2 Counterfeit pharmaceuticals: scope and data

The definition of illicit, falsified, substandard or counterfeit pharmaceuticals is subject to debate. This chapter clarifies the scope and then provides background information on the data sources used for this study.

Definition and scope

Before turning to the quantitative analysis of trade in counterfeit pharmaceuticals, it is important to be clear what we mean by the term "counterfeit pharmaceuticals".

As in previous OECD studies on trade in counterfeit goods, this study generally looks at traded pharmaceutical products that infringe trademarks, and refers to them as counterfeit (or fake) pharmaceuticals or medicines. In this context, it stays in line with the definition used by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS),[1] and parallels the approach taken by the World Health Organization (WHO), in which counterfeit pharmaceuticals are described as "[…] deliberately and fraudulently mislabeled with respect to identity and/or source" (WHO, 1999). This is the definition of "counterfeit" used in this study.

The definition of illicit, falsified, substandard or counterfeit pharmaceuticals has been debated many times at several international fora. For example, issues related to the definition of "counterfeit medicines" were addressed at both the WTO and the WHO. At the WTO, the TRIPS Council discussed the negative economic impact that counterfeiting could have on economies, as well as the threats that counterfeit products could pose to health and safety.[2] Some countries noted that a distinction should be made between IPR infringement and substandard products and cautioned against IP enforcement measures that could not guarantee products of quality, but would potentially undermine access to affordable medicines. Counterfeit medicines, including their impact on health and the economy, as well as the need to distinguish

them from generic medicines, were also discussed in the context of the detention of in transit generic medicines by EU Customs.[3] In 2017, citing the confusion surrounding substandard and falsified products and the protection of intellectual property rights, the WHO adopted new definitions (WHO, 2017a and b). The new definitions refer to products which are either:

- Substandard: Also called “out of specification”, these are authorised medical products that fail to meet either their quality standards or specifications, or both.
- Unregistered/unlicensed: Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

This study takes note of these debates, but is not intended to constitute any sort of new definition of counterfeit pharmaceuticals.

Several additional important issues should be kept in mind in the context of the scope of the study, and the term “counterfeit pharmaceuticals”:

- Even though counterfeit medicines are often substandard, it is not their quality that determines whether or not they are counterfeit. In fact, some traded fake medicines that infringe trademarks may still have active ingredients, although interviews with enforcement and industry experts indicate such cases are virtually non-existent.
- In many reports quantitative analysis also includes stolen and diverted pharmaceuticals (Box 2.1). This is because, as for any quantitative analysis on illicit markets, research on trade in counterfeit medicines is largely data driven. Unfortunately the existing datasets rely on largely incompatible and different methodologies and taxonomies that in some cases also include stolen and diverted goods.4 Importantly, stolen and diverted goods enter the market without the consent of IP right owners, and in many instances they also deceive final consumers. Hence, in many aspects they closely resemble counterfeit goods that were produced without the consent of the IP right owner.
- Due to data limitations this study does not look at potential or actual patent infringements.

To reiterate, as the main quantification exercise of the share of counterfeits in trade in this study is based on customs seizure statistics focusing on IPR infringement, stolen or diverted medicines are not included in this estimate unless they infringe a trade mark, irrespectively of their medical or regulatory properties.

Box 2.1. Diversion and theft of pharmaceuticals

According to the Pharmaceutical Security Institute (PSI, 2019), illegal diversion occurs when a genuine pharmaceutical product is approved and intended for sale in one country, but is then illegally intercepted and sold in another country. These actions are often accomplished through the use of false statements or declarations. At times, drug regulators in the second country have not approved the use of the diverted drug.

Illegal diversion may also occur within the same geographic area, within the same country or city. This involves diverting discounted medicines from one intended group of consumers to another group buying medicines in an unregulated open market. For example, in Latin America, illegal diversion occurs when a government purchases drugs at discounted prices for use in state hospitals and these drugs are diverted to open air or "street" markets.

Pharmaceutical theft is defined as the illegal taking of medicines (PSI, 2019). Thefts include burglary, robbery or the embezzlement of goods. The responsible individuals may be insiders such as employees, or outsiders such as professional thieves. The theft may occur anywhere in the distribution chain such as at the site of manufacture, freight forwarder, distribution centres, warehouses, pharmacies, or hospitals.

Importantly, as with cases of counterfeiting, diversion and theft escape the control of the IP right owner. In addition, diverted and stolen medicines are often stored and transported in poor conditions, which might have negative effects on their active ingredients. Moreover, these medicines can be unlawfully supplied to the public without observing prescription conditions. Consequently, diverted and stolen drugs can potentially be damaging to consumers' health. They also contribute to a general "blurring" of the marketplace.

Data

This study relies on two main sets of data: customs seizures data and other enforcement data. These datasets are described below.

Customs seizures of fake pharmaceuticals

Following the approach taken in the OECD (2008) and then in the OECD/EUIPO (2016 and 2019) reports, a large volume of analysis in this report is based on data on customs seizures of counterfeit pharmaceuticals.

Data on customs seizures originate from national customs administrations. This report relies on customs seizures data received from:

- The World Customs Organization (WCO).
- The European Commission's Directorate-General for Taxation and Customs Union (DG TAXUD).
- United States Department of Homeland Security (DHS), which submitted seizure data from US Customs and Border Protection (CBP), the customs agency of the United States, and from the US Immigration and Customs Enforcement (ICE).

The database compiled for this research contains a wealth of information about fake pharmaceuticals that can be used for quantitative and qualitative analysis. In most cases the database reports, for each seizure: date of seizure, mode of transport of fake products, departure and destination economies, name of legitimate brand owner, number of seized products and their approximate value.

There are two methods for reporting the value of counterfeit goods: 1) declared value (value indicated on customs declarations), which corresponds to values reported in the general trade statistics; and 2) replacement value (price of original goods). The structured interviews with customs officials and the descriptive analysis of values of selected products conducted in OECD/EUIPO (2019) revealed that the declared values are reported in most cases.

Importantly, the DG TAXUD, CBP-ICE and WCO datasets rely on data entries collected and processed by customs officers. These data are primarily designed to improve the work of customs, e.g. to prepare risk profiling processes and share national experiences. As with any other administrative data they need careful consideration before use in quantitative analysis. In particular, these data are created by customs and for customs. Customs expertise in spotting counterfeit medicines might sometimes be limited due to lack of resources or training. Indeed, customs seizures of fake pharmaceuticals refer mostly to "common" products (e.g. painkillers or sexual dysfunction treatments), yet other enforcement sources noted that there are other medicine categories (such as cardiovascular and cancer treatment) that are more targeted by counterfeiters. Consequently, these other enforcement sources of data, described below, would be valuable for the rest of the analysis.

Other enforcement data

While customs data provide valuable information on the global trade in counterfeit pharmaceuticals, other data sources offer the basis for more reliable and robust analysis of fake medicines.

An additional dataset used in this study comes from the Counterfeiting Incident System (CIS) of the Pharmaceutical Security Institute (PSI, see Box 2.2). This database comprises cases of fraudulent manufacture, mislabelling of drugs and fraudulent packaging. This database originally refers to enforcement actions carried out by all kinds of enforcement agencies, such as police, health inspection service, customs, etc.

The database is organised into incidents. An incident is a discrete event triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals. An incident is a unique occurrence, and has an assigned date, time, place and type of pharmaceutical product involved. All reports arriving in the database are reviewed to determine if they are related to an earlier incident, which would indicate ongoing criminal activity. CIS incidents come from a variety of sources, including open media reports, PSI member company submissions, and public-private sector partnerships.

To summarise, the OECD/EUIPO database on global customs seizures of counterfeit pharmaceuticals and the CIS enforcement database on incidents counterfeiting, theft and illegal diversion of pharmaceutical products worldwide are based on two completely different types of data collection. However, together they offer a wealth of valuable insight into the size and scope of the global market of illicit pharmaceuticals, as studied in the following chapters.

Box 2.2. Pharmaceutical Security Institute (PSI)

The Pharmaceutical Security Institute (PSI) is a non-profit, global organisation established by pharmaceutical companies with a mission to 1) protect public health; 2) share information on the counterfeiting of pharmaceuticals; and 3) support the initiation of enforcement actions through appropriate authorities. It comprises the security departments of 25 pharmaceutical companies. Activities are supported by a secure database to which members report (IOM, 2013). In 2018, the institute reported that the number of incidents involving counterfeiting, illegal diversion and theft incidents rose to an all-time high of 4 405, which was more than double than the 2014 level. North America accounted for the largest number of seizures (1 750), followed by Asia (1 426). Every region except Europe have experienced an increase in pharmaceutical crime incidents since 2017, with a total of 145 countries affected. The contributions made by organisations like PSI to law enforcement are significant. Security departments in major pharmaceutical firms reportedly gather 80% of the evidence for criminal prosecution (IOM, 2013).

Notes

[1] The TRIPS Agreement, in its footnote 14, contains a definition of "counterfeit trademark goods". These are "goods … 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 …"

[2] See www.wto.org/english/news_e/news12_e/trip_05jun12_e.htm.

[3] See TRIPS Council meeting of 3 March 2009, WTO Document IP/C/M/59, para.122; TRIPS Council meeting of 8-9 June 2009, WTO Document IP/C/M/60, para.115; TRIPS Council meeting of 27-28 October 2009, WTO Document IP/C/M/61, para.254.

[4] Importantly, this does not concern the estimate of the share of counterfeit pharmaceuticals in trade, as this estimate relies on seizures statistics, focusing on IPR infringement.

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