it is not unusual for the name of the medicine to contain part of the name of its active ingredient, or part of the name of the disease to be treated. Fisidine, Fusoival, Fusicare, Fusic are all antibiotic creams that contain fusidic acid as the active ingredient. The similar names of these creams indicate medical equivalency. Both branded medicines and generic medicines may have similar names and/or packaging. Using TRIPS plus standards, the term "counterfeit" is usually extended to include the confusingly similar goods to a branded product. So, under this definition, the lawfully-available generic medicines that are not intended to deceive consumers may be considered as counterfeit because they are confusingly similar.

One case illustrating the harmful effects of applying TRIPS plus standards occurred in May 2009, when an equivalent of 76,000 cases of the generic medicine Amoxicillin was

¹⁹ US Food and Drug Administration, 'Generic Competition and Drug Prices' (Food and Drug Administration, 28 November 2017) <<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>> accessed 12 July 2018.

²⁰ Jennifer Brant and Rohit Malpani, 'Eye on the Ball Medicine regulation—not IP enforcement—can best deliver quality medicines' (2011) Oxfam GB for Oxfam International <<https://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf>> accessed 25 July 2018..

seized in the Frankfurt airport. These medicines were in their route from India to Vanuatu. The medicines were seized on grounds of suspected civil trademark infringement, because this medicine is confusingly similar to a branded product "Amoxil." The medicines were released after three weeks, when the pharmaceutical company GSK that owns the brand name "Amoxil" informed the German customs authorities that there was no trademark infringement as the name "Amoxicillin"²¹ cannot be trademarked.²²

Although the medicines were released after GSK acknowledged the absence of trademark infringement, these medicines should not be seized from the beginning as they did not infringe any IPRs. In this case, the customs official applied TRIPS plus provisions relying on EU custom regulation 1383/2003 which enables them to apply border measures to goods in transit including medicines.

In this case two TRIPS plus provisions were applied. The first one is the seizure of the medicines in transit. The second TRIPS plus provision is that generic medicines were considered to be infringing trademarks because they were confusingly similar to branded medicines. This may be accepted in many fields of technology but the pharmaceutical field is different as the generic medicines should have similar names and packaging to the branded medicine.

Unfortunately, applying TRIPS plus provisions in this case only harms access to legally produced medicines.

B. TRIPS PLUS AND PATENT PROTECTION.

Using TRIPS plus standards for patent protection is no less harmful than using TRIPS plus standards for trademark enforcement. One good illustration occurred in Europe. The European Union (EU) Customs Regulation 1383/2003 enables customs officials to apply border measures to detain imports, exports, and goods in transit which are suspected of infringing intellectual property rights (IPRs).

EU customs officials used their authority and detained approximately 120 shipments in a period of 18 months. These shipments were detained and sometimes destroyed. One of these shipments contained life-saving generic medicines originating from India and headed to developing countries, where these medicines do not infringe any IPRs. This shipment carried medicines for HIV, heart disease, dementia and schizophrenia. Because of this, many patients had to wait several months to obtain their medicines.

In this case, the customs official again applied EU custom regulation 1383/2003 and applied border measures to goods in transit.

In 2010, India initiated a WTO dispute against Europe. Europe said that their regulation and enforcement helps to eliminate unsafe counterfeit medicines from Europe and also from developing countries and LDCs which often do not have enough capacity to recognize the counterfeit medicines.

However, India said that this regulation violates many WTO and TRIPS agreement rules. One of these rules is the territoriality principle, because even if the generic medicines violated a patent in Europe, they did not enter the European market as they were only in transit. Those generic medicines were not violating any IPRs in India or in the countries for which the medicines were bound. This regulation also is inconsistent with article 41 of the TRIPS Agreement which requires member states to avoid creation of IP-related barriers to legitimate trade. In addition to violating some WTO and TRIPS rules, this regulation conflicts with the EU's commitment to prioritize public health under Doha Declaration.²³

Late in the same year, India and Europe announced that they had reached an agreement. The regulation was revised, and India cancelled the dispute. Europe will no longer intercept in-transit generic medicines unless there is adequate evidence that those medicines will enter the European market. The EU has passed new EU regulation No 608/2013 to replace the challenged regulation 1383/2003.²⁴

Despite the new EU regulation No 608/2013, India raised some questions to the European Union regarding the new regulation and the EU's enforcement of intellectual property rights in relation to goods in transit during the council for TRIPS meeting held in October 2017.

The questions posed by India were as follows:

Can the EU provide a list of all the applicable custom laws issued by the EU which could be in the form of regulations/directives/guidelines etc.?

Can the EU clarify whether Regulation (EU) No 608/2013 is directed only to goods intended and/or suspected of entering into the EU market?

Does Regulation (EU) No 608/2013 provide any substantive right to an IPR holder or is it merely enforcing the existing IP rights? It is also

²¹ Some generic drugs names are no more than the names of their active ingredients.

²² Brant and Malpani (n 18).

²³ Brant and Malpani (n 18).

²⁴ Brook K. Baker, 'Settlement of India/EU WTO Dispute re Seizures of In-Transit medicines: why the proposed EU border

regulation is not good enough' (2012) PIJIP Research paper series <
<https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1026&context=research>> accessed 4 September 2018.

requested that the EU provide a list of existing laws/ regulations/ directive/guidelines issued by the EU governing IPR.

Are there any IPRs or infringement of IPRs which are excluded from the scope of Regulation (EU) No 608/2013? Specifically, please clarify whether goods which are not intended for free circulation in the EU market and are also not suspected of entering into the EU market, are exempted from the scope of Regulation (EU) No 608/2013.

Is it mandatory for goods originating from outside the EU to be 'released for free circulation' by EU customs authorities before they are placed on the EU market? Are there any other customs approved use(s) by which goods originating from outside the EU may be placed on the EU market?

Can the EU clarify the factors which are taken into consideration by the EU customs authorities while undertaking risk analysis criteria as provided in recital 16 of Regulation (EU)2015/2424 and recital 22 of Directive (EU)2015/2436?

Can the EU clarify whether paragraphs 2.2 and 3.2 of the Commission notice would apply to medicine(s) as well?

The European Union's initial response was that the EU is compliant with its TRIPS obligations including those related to enforcement and that they are not aware of a single recent case in the EU where there was an issue of seizure of legally transiting products.²⁵ The EU subsequently provided answers to India in relation to other questions above.²⁶

²⁵ The World Trade Organization, "minutes of meeting during the council for Trade-Related Aspects of Intellectual Property Rights held in the Centre William Rappard on 19-20 October 2017" (council for TRIPS meeting, 2 February 2018).

²⁶ See the subsequent communication from India on 18 October 2018 (IP/C/W/636)

²⁷ ACTA was negotiated from 2007 through 2010 by the US, the EU, Switzerland, Canada, Australia, New Zealand, Mexico, Singapore, Morocco, Japan, and South Korea. The negotiation was completely secret and the first text was only officially released in 2010. Eight out of the eleven negotiating countries signed the agreement in October 2011. ACTA has the following provisions which will have global consequences in digital freedom and in the pharmaceutical field:

²⁸ ARTICLE 16: BORDER MEASURES states that "

1. Each Party shall adopt or maintain procedures with respect to import and export shipments under which: (a) its customs authorities may act upon their own initiative to suspend the release of suspect goods; and (b) where appropriate, a right holder may request its competent authorities to suspend the release of suspect goods.

As a conclusion, applying current TRIPS Agreement provisions for enforcement is enough to fight counterfeit medicines and there is no need to increase the protection using TRIPS plus provisions as it may increase the problem instead of solving it. Applying TRIPS plus provisions may decrease the access to affordable medicines which will make patients in developing countries and LDCs try to find cheaper medicines in the open market or on-line which might lead to buying counterfeit medicines. So, it is a public health problem more than an IPRs problem and it is better to try to solve this problem without using TRIPS plus provisions.

C. THE ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)

ACTA is an agreement which was intended to create new global intellectual property (IP) enforcement standards that apply many TRIPS plus standards.²⁷ ACTA included many provisions which allow countries to adopt procedures with respect to suspect in-transit goods.²⁸ Applying those provisions would lead to the same hazardous effects on access to medicines, as was illustrated in the cases above regarding both trademark and patent enforcement.

(i) STOP ACTA PROTESTS

Thousands protested in several European countries to prevent the ratifying of ACTA in Europe.²⁹ As a result of these protests, ACTA was rejected by the European Parliament, which used its powers under the Lisbon Treaty to reject an international trade agreement for the first time. ACTA was rejected by a crushing 92% majority of the European Parliament in the summer of 2012 (478 against and 39 in favor, with 165 abstentions).³⁰

2. A Party may adopt or maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under customs control under which: (a) its customs authorities may act upon their own initiative to suspend the release of, or to detain, suspect goods; and (b) where appropriate, a right holder may request its competent authorities to suspend the release of, or to detain, suspect goods.

²⁹In German cities more than 25,000 demonstrators, in Sofia about 4,000 Bulgarians, in Paris, about 1,000 people, In Prague, Czech Republic, about 1,500 people. In Romania 2,000 people and In Bratislava, hundreds of young Slovaks and 1,000 people demonstrated in Budapest.

³⁰CHARLES ARTHUR, 'Acta Down, But Not Out, As Europe Votes Against Controversial Treaty' *The Guardian* (London, 4 July 2012).

<[HTTP://WWW.THEGUARDIAN.COM/TECHNOLOGY/2012/JUL/04/ACTA-EUROPEAN-PARLIAMENT-VOTES-AGAINST](http://www.theguardian.com/technology/2012/jul/04/acta-european-parliament-votes-against)> ACCESSED 12 JULY 2018.

(ii) ACTA IS DOWN BUT NOT DEAD

The success of protests against ACTA, will make some believe that ACTA is dead, which is not necessarily the case. This is mainly because many developed countries will try to ratify this agreement as soon as possible. For example, the Japanese legislative branches ratified the agreement, with effectively no real debate.³¹ This means that Japan is the first country to ratify ACTA, but not the last. LDCs and developing countries should oppose ACTA as it will harm the access to affordable medicines especially in those countries.³²

4. HOW TO OVERCOME COUNTERFEITING WITHOUT AFFECTING ACCESS TO MEDICINE?

Fighting counterfeit medicines is very difficult, but there are some efforts that may help to overcome them. The most important thing is to try to fight counterfeit medicines without affecting access to real medicine by fighting generic medicines for example. The following are some ways that will help to fight counterfeit medicines without affecting access to medicine.

A. TECHNOLOGY MEASURES

Technology measures are one of the most effectively known ways to address the issue of counterfeit medicines. Following are some examples:

(i) TRACKING TECHNOLOGY

The first method of tracking technology is the serial number. Using any cell phone, a patient can send the unique serial number printed on secondary packaging via SMS text message to a central database. The database automatically verifies if the serial number was checked before. If the serial number is free and has not been used before, then the medicine is authentic. However, if the number was previously used, then the medicine may be counterfeit, or an authentic package filled with counterfeit medicine. While this method is effective, it may give false results if someone checked the serial number of an authentic package first and then again at a later date, as the authentic package will be recognized as counterfeit.³³

The second technology is the Radio Transmitters Identification (RFID), which uses tiny radio transmitters. When affixed to the package of medicines, they emit a unique electronic products code, which would allow for each individual package to be tracked through each step of the supply chain from manufactures to distributors,

wholesalers and finally pharmacies. Using this technology, counterfeit medicines can be detected and removed from the medicine supply and the wholesalers will not be able to sell medicines that they have purchased illegally. The disadvantages of this technology are that it is costly, and requires a complicated infrastructure for tracking the medicine through the distribution system. In addition, there is a question of whether this technology could affect biological medicines.³⁴

(ii) OVERT (VISIBLE FEATURES)

There are many visible features that can be used in order to fight counterfeit medicines. Examples of those visible features are holograms, optical viable devices (OVD), color shifting security inks, and films and watermarks.

Holograms are the most familiar feature. A hologram incorporates an image with some illusion of 3D construction, or apparent depth and special separation. However, some hologram labels have been easily and expertly copied or simulated, and may often rely on a hidden converting element for authentication.

An Optical Viable Device (OVD) is similar to a hologram but without any 3D. It generally involves image flip or transitions, often including color transformations or monochromatic contracts. Color shifting security inks and films show changes in color according to the viewing angle.

(Source: Howard Zucher, 'Combating Counterfeit Drugs: Building Effective Collaboration' WHO Presentation at Conference of Rome, February 2006)



A: Genuine hologram, B: early fake hologram, C: within several months, fake hologram nearly identical to genuine was produced.³⁵

³¹Maira Sutton, 'Japan Was the First to Ratify ACTA. Will They Join TPP Next?' (Electronic frontier foundation, 26 October 2012) <<https://www.eff.org/deeplinks/2012/10/japan-ratify-acta-will-they-join-tpp-next>> accessed 12 July 2018.

³² Maira Sutton, 'US Trade Office Calls ACTA Back from the Dead and Canada Complies' (Electronic Frontier Foundation, 1 March 2013) <[https://www.eff.org/deeplinks/2013/03/us-trade-](https://www.eff.org/deeplinks/2013/03/us-trade-office-calls-acta-back-dead-and-canada-complies)

[office-calls-acta-back-dead-and-canada-complies](https://www.eff.org/deeplinks/2013/03/us-trade-office-calls-acta-back-dead-and-canada-complies)> accessed 12 July 2018.

³³ Fred Jordan and Martin Kuller, 'Identifying counterfeit medicines with industry suitable technique' (2012) 32 Pharmaceutical Engineering.

³⁴ Yankus (n 6).

³⁵ Yankus (n 6) 14.

(iii) COVERT

These are visible, but not immediately apparent, security measures, which often include hidden features such as UV markers or micro batch codes.

(iv) FORENSIC

They are extremely covert measures that require special equipment to detect. They include chemical tags that can be tested for the elemental analysis to verify position.

B. ROLE OF DRUG REGULATORY AUTHORITY (DRA)

The main function of a DRA is to ensure that only safe, effective, and quality medicines are imported, manufactured, traded, and consumed. This means that an effective DRA is the core component to fight counterfeit medicines.

ADRA has the following functions:

- Marketing authorization (registration) for new products and management of variations of marketing authorization;
- Quality-control laboratory testing;
- Monitoring of adverse reactions to medicines;
- Provision of medicines information and promotion of rational use;
- Good Manufacturing Practice (GMP) inspections and licensing of pharmaceutical establishments, including manufacturers, wholesalers, and distribution channels;
- Enforcement operations, including risk-based inspections; and
- Monitoring the utilization of medicines.

In developed countries, there are stringent regulatory authorities that are effective, like the FDA in the USA and the European Medicines Agency (EMA) in Europe. In developing countries and LDCs, these authorities are less effective—this is the main reason that counterfeit medicines are found in these countries in higher percentages than in developed countries. So, developing countries and LDCs should make more effort in order to improve their DRAs. This mission may be difficult but it is not impossible. A good example of this is the case of Brazil. Brazil is a developing country that had very little or no drug regulatory capacity. Since the 1990s, Brazil worked hard to create a national regulatory (ANVISA) structure for medicines. Today, it has an extensive system of drug regulation in place, including registration, quality assurance, inspections, pharmacovigilance, monitoring of clinical trials, and oversight of marketing practices.³⁶

C. IMPACT

IMPACT was launched by WHO, and aims to raise the awareness and develop global solutions for counterfeit medical products. However, IMPACT has never been approved by the World Health Assembly (WHA), the governing body of the WHO, as many developing

countries with civil-society groups have aggressively sought to arrest the progress of IMPACT. This is mainly because they believe IMPACT introduces TRIPS-plus enforcement rules to its definition.

The definition by IMPACT, illustrated earlier, states that “a medical product is counterfeit when there is a false representation (A) in relation to its identity and/or source.” This is very broad, and introduces TRIPS plus rules because the footnote by IMPACT (A) explains: “counterfeiting is done fraudulently and deliberately.”³⁷ This means that the definition includes elements from both civil and criminal trademark infringement. This may lead to considering generic medicines, with trade names similar to the name of a branded product, as counterfeit on the basis of this definition. In other words, this definition has the same effect as the trademark enforcement illustrated above, which limits access to the affordable generic versions of medicines.

Although IMPACT was never approved by WHA and is no longer operational, this definition is a good example of how, when defining counterfeit medicines, it is very important to be accurate and clear in order to fight only the counterfeit medicines and not affect access to legally produced medicines.

D. INTERPOL (International Criminal Police Organization)

INTERPOL is the world’s largest international police organization, with 190 member countries. It works to ensure that police around the world have access to the tools and services necessary to do their jobs effectively. INTERPOL plays an important role in protecting the public from counterfeit medicines from both physical outlets and Internet suppliers. It is a partner with many stakeholders and organizations, including:

- World Health Organization (WHO)
- Permanent Forum on International Pharmaceutical Crime (PFIPC)
- Pharmaceutical Security Institute (PSI)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Health Sciences Authority, Singapore (HSA)
- Council of Europe
- European Commission
- Institute of Research Against Counterfeiting Medicines (IRACM)
- United Nations Office on Drugs and Crime (UNODC)
- HMA Working group of Enforcement Officers (WGEO)
- World Intellectual Property Organization (WIPO)

These partnerships allow INTERPOL to co-ordinate with IMPACT in many operations to address counterfeit medicines: for example, Operation Storm II (July-

³⁶ Brant and Malpani (n 18) 15-21.

³⁷ Clift (n 12) 14

November 2009),³⁸ and Pangea (targeting the Internet). These operations resulted in arresting and closing of many illicit websites.³⁹ These operations show the importance of coordination between different organizations in order to protect against counterfeited medicines.

5. THE SITUATION IN EGYPT

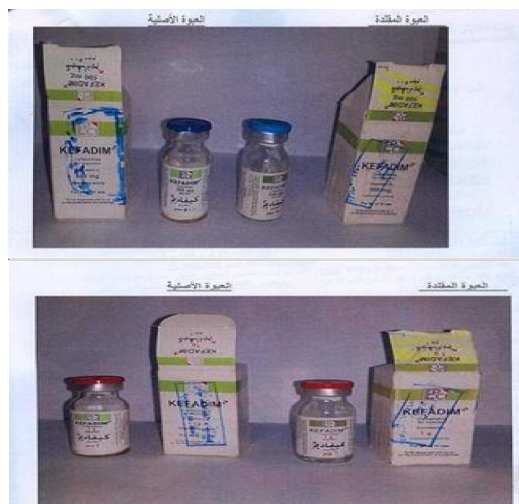
In Egypt, there are many efforts to seize counterfeit medicines. The following are some examples of national efforts:

A. DRA IN EGYPT.

The DRA in Egypt is not fully efficient, and needs to be more effective. Normally, the DRA has the following functions:

- *Enforcement operations, including risk-based inspections:* in Egypt, there is no risk-based enforcement but there is enforcement of counterfeit medicines upon request.
- *Marketing authorization:* in Egypt, the only condition to register the medicine is that the product has to be registered in another country.
- *Quality-control laboratory testing:* there is no complete quality control for all batches of the medicine. The Ministry of Health (MOH) takes random samples of batches to examine, but this is not a regular practice. The only complete quality testing occurs for antibiotics, sterile and biological medicines, as the MOH takes 100% samples of all batches.
- *Monitoring of adverse reactions to medicines:* there is no capacity in Egypt to monitor and test the adverse reactions of a medicine but MOH takes into consideration if the medicine is recalled from any other countries.⁴⁰
- *Good Manufacturing Practice (GMP) inspections:* in Egypt, there is complete GMP by MOH.

As illustrated, the enforcement of counterfeit medicine is regulated by the DRA, but not with full capacity. The following is an example of counterfeit medicine seized by the DRA in Egypt, and counterfeit medicine which was withdrawn by MOH.⁴¹



B. CUSTOMS AUTHORITY'S ROLE

The Customs Authority plays an important role in fighting counterfeit medicines before entering the country. INTERPOL, IMPACT, Egyptian police and the Egyptian Customs have coordinated six operations in order to seize counterfeit medicines. These operations resulted in seizure of ten containers containing thousands of counterfeit medicines, which were intended to enter the Middle East market.

Also, three containers were seized by Egyptian customs in the Suez Canal, and 3,300 bottles of counterfeit pharmaceuticals at Cairo airport. Among the counterfeit medicines found, a wide range of medicines were identified, including lifestyle products and others intended for organ-transplant patients, and serious diseases such as cancer, diabetes, heart disease, epilepsy or schizophrenia.⁴²

6. CONCLUSION

For many goods, the effect of counterfeiting is principally financial and economic. Consumers may benefit from lower prices or lose from poor-quality imitations, but falsified medicines which were discussed in this paper are more dangerous and may cause death.

Although having a clear definition of what constitutes counterfeit or falsified will not help in overcoming this problem, there is a need to establish the parameters of

³⁸ INTERPOL, Pharmaceutical crime, operations, Operation Storm <<https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Storm>>, accessed 22 July 2018.

³⁹ INTERPOL, 'Overview' <<http://www.interpol.int/About-INTERPOL/Overview>> accessed 22 July 2018.

⁴⁰ Egyptian Pharmacovigilance Center, 'Withdrawal & Recall of Syrups Containing Pizotifen' (2013) 4(9) EPVC Newsletter <http://www.ems.org.eg/userfiles/file/Newsletter/Newsletter%20forty%20four%20-%20Sept_%202013.pdf> accessed 22 July 2018.

⁴¹ Egyptian Pharmacovigilance Center, 'Batches recall from the Egyptian market due to counterfeit' (2015) 6(4) EPVC Newsletter <<https://www.slideshare.net/aminmohamed/63-newsletter-sixty-threeapril-2015-1>> accessed 22 July 2018.

⁴² INTERPOL, 'Millions of medicines seized in largest INTERPOL operation against illicit online pharmacies' (25 September 2017) <<https://www.interpol.int/News-and-media/News/2017/N2017-119>> accessed 23 July 2018.

what should be considered counterfeit. This is mainly because if the definition is too broad, it will include other generally acceptable categories of medicines, like generic medicines, and thus may limit the access to affordable medicines.

As discussed in this paper, the increasing of IPRs enforcement by applying TRIPS plus provisions will not help to fight the counterfeit medicines, but it will significantly decrease the access to affordable medicines. This means that counterfeit medicines are a public health problem and they have nothing to do with IP. WHO has recognized that and updated it is definition of counterfeit medicine. The new definition uses the term “falsified” instead of counterfeit in order to include all the various types of deliberate misrepresentation of a medical product in such a way which enables the specific exclusion of intellectual property rights.

However, there are many other ways that could help in fighting the counterfeit without affecting access to medicines. Technological measures are effective ways to combat counterfeiting, and they offer a very promising solution. Also, many international organizations play important roles in fighting counterfeit medicines, for example INTERPOL. INTERPOL, for instance, has coordinated a number of successful operations to seize and destroy counterfeit medicines at both physical and online sources. It is highly recommended that the international organizations work together to obtain better results in seizing and destroying the counterfeit medicines.

Egypt, like many other countries, suffers from counterfeiting medicines. The DRA in Egypt plays a role in fighting such medicines, but with very limited capacity. However, many successful operations were conducted in Egypt by the Egyptian police and customs under the umbrella of INTERPOL and IMPACT. These operations resulted in the successful seizure of thousands of counterfeit medicines, showing that there is much that can and should continue to be done in this area.

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