Illicit Trade

Trade in Counterfeit Pharmaceutical Products

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Trade in Counterfeit Pharmaceutical Products

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Preface

Globalisation, trade facilitation, and the rising economic importance of intellectual property are all drivers of economic growth. However, they have also created new opportunities for criminal networks to expand the scope and scale of their operations, free-riding on intellectual property and polluting trade routes with counterfeit goods. The consequences for the economy and for citizens are serious. Trade in counterfeit goods not only damages economic growth but also undermines good governance, the rule of law and citizens' trust in government, and can ultimately threaten political stability. In addition, in some cases, such as that of fake pharmaceuticals, counterfeit goods can have serious health and safety implications for citizens.

We are confident that this new evidence will make a major contribution to the understanding of the volume, magnitude and harmful societal effects of illicit trade in counterfeit medicines. We are confident that the results about both the economic harm caused by this threat and its damaging impact on health will urge policy makers to shape effective solutions to combat and deter this scourge.

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Foreword

Illicit trade in fake goods is a significant and growing threat in a globalised and innovation-driven economy, undermining good governance, the rule of law and citizens' trust in government. It not only has a negative impact on the sales and profits of affected firms and on the economy in general, but also poses major health and safety threats to consumers.

To provide policy makers with solid empirical evidence about this threat, the OECD and the EU Intellectual Property Office (EUIPO) joined forces to carry out a series of analytical studies that deepen our understanding of the scale and magnitude of the problem. The results have been published in a set of reports: *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact* (2016), *Mapping the Real Routes of Trade in Fake Goods* (2017), *Trade in Counterfeit Goods and Free Trade Zones: Evidence From Recent Trends* (2018), Why do countries Export Fakes (2018), *Misuse of Small Parcels for Trade in Counterfeit Goods* (2018) and *Trends in Trade in Counterfeit and Pirated Goods* (2019). The results are alarming. They show that trade in counterfeit and pirated goods amounted to up to 3.3 % of world trade in 2016, up from 2.5 % in 2013; when considering only the imports into the EU, they amounted to up to 6.8 % of imports, compared with 5 % three years earlier. Counterfeiters operate swiftly in the globalised economy, misusing free trade zones, taking advantage of many legitimate trade facilitation mechanisms and thriving in economies with insufficient governance standards.

Trade in counterfeit and pirated goods is a dynamic and constantly changing phenomenon. Continuous measurement efforts are needed to monitor this risk. This report presents updated figures on the scale, scope and magnitude of trade in counterfeit pharmaceuticals, based on a statistical analysis of a unique database of half a million seizures of counterfeit goods. Structured interviews with trade and customs experts also contributed to the analysis.

This report builds on previous analyses, focusing on the situation in one particular sector: pharmaceuticals. Counterfeits imply not only possible economic damages for this sector, but also significant health threats, since fake medicines are often not properly formulated and may contain dangerous ingredients. Counterfeit medicines have included medicaments for serious diseases, including malaria, HIV/AIDS and cancer. The scale is huge – in 2016, international trade in counterfeit pharmaceuticals reached USD 4.4 billion.

This report responds to major policy concerns. The first is the negative effect that counterfeit trade has on legitimate competitive advantage of rights holders, and consequently on innovation, employment and long-term economic growth. The second one is the damaging impact of crime and illicit trade activities on good governance, public health and safety.

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At the OECD this study was conducted under the Task Force on Countering Illicit Trade (TF-CIT). The study was shared with other OECD committees with relevant expertise in the area of trade, health policy and innovation.

The report was prepared by Piotr Stryszowski, Senior Economist and Florence Mouradian, Economist at the OECD Directorate for Public Governance jointly with Michał Kazimierczak, Economist at the European Observatory on Infringements of Intellectual Property Rights of the EUIPO and Nathan Wajsman, Chief Economist, EUIPO. Peter Avery, Senior Consultant, provided valuable input. The authors wish to thank the OECD experts, who provided valuable knowledge and insights: Morgane Gaudiau and Nikolai Malyshev from the OECD Public Governance Directorate, Valérie Paris and Martin Wenzl from the OECD Directorate for Employment, Labour and Social Affairs, and Susan Stone from the OECD Trade Directorate.

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The database on customs seizures was provided by the World Customs Organization (WCO) and supplemented with regional data submitted by the European Commission's Directorate-General for Taxation and Customs Union, the US Customs and Border Protection Agency and the US Immigration and Customs Enforcement. Additional enforcement data were provided by the Pharmaceutical Security Institute. The authors express their gratitude for the data and for the valuable support of these institutions.

Acronyms and abbreviations

ACIM	Action against Counterfeit & Illicit Medicines
AED	Advance electronic data
AMR	Antimicrobial resistance
ASOP EU	Alliance for Safe Online Pharmacy in the EU
ASOP Global	Alliance for Safe Online Pharmacies - Global
ATD	Anti-tamper device
CBP	US Customs and Border Protection
DEA	Drug Enforcement Administration
DG TAXUD	European Commission's Directorate-General for Taxation and Customs Union
EAASM	European Alliance for Access to Safe Medicines
EU	European Union
EUIPO	European Union Intellectual Property Office
FDA	Federal Drug Administration
FMD	Falsified Medicines Directive
FTZ	Free trade zone
ICANN	Internet Corporation for Assigned Names and Numbers
ICC	International Chamber of Commerce
ICE	US Immigration and Customs Enforcement
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IMF	International mail facility
INTERPOL	International Criminal Police Organization
IOM	Institute of Medicines of the National Academies
IP	Intellectual property
IPR	Intellectual property rights
IRACM	International Institute of Research against Counterfeit Medicines
MHRA	Medicines and Healthcare products Regulatory Agency
NAPB	National Association of Boards of Pharmacy

NMRA	National or regional Medicines Regulatory Authority
OCG	Organised crime groups
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-counter
PPC	Pay-per-click
PSI	Pharmaceutical Security Institute
R&D	Research and development
RCAP-e	Relative comparative advantage for production
RCAT-e	Relative comparative advantage for being a transit point
RPSGB	Royal Pharmaceutical Society of Great Britain
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNICEF	United Nations International Children's Emergency Fund
UNICRI	United Nations Interregional Crime and Justice Research Institute
UNIDO	United Nations Industrial Development Organization
UNODC	United Nations Office on Drugs and Crime
VIPPS	Verified Internet Pharmacy Practice Sites
WCO	World Customs Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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Executive Summary

This report, one in a series of studies by the OECD and the European Union Intellectual Property Office (EUIPO), is designed to enhance understanding of the issues and challenges facing governments, businesses and society posed by the trade in fake pharmaceutical products.

Illicit markets for counterfeit pharmaceuticals are attractive for counterfeiters, given their high profit margins, low risks of detection and prosecution, weak penalties, and the ease with which consumers can be deceived into believing that the counterfeit products are genuine. In 2016, international trade in counterfeit pharmaceuticals reached USD 4.4 billion, threatening public health and safety, while enriching criminals and organised crime. This does not include a very large volume of domestically produced and consumed illicit pharmaceuticals. Counterfeit medicines not only cause economic damage for the sector, but are also a significant threat to public health, since they are often not properly formulated and may contain dangerous ingredients.

Over the period 2014-2016, seized counterfeits included medicaments for serious diseases, including malaria, HIV/AIDS and cancer. They also included antibiotics, lifestyle treatments, pain killers, diabetes treatments and central nervous system medicines.

What did this research find?

The study compiled and analysed a unique international set of customs seizure data and other enforcement data, combined with structured interviews with industry, trade and customs experts, to quantify the value, scope and trends of the trade in counterfeit pharmaceutical products.

It found that the People's Republic of China, Hong Kong (China), Singapore and India are the main provenance economies for counterfeit medicines. While China and India are the primary producers of fake medicines, the United Arab Emirates, Singapore and Hong Kong (China) serve as transit economies. Other relevant transit points for fake pharmaceuticals include Yemen and Iran.

From these locations, fake pharmaceutical products may be shipped anywhere in the world, although African economies, Europe and the United States appear to be the main targets.

What are the challenges?

Successful marketing of counterfeits requires counterfeiters to penetrate supply chains which, for the most part, are closely monitored by producers and regulators. While the wholesalers that are responsible for distributing most pharmaceutical products are secure, there are thousands of second-tier distributors that are more vulnerable to penetration by counterfeiters. Detection of counterfeits requires expert examination, which can be costly. The ability of counterfeiters to package products in a way that mirrors genuine products is key to their success, as is their ability to make the products resemble the originals.

The use of free trade zones has facilitated trade in counterfeit pharmaceuticals, providing a venue for packaging and repackaging products in ways that effectively disguise their true origin.

Challenges exist in all countries, but are particularly large in developing countries, where informal distribution is more widespread and less secure. Challenges for all countries have increased with the development of rogue on-line pharmacies, which often dispense counterfeit products cheaply. Consumers have demonstrated a willingness to take risks buying products online, sometimes disregarding the consequences of purchasing and using products that may not be properly formulated.

Trade in counterfeit medicines has also been fuelled by the explosive growth in the use of the post to ship products. More than 95% of customs seizures of pharmaceutical products during 2014-16 involved postal and express mail services, which was well above the average for other products. Inadequate information on postal shipments makes it difficult to detect and intercept products in national and international trade. In the case of imports, documentation is generally only available to customs officials in paper form, at the time of importation and can be easily incorrect.

Governments and industry have been working hand-in-hand to combat counterfeit, substandard and falsified pharmaceuticals. Actions taken range from legislative measures to enforcement and awareness-raising campaigns. On an international level, many initiatives are underway to tackle the growing problem of counterfeit pharmaceuticals, including crime-fighting programmes run by INTERPOL and the World Health Organization.

What are the impacts?

The impacts of counterfeit medicines are felt on many levels:

- Damage to the health of individuals or failure to treat their medical needs adequately. Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malarial medication might be responsible for an additional 116 000 deaths.
- Loss of sales and damage to the reputations of legitimate producers. Companies registered in the United States are hit hardest by the trade in counterfeits: almost 38% of all seized counterfeit medicines infringe the intellectual property (IP) rights of firms registered in the United States. However, other OECD countries are also badly affected (notably Switzerland, Germany and France).
- Costs and lost revenues to governments and economies. One estimate suggests that the cost to EU governments of revenues foregone from counterfeit medicines is on the order of EUR 1.7 billion.
- Costs of treating patients who have suffered adverse health consequences as a result of consuming counterfeit medicines.
- Environmental pollution from dirty practices by an unregulated criminal activity involving potentially toxic chemicals.
- Social costs in terms of an increase in organised crime and job losses, which are estimated at more than 80 000 jobs in the EU pharmaceuticals sector and other sectors that sell goods and services to it.

What's next?

Illicit trade in counterfeit and pirated goods is a significant and growing problem, having risen from 2.5 % of world trade in 2013 to 3.3 % in 2016. Globalisation is opening up new opportunities for criminal networks to expand the scope and scale of their illicit trade in counterfeit and pirated goods.

The analysis in this report is intended to help both public and private sector decision makers better understand the nature and scale of the global trade in counterfeit pharmaceuticals, and develop appropriate, coherent and evidence-based policy responses. Issues requiring urgent attention include insufficient deterrence due to relatively light penalties, the emergence and role of e-commerce, and frameworks and factors related to misuse of small parcels for trade in counterfeit medicines

1 Introduction

Illicit trade in counterfeit and pirated goods is a growing and significant problem. Globalisation opens up new opportunities for criminal networks to expand the scope and scale of their operations in illicit trade in counterfeit and pirated goods. Trade in counterfeits also undermines good governance, the rule of law and citizens' trust in government, and can ultimately threaten political stability.

In order to improve the factual understanding of counterfeit and pirated trade and provide evidence for policymakers to formulate policies, the OECD and the European Union Intellectual Property Office (EUIPO) have carried out a series of studies designed to enhance understanding of the issues and challenges facing governments, businesses and society at large. The last OECD/EUIPO (2019) report found that imports of counterfeit and pirated goods amounted to up to USD 509 billion in 2016, or around 3.3% of global trade, and that some provenance economies[1] are more important sources of counterfeit and pirated products than others, either as key producers or strategic points of transit. The counterfeits are shipped by land, sea and air, in both large containers and in small packages, misusing modern logistical solutions such as small parcels or free trade zones.

This report builds on previous analysis, focusing on the situation in one particular sector: pharmaceuticals. It is a sensitive and important sector, regulated in many countries out of public health and safety concerns. Counterfeit medicines imply not only possible economic damages for this sector, but also significant health threats, since fake medicines are often not properly formulated and may contain dangerous ingredients.

In addition, consumers are not very aware of the problem of counterfeiting of pharmaceuticals and can be easily deceived into thinking that the products that they are purchasing are genuine. For example, around 90% of Italian consumers who purchased counterfeit pharmaceutical products did so unknowingly, believing them to be genuine (OECD, 2018a). The analysis in this report will help both public and private sector decisionmakers better understand the nature and scale of the global trade in counterfeit pharmaceuticals, and develop appropriate, coherent and evidence-based policy responses.

As with the previous reports, this study provides insights into the current situation as regards counterfeiting in the pharmaceutical industry. It draws on customs seizures data, as well as data from other enforcement agencies and publicly available information.

The report begins by defining the terms used and the data sources. Chapter 3 provides an overview of the pharmaceutical industry, and then Chapter 4 outlines the volume and scope of the global market for counterfeit pharmaceuticals. Chapter 5 explores the supply chain, including the modes of transport and distribution used to trade counterfeit pharmaceuticals. Chapter 6 examines the factors driving this global trade, while Chapter 7 assesses the impacts – from individuals up to entire economies. Chapter 8 summarises some of the global initiatives underway to combat this serious threat to public health.

Notes

[1] As described in the OECD (2008) and OECD/EUIPO (2016 and 2019) studies, a *provenance economy* is an economy detected and registered by any reporting customs agency as a source of any item that has been intercepted in violation of an IP right, whatever the amount or value concerned. Consequently, *provenance economies* include those economies of origin where the actual production of infringing goods is taking place, as well as those economies that function as ports of transit through which infringing goods pass prior to the economy of destination.

References

OECD (2018a), *Trade in Counterfeit Goods and the Italian Economy: Protecting Italy's intellectual property*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264302426-en

OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/g2g9f533-en.

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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3 Industry overview

The pharmaceutical industry is an important and growing sector for many economies. This chapter charts its growth and importance, and describes the geographical distribution of the major companies. It then outlines the trends in international trade in pharmaceuticals, and finishes by highlighting the high intellectual property intensity of the sector.

The pharmaceutical sector is a multi-billion dollar industry, with global sales estimated at USD 1.2 trillion in 2018, a USD 100 billion increase over 2017 (IQVIA Institute, 2019). Growth in sales, which averaged 6.3% during the 2014-18 period, are expected to average 3-6% per year to 2023, reaching more than USD 1.5 trillion. Growth is seen as being driven by the United States, which is expected to account for 40% of the market by 2023. Growth in emerging markets is also expected to be strong, with sales in China approaching the combined sales of the five major European markets (France, Germany, Italy, Spain and the United Kingdom) by 2023.

The industry also represents a significant share of total employment (between and 0.8 to about 1%) in countries such as Switzerland, Slovenia and Denmark. Many of these jobs are in research and development activities (IFPMA, 2017). In the United States, with around 480 000 people in the sector, the pharmaceutical industry represents 0.3% of total employment (OECD, 2018b).

While there are many firms in the industry, the largest companies command an important share of the total market. The 50 largest firms accounted for USD 653 billion in sales in 2017, which represented slightly more than half the global sales of all companies (Christel, 2018; IQVIA Institute, 2019). Most of the largest 50 companies were headquartered in OECD countries, 16 were headquartered in the United States, and 10 in Japan). Importantly, 27.8% of sales was associated with the firms headquartered in the EU countries (Table 3.1)

Table 3.1. Largest 50 pharmaceutical companies, by country of headquarters, 2017

Country	Total sales, including exports		Number of companies
	Millions USD	% of total	
United States	291 543	44.7	16
Switzerland	83 607	12.8	2
Japan	55 938	8.6	10
United Kingdom	48 450	7.4	2
Germany	45 104	6.9	5
France	38 644	5.9	2
Ireland	21 059	3.2	3
Israel	18 261	2.8	1
Denmark	16 971	2.6	1
Australia	7 522	1.2	1
India	6 491	1	2
Canada	5 053	0.8	1
Belgium	4 663	0.7	1
Spain	3 876	0.6	1
Italy	3 072	0.5	1
South Africa	2 591	0.4	1
Total	**652 815**	**100**	**50**

Source: Christel, M. (2018), "2018 Pharm Exec 50", http://files.pharmtech.com/alfresco_images/pharma/2018/09/19/b7bd929d-df36-462d-93ce-bcd8a8237e06/PharmExec_%20Regular%20Issue%20_June2018.pdf.

The top 50 companies varied significantly in size, ranging from less than USD 3 billion in sales, to over USD 40 billion (Table 3.2). The 10 largest companies accounted for more than 50% of sales of these 50 pharmaceutical companies. Importantly production of pharmaceuticals by these companies does not necessarily takes place in the economy, in which they are domiciled.

Table 3.2. Size of the largest pharmaceutical companies, 2017

Level of sales (billions USD)	Number of companies	% of total sales
41-50	3	19.8
31-40	3	15.9
21-30	4	15.9
11-20	12	29.4
1-10	28	19.0
Total	50	100.0

Source: Christel, M. (2018), "2018 Pharm Exec 50", http://files.pharmtech.com/alfresco_images/pharma/2018/09/19/b7bd929d-df36-462d-93ce-bcd8a8237e06/PharmExec_%20Regular%20Issue%20_June2018.pdf.

International trade in pharmaceutical products

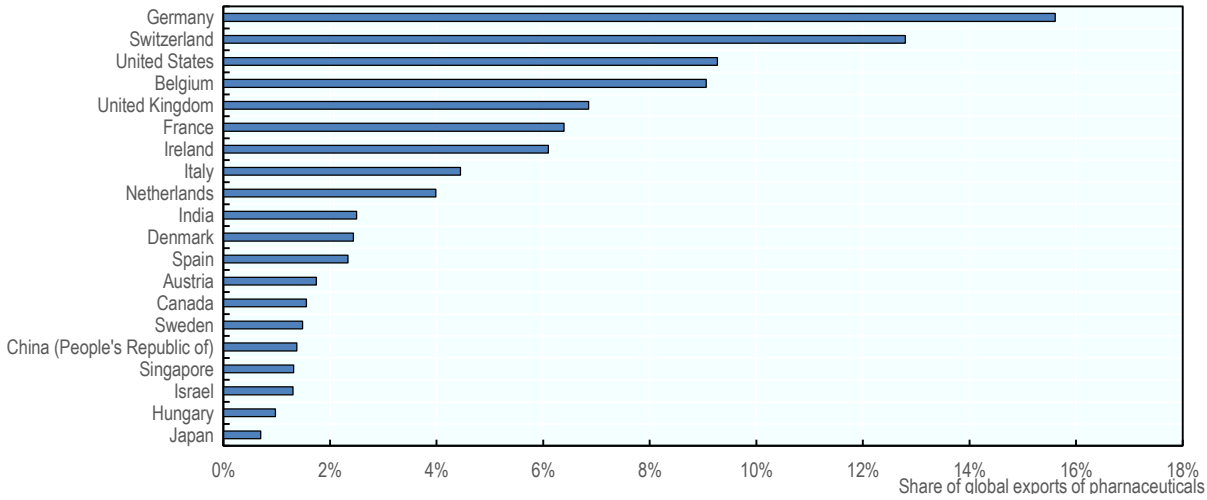
With respect to trade, the pharmaceutical products are classified under product category 30 of the Harmonized System.[1] This category includes in particular medicines, either in measured doses or packed for retail sale; and other pharmaceutical goods, such as sterile surgical catgut, suture materials, first aid boxes and kits, and dental cements and fillings. All goods classified in this category are listed in detail in Annex B.

In 2013, the global value of export of pharmaceutical products amounted to USD 487 billion, around 2.6% of total world trade in that year. In 2016, it amounted to USD 500 billion, or around 3.2% of total world trade

in that year. This means that global trade in the pharmaceutical sector increased both in absolute and relative terms between 2013 and 2016.

Over the 2014-2016 period, the largest exporters of pharmaceuticals were EU28 countries,[2] as well as Switzerland, the United States, India, China, Singapore, Israel and Japan (see Figure 3.1). Together, these economies represented more than 92% of the total value of global exports of pharmaceuticals.

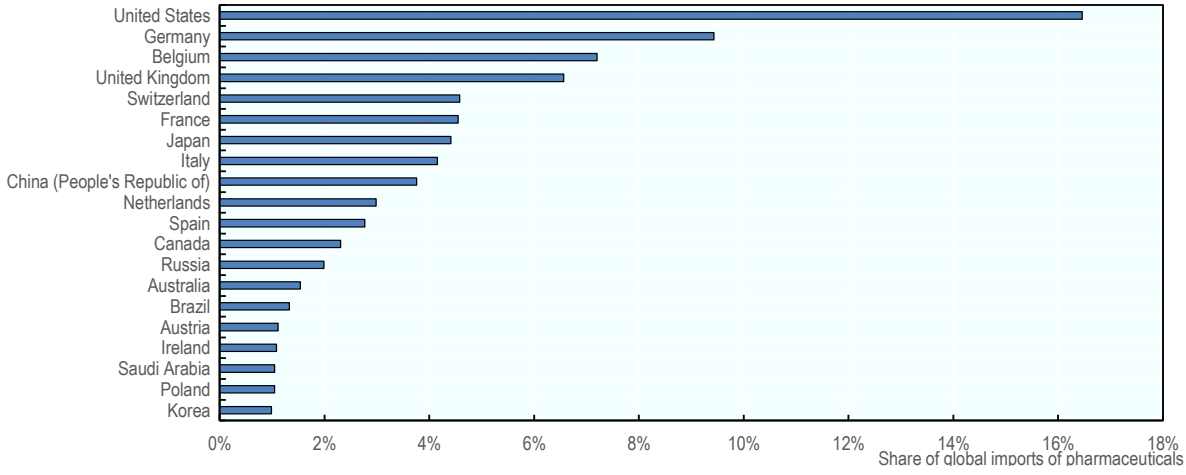
Figure 3.1. Top 20 exporters of pharmaceuticals, 2014-2016



Notes: Pharmaceutical products refer to the HS 30 product category as defined by the UN Trade Statistics Division (2019). All goods include in this product category are presented in detailed in Table C.1 of Annex C.
Source: UN Trade Statistics Division (2019), *UN Comtrade Database*, United Nations Trade Statistics Division, New York, https://comtrade.un.org.

In the same period, the United States was the leading importer of pharmaceutical products, importing more than 16% of the total value of global imports of pharmaceutical goods (Figure 3.2). It was followed by several EU28 economies (in particular Germany, Belgium, UK, France and Italy), Switzerland, Japan, and China.

Figure 3.2. Top 20 importers of pharmaceuticals, 2014-16



Notes: Pharmaceutical products refer to the HS 30 product category as defined by the UN Trade Statistics Division (2019). All goods include in this product category are presented in detailed in Table C.1 of Annex C.
Source: UN Trade Statistics Division (2019), *UN Comtrade Database*, United Nations Trade Statistics Division, New York, https://comtrade.un.org.

Regarding trade balances, one-third of OECD countries are net exporters of pharmaceuticals. In 2015, Switzerland, Germany and Ireland were the biggest net exporters of pharmaceuticals, with trade surpluses of USD 41 billion, 28 billion and 27 billion respectively (OECD, 2018b).

IP intensity of the pharmaceutical industry

The pharmaceutical industry is relatively IP-intense, which can be measured in terms of both trademark and patent-intensity. According to the data provided by WIPO (2019), the number of trademark applications for the goods covered by the Nice product classification 05[3] was 390 888 in 2016 (compared to 282 311 in 2013). This represents around 4.3% of all world trademark applications registered that year, and made pharmaceuticals (class 05) the 4th most intense industry in terms of trademark applications out of the 34 goods classes covered in the Nice product classification.[4]

The Chinese intellectual property office received the largest share of trademark applications in the pharmaceutical sector in 2016 (32%), followed by India (13%), the United States (5%) and the European Union Intellectual Property Office (3.4%).

The number of patent applications for technology classes related to the pharmaceutical industry was 108,964 in 2016 (compared to 80,214 in 2013).[5] This represented more than 4% of all world patent applications and made technologies related to the pharmaceutical industries the 7th most intense in terms of patents out of 35 fields of technology recorded by the WIPO (2019).

The industry has a keen interest in protecting its intellectual property rights as investment in the development of new products is an expensive undertaking, but key to their long-term success. The cost and importance of new products is reflected in the relatively high level of spending on research and development (R&D), which amounts to nearly USD 150 billion per year (IFPMA, 2017). The R&D process itself is a lengthy one, as it can take 10 to15 years to develop a new medicine or vaccine.

Overall, the pharmaceutical sector is one of the most research intensive, accounting for an estimated 22% of all total R&D across all industries in 2018, only slightly less than the computer and electronics sector.[6] The pharmaceutical industry invests up to around 40% of its gross value added (GVA) in R&D in Japan and the United States. The industry R&D accounts for 30% of all private R&D in countries like Switzerland and Belgium, and 24-25% in Slovenia and Denmark (OECD, 2018b). The importance of R&D is also reflected in the high ratio of R&D expenditures to total sales (Table 3.3.).

Table 3.3. R&D intensity in the 50 largest pharmaceutical firms, 2017

Firm	Sales	R&D expenditures	Ratio of R&D expenditures to sales
	Billions of USD	Billions of USD	%
Pfizer	45 345	7 627	16.8
Novartis	41 875	7 823	18.7
Roche	41 732	9 181	22
Merck & Co	35 370	7 563	21.4
Johnson & Johnson	34 397	8 360	24.3
Sanofi	34 078	6 184	18.1
GlaxoSmithKline	28 668	4 978	17.4
Abbvie	27 743	4 829	17.4
Gilead Sciences	25 662	3 523	13.7
Amgen	21 795	3 482	16
AstraZeneca	19 782	5 412	27.4
Bristol-Myers Squibb	19 258	4 823	25
Eli Lilly	18 532	4 973	26.8
Teva Pharmaceutical Industries	18 261	1 848	10.1
Bayer	17 544	3 624	20.7
Novo Nordisk	16 971	2 129	12.5
Allergan	14 906	1 599	10.7
Shire	14 449	1 565	10.8
Boehringer Ingelheim	14 262	3 067	21.5
Takeda	13 577	2 937	21.6
All others[1]	142 945	26 677	18.7
Total[1]	647 152	122 204	18.9

Note: [1]Excluding two firms, for which data on R&D were unavailable
Source: Christel, M. (2018), "2018 Pharm Exec 50", http://files.pharmtech.com/alfresco_images/pharma/2018/09/19/b7bd929d-df36-462d-93ce-bcd8a8237e06/PharmExec_%20Regular%20Issue%20_June2018.pdf.

Notes

[1] The Harmonized Commodity Description and Coding System generally referred to as "Harmonized System" or simply "HS" is a multipurpose international product nomenclature developed by the World Customs Organization (WCO). It comprises about 5,000 commodity groups; each identified by a six digit code, arranged in a legal and logical structure and is supported by well-defined rules to achieve uniform classification. The system is used by more than 200 countries and economies as a basis for their Customs tariffs and for the collection of international trade statistics. Over 98 % of the merchandise in international trade is classified in terms of the HS. For more information, see WCO (2019).

[2] All findings in this study that refer to the EU, were based on data from time periods before January 2020, hence these findings also include United Kingdom.

[3] Nice classification system is a of classifying goods and services for the purpose of registering trademarks. It is specified by the World Intellectual Property Organization. This number includes the trademarks applications included in the Nice product classification 05 (Pharmaceutical and veterinary preparations; sanitary preparations for medical purposes; dietetic food and substances adapted for medical or veterinary use, food for babies; dietary supplements for humans and animals; plasters, materials for

dressings; material for stopping teeth, dental wax; disinfectants; preparations for destroying vermin; fungicides, herbicides).

[4] These data are based on the indicator "Total applications by class (direct and via the Madrid system)"

[5] Based on the indicator "Patent publications by technology".

[6] See https://www.strategy-business.com/feature/What-the-Top-Innovators-Get-Right?gko=e7cf9.

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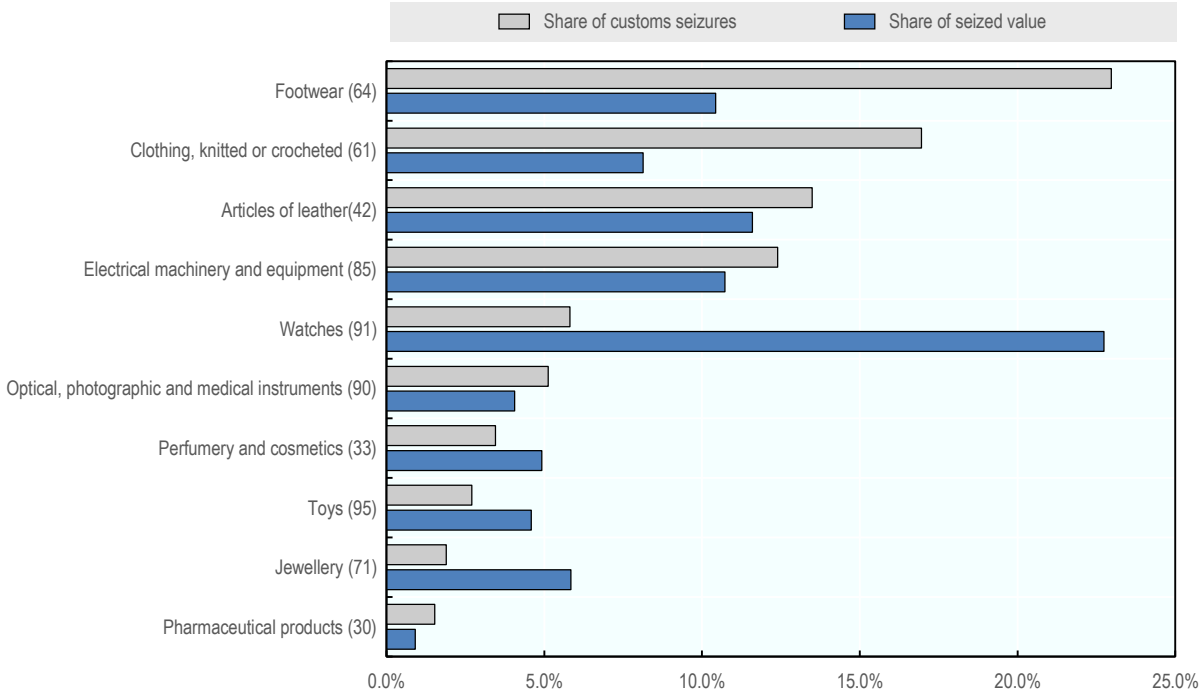
4 Mapping the scale of the fake pharmaceutical challenge

Pharmaceuticals are particularly vulnerable to counterfeiting. This chapter looks at the scale of the counterfeiting challenge, drawing on customs seizures and enforcement action data to track the recent growth in incidents. It also reveals the types of products most commonly counterfeited, and maps the intellectual property rights holders most affected. It then reports on analysis into the main trade routes for fake pharmaceuticals, including making the distinction between countries which produce the fakes and those which act as transit points on their way to their final markets.

Scale of the problem

The high IP-intensity of the pharmaceutical industry and strong demand make pharmaceuticals vulnerable to counterfeiting. This is confirmed by the available data. Between 2014 and 2016, the 2019 OECD/EUIPO report indicates based on customs seizures that of 97 recorded product categories, pharmaceuticals were the 10th most counterfeited type of product (OECD/EUIPO, 2019; Figure 4.1).

Figure 4.1. Top product categories counterfeit or pirated, 2014-2016

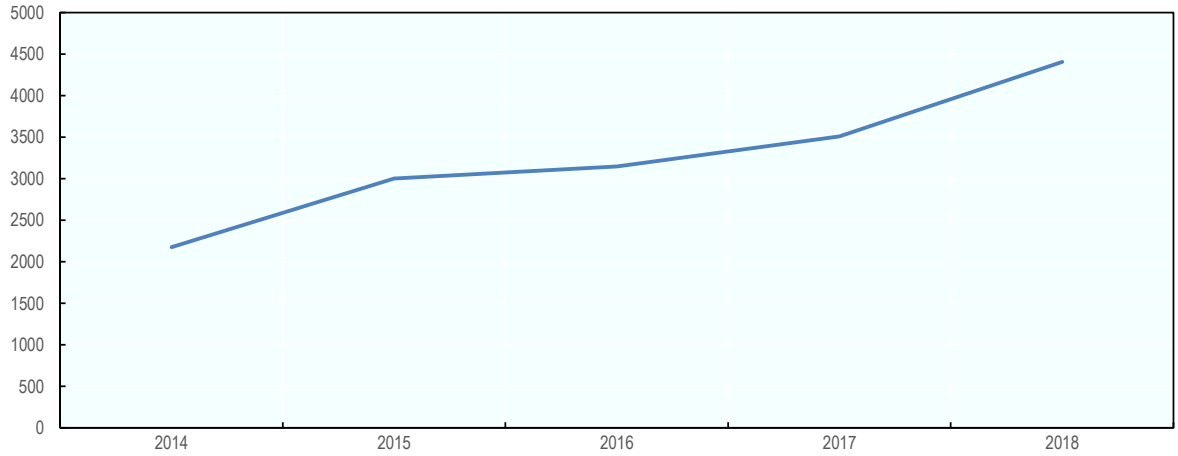


Note: Figures in parenthesis are Harmonized Systems (HS) codes. See WCO (2019) for a complete list of HS product categories.
Source: OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, https://doi.org/10.1787/g2g9f533-encustoms seizures data of IP-infringing products.

According to the OECD/EUIPO (2019) study, the value of global trade in counterfeit pharmaceuticals was up to USD 4.4 billion in 2016. This represents 0.84% of total world-wide imports in pharmaceutical products.

The significant scale of counterfeiting in the pharmaceutical sector can also be seen in other enforcement data gathered in the PSI dataset. This dataset contains data on 16 240 counterfeiting, illegal diversion and major theft incidents over the last five years (2014 to 2018). Figure 4.2 shows the annual totals of pharmaceutical crime incidents during that period. The chart shows that from 2014 to 2018, total incidents increased by 102%. Two elements continue to play a central role in these increases: better reporting by government agencies and increased reporting by a larger number of PSI member companies over the last five years. In terms of members' reporting, 33% more cases were submitted to the institute for review and assessment in 2018 than in 2014.

Figure 4.2. Number of total incidents by year, 2014-18



Note: An incident is a discrete event triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals. As noted in the text, increased reporting by a larger number of PSI member companies over the last five years has also contributed to this increase.
Source: PSI database. The large scale of counterfeiting in the pharmaceutical sector is confirmed by other studies. The WHO estimated that the share of counterfeit, (including those which are of bad quality) on the market ranges from over 10% of total sales in low and middle-income countries to 1% in developed countries.[1] INTERPOL reports estimate that falsified medical products could account for as much as 30% of the market in some countries in Asia, Africa and Latin America and more than 20% in economies of the former Soviet Union (Tracit, 2019).

Other studies confirm these observations. For example, in a meta-analysis of 96 studies that tested 50 samples or more, comprising over 67 000 samples, Ozawa et al. (2018) estimate that the prevalence of substandard and falsified medicines in low- and middle- income countries was 13.6%. Among the studies included in the meta-analysis the highest prevalence of the falsified and substandard medicines was registered in Africa (18.7%) and Asia (13.7%).

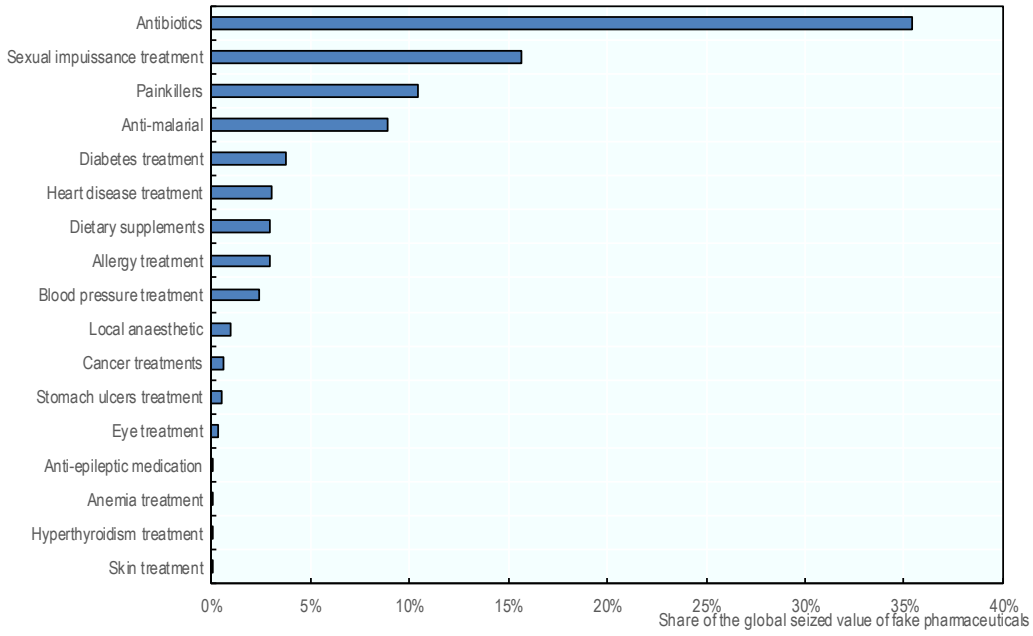
A study carried out by the UNODC in 2013 examining transnational crime in East Asia and the Pacific includes a close examination of the situation in pharmaceuticals (UNODC, 2013). Forensic testing revealed that one-third to two-thirds of the samples tested in the region were fraudulent. While counterfeiters could likely attain a far higher rate of return in developed countries, it is surmised that the low risk of detection greatly enhances the appeal of the lower-price markets. Interest in lower-priced, high-volume products also surfaced in a 2017 WHO monitoring report on substandard and falsified medical products (WHO, 2017b). Relatively low-priced antibiotics were reported by more countries than any other medicine. The total number of fraudulent antibiotic reports accounted for 17% of total reports on substandard or falsified products, a rate exceeded only by anti-malarial treatment (20%) (Tracit, 2018; WHO, 2017b).

Types of counterfeit pharmaceuticals

A closer look at the types of pharmaceutical products that are counterfeited is alarming. Over the period 2014-2016, seized counterfeits included medicaments for various kinds of diseases, including malaria, HIV/AIDS and cancer (Figure 4.3).

A more detailed review of the customs data shows that counterfeit antibiotics, lifestyle drugs and painkillers were the most targeted by counterfeiters. Other types of counterfeit pharmaceuticals often seized by customs authorities worldwide include those targeting treatment for malaria, diabetes, epilepsy, heart diseases, allergy, blood pressure, cancer, and stomach ulcers ailments as well as local anaesthetics.

Figure 4.3. Most counterfeit types of pharmaceuticals seized by customs, 2014-2016

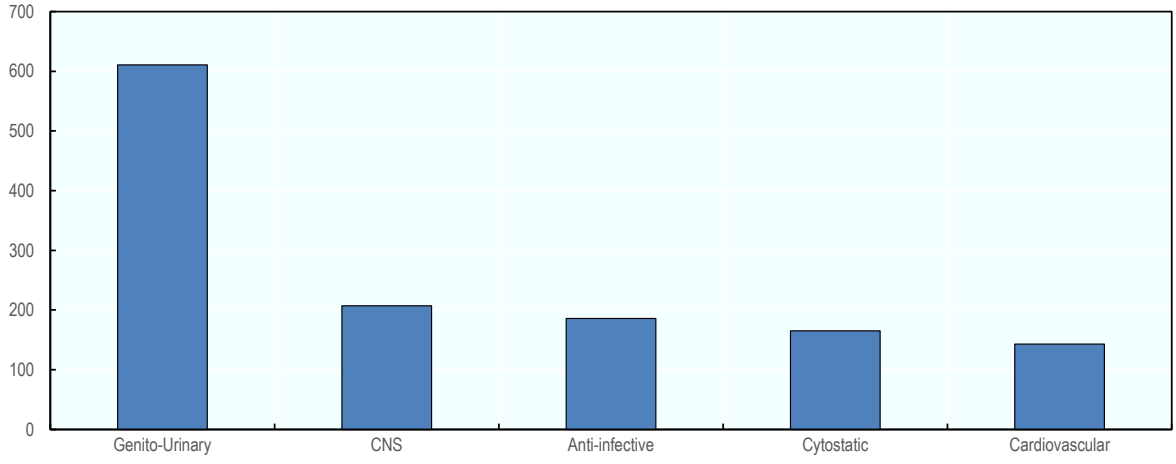


Source: OECD/EUIPO database.

A more detailed picture can be derived from the PSI dataset, which takes into account a broader range of counterfeit medicines, and also includes stolen and diverted pharmaceuticals. These data show that medicines in the genito-urinary, central nervous system and anti-infective therapeutic categories contained the largest number of incidents (Figure 4.4).

Figure 4.4. Top five therapeutic categories reported in counterfeiting incidents

Number of incidents, 2018



Source: PSI database.

Medicines within the genito-urinary therapeutic category continue to be the most frequently targeted by counterfeiters. Due to increased activity and new sources of information, the counterfeiting of drugs in the genito-urinary category were detected at a much higher rate in 2018.

The second therapeutic category most frequently targeted by counterfeiters is the central nervous system (CNS), which surpasses anti-infective treatments. Since 2016, CNS drugs have experienced a 57% increase in counterfeiting incidents. This is consistent with the increased reporting of counterfeit benzodiazepines and opioid pain medications in North America and Europe.

In addition, the scope of categories of medicines targeted by counterfeiters keeps broadening. Products found in a single incident ranged from 1 to 71 different drugs. Concerning counterfeiting incidents only, the PSI reported 533 different products from 15 different therapeutic categories in 2018. This is an 18% increase in the number of products targeted by counterfeiters over 2017.

According to the industry, the vast majority of counterfeit drugs do not contain the correct active ingredients in the correct proportions. In addition, many of these counterfeit drugs contain undeclared active ingredients that might have serious unwanted health consequences. These can pose a very serious threat to consumer health, ranging from mild to life threatening.

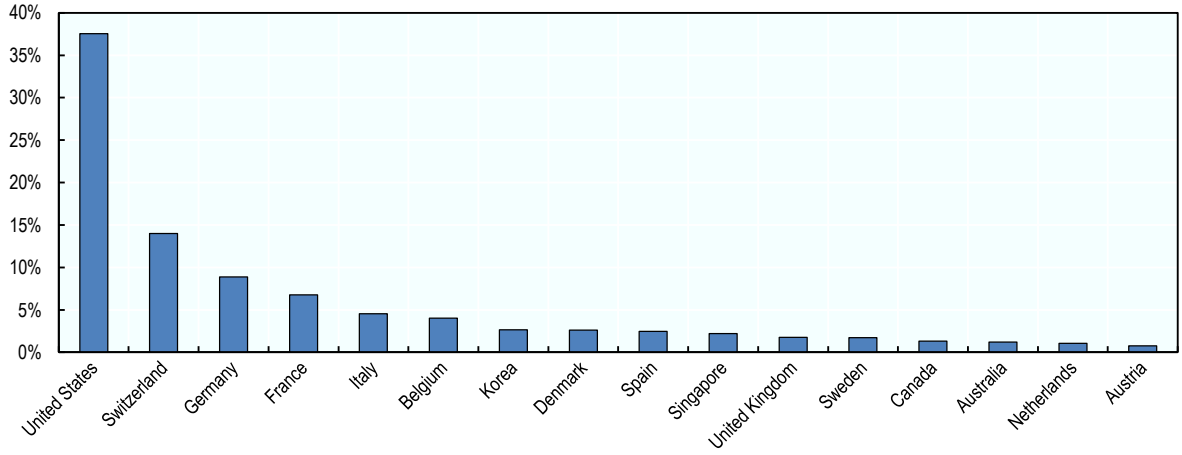
Which IP right holders are most affected?

Which countries are most affected? The OECD/EUIPO database (2019) on customs seizures (see Chapter 3) indicates that US brands were largely the most affected by the trade in counterfeit pharmaceutical goods over the 2014-2016 period. They were followed by European economies, including United Kingdom, France, Austria, Germany, and Switzerland.

This result is not surprising given that the United States, Switzerland, Germany and France are the largest producers of pharmaceuticals worldwide (Figure 4.5). According to data provided by the United Nations Industrial Development Organization's (UNIDO) Industrial Statistics Database (UNIDO, 2019; see Annex A for a description of the data), the share of the United States in the global output of pharmaceuticals was 37.6% in 2016, making it the leading producer of pharmaceutical products and medicines worldwide. It was followed by Switzerland (14%), Germany (8.9%) and France (6.8%).

Figure 4.5. Top 15 pharmaceutical-producing economies, 2016

Share of global output of pharmaceuticals



Source: UNIDO (2019), *INDSTAT Database*, United Nations Industrial Development Organization, Vienna, https://stat.unido.org/, accessed July 2019.

Trade routes for counterfeit pharmaceuticals

The production of counterfeits is carried out on all continents both on an industrial scale and on a smaller and less sophisticated scale (WHO, 2017b). The packaging and the medicines are often manufactured and printed in different countries and then shipped to a final destination where they are assembled and distributed. For example, fake medicines originating in Asia might be packed in falsified packaging originating in Africa or the reverse. Products are sometimes concealed or smuggled and declared as something other than medicines.

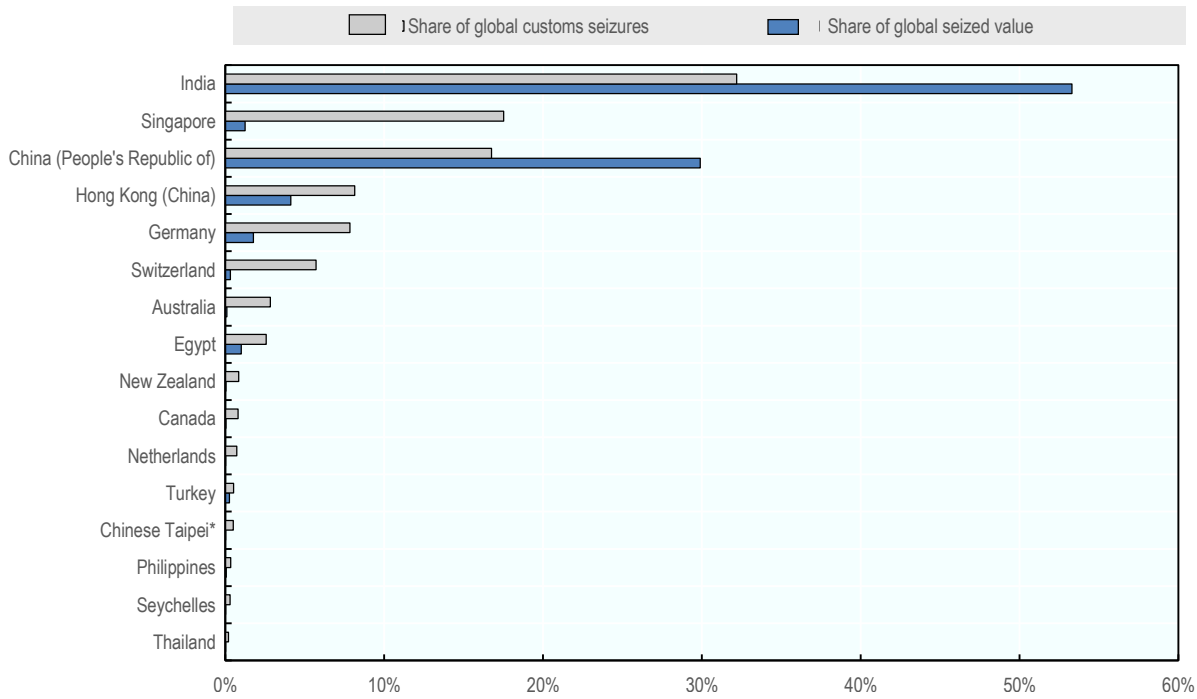
Key provenance economies

India remains the main provenance economy of counterfeit pharmaceuticals, being the origin of 53% of the total seized value of counterfeit pharmaceutical products and medicines worldwide in 2016 (compared with 53% for the 2011-2013 period) (Figure 4.6 and OECD/EUIPO, 2017). It was followed by China (30% for the 2014-2016 period versus 33% for the 2011-2013 period), United Arab Emirates (4% in both periods), and Hong Kong (China) (4% versus 3%).

In terms of the number of global customs seizures, Singapore (17.5%), Germany (7.8%), Switzerland (5.7%), Australia (2.8%) and Egypt (2.5%) are also identified as key provenance economies. Except for Germany, the others were already amongst the top 10 provenance economies for counterfeit pharmaceutical products and medicines for the 2011-2013 period.

According to the data gathered in the OECD/EUIPO database on global customs seizures, between 2014 and 2016, the top four provenance economies for counterfeit pharmaceuticals traded worldwide are the same as for the period 2011-2013. This suggests relative stability in the main sources of fake medicines in global trade.

Figure 4.6. Top provenance economies for counterfeit pharmaceuticals, 2014-2016



Source: OECD/EUIPO database.

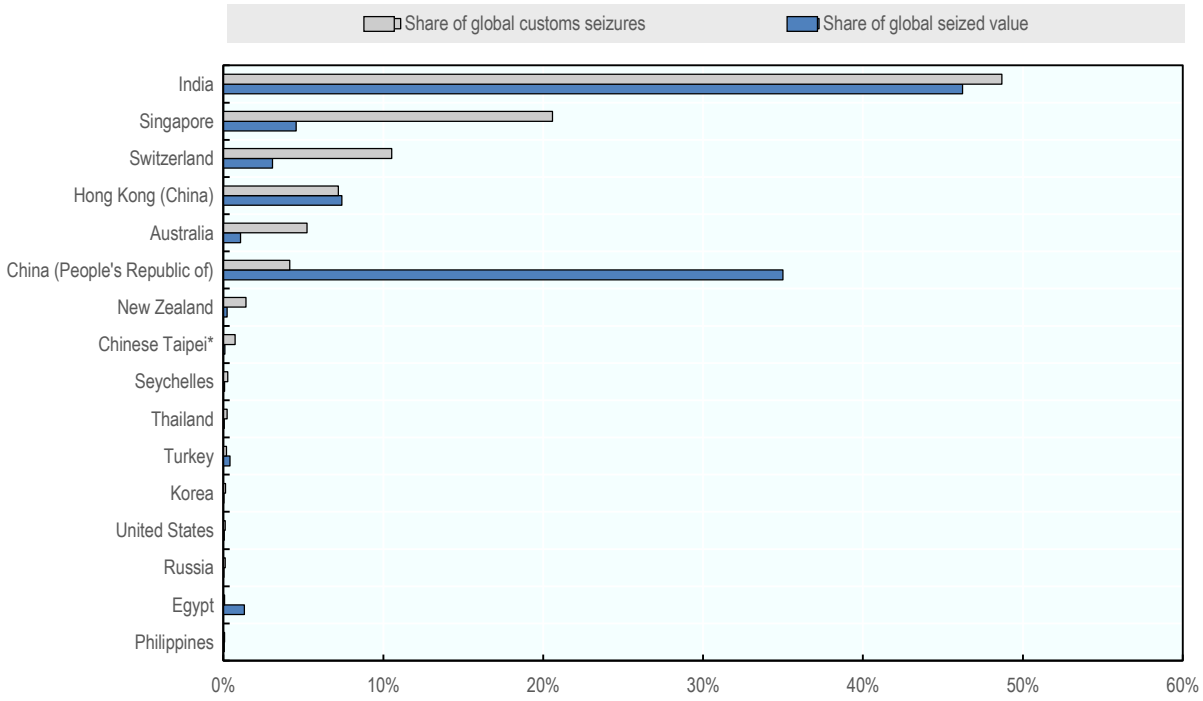
Key sources: the case of the EU

The range of provenance economies of counterfeit pharmaceuticals imported to the EU is more limited than worldwide. However, it is interesting to note that the top three provenance economies of fake medicines and pharmaceutical products imported to the EU are exactly the same as for those traded worldwide.

In terms of value, India is the main provenance economy of counterfeit pharmaceuticals shipped to the EU, being the origin of 47% of the total value of counterfeit pharmaceutical products and medicines seized by EU customs authorities (Figure 4.7). It is followed by China (37%) and Hong Kong (China) (8%).

Although a main source of counterfeit pharmaceuticals globally, the United Arab Emirates is not an important provenance of these type of fake goods for EU economies. The provenance economies of Singapore, Switzerland, Australia, and Chinese Taipei are more important.

Figure 4.7. Top provenance economies of counterfeit pharmaceuticals imported into the EU, 2014-2016



Source: OECD/EUIPO database.

Comparing the customs seizures intensities of infringing pharmaceuticals with legal trade intensities for each provenance economy helps to identify the economies which are most likely to be the places of manufacturing of fake pharmaceuticals. The methodology used to calculate these indices is presented in Annex A. These indices express the likelihood of an economy to be a significant provenance of counterfeit medicines, and confirm that India, China and Hong Kong (China) are the economies most likely to export counterfeit pharmaceuticals (Table 4.1). Interestingly this mirrors the case for the 2011-2013 period (see OECD/EUIPO, 2017).

The share of the United Arab Emirates and Singapore in the global trade of fake pharmaceuticals for the 2014-2016 period appears to have increased since the 2011-2013 period. However, some Middle Eastern economies such as Yemen, Iran and Lebanon have disappeared from the ranking of the top economies

most likely to export counterfeit pharmaceutical products. On the other hand, Egypt and some Far East Asian Economies (Pakistan, Philippines and Indonesia) have entered the top 10 and are now major potential sources of fake pharmaceuticals in global trade.

Table 4.1. The 10 economies most likely to be a provenance of counterfeit pharmaceutical products

GTRIC-e for pharmaceuticals; average 2014-2016

Provenance economy	GTRIC-e
Hong Kong (China)	1.000
India	1.000
China (People's Republic of)	1.000
United Arab Emirates	0.947
Egypt	0.838
Philippines	0.674
Singapore	0.657
Viet Nam	0.631
Indonesia	0.388
Pakistan	0.332
Cameroon	0.332
Turkey	0.309

Note: A higher score on the GTRIC Index indicates a greater likelihood that the economy in question is a source of counterfeit goods.

The statistics suggest that these top three provenance economies are also the same for the EU (Tables 4.1 and 4.2). The provenance economies most likely to export counterfeit pharmaceutical products to the EU are indeed India, Hong Kong (China) and China. This list also includes some Far East Asian economies (Philippines, Thailand), Singapore and Switzerland. Russia and Turkey are also ranked among top 10 potential provenance economies of counterfeit pharmaceuticals and medicines for the EU, though they play a minor role in the global trade of counterfeit pharmaceuticals. Conversely, while listed as a main provenance of counterfeit pharmaceutical products in global trade, the United Arab Emirates does not appear to be a major threat for the EU in this sector.

Table 4.2. Top ten economies most likely to be a provenance of counterfeit pharmaceuticals imported into the EU

GTRIC-e for pharmaceuticals to the EU; average 2014-2016

Provenance economy	GTRIC-e
Hong Kong (China)	1.000
India	1.000
China (People's Republic of)	0.997
Philippines	0.996
Russia	0.716
Singapore	0.633
Turkey	0.599
Iran	0.572
Thailand	0.474
Switzerland	0.300
United States	0.254

Note: A higher score on the GTRIC Index indicates a greater likelihood that the economy in question is a source of counterfeit goods for EU economies.

Producers and transit points

While the original database of customs seizures can be used to identify the provenances of counterfeit pharmaceuticals, some additional analysis needs to be done to chart the trade routes of counterfeit pharmaceuticals and to distinguish producers and transit points.

Determining the main producing economies of fake pharmaceuticals and the key transit points relies on two different methodologies:

1. Using customs data to distinguish fake pharmaceutical producing economies from transit economies. The details of this methodology are given in Annex A. The first section below presents the results of this process, identifying the main producers and transit points of fake pharmaceuticals shipped worldwide and those specifically targeting the EU.
2. Using arrest data to identify main distributor and manufacturing countries. PSI has been collecting information on arrests as an indicator of governments' commitment to address pharmaceutical crime. The PSI has categorised for each country the types of activity the subjects were engaged in when they were arrested into four categories: point of sales arrests, distributors, manufacturers, or individual involved in stealing.

Using customs data to distinguish fake pharmaceutical-producing economies from transit economies

Methodology

Using the methodology developed in the OECD/EUIPO (2017) report, the authors developed a quantitative exercise to determine the producers and transit points of fake pharmaceuticals in global trade. This exercise first uses the list of the top provenance economies identified by the indices described in Chapter 2. In a second step, the methodology uses two sets of statistical filters to distinguish producers from transit points among the main provenance economies identified in the first step (see Annex A for more details):[2]

1. A filter that looks at the production capacities of a given economy in the pharmaceutical sector (Relative comparative advantage for production, RCAP-e indices). This filter is developed based on the UN INDSTAT production data (see Annex A). The production of pharmaceutical goods and medicines relies on certain skills and resources and also exhibits certain returns-to-scale properties. We assume that only economies that have sufficient production capacity for legitimate pharmaceutical goods and medicines are able to leverage this capacity to produce their corresponding counterfeits.
2. A filter that checks the degree to which a given economy specialises in re-export of pharmaceuticals (Relative comparative advantage for being a Transit point, RCAT-e), e.g. through development of an advanced logistical infrastructure, or by virtue of its convenient geographical location. Where these factors facilitate transit of genuine pharmaceutical products, they can also facilitate transit of fake pharmaceutical goods and medicines.

The details of the calculation of both indices are presented in Annex A. A complete list of RCAP-e and RCAT-e indices are presented in Table B.2 and Table B.3, respectively.

Both filters are applied to distinguish the producing economies from the key potential transit points of counterfeit pharmaceutical products and medicines traded worldwide. Intuitively, if an economy is *not* a significant producer of pharmaceuticals and at the same time is a large re-exporter of these goods in legitimate trade, then it is likely to be a transit point. Similarly, the main provenance economies of counterfeit pharmaceuticals that are significant producers of genuine pharmaceutical products but insignificant re-exporters are likely to be producers of fake pharmaceutical goods and medicines.

More specifically, if an economy is listed as a top provenance for counterfeit pharmaceuticals (see Table 4.1 and Table 4.2) and has a high RCAP-e index and a low RCAT-e index, it will be classified as a producer. If it has instead a low RCAP-e index and a high RCAT-e index, it will be classified as a transit point.

This exercise results in a list of producers and a list of transit points. Together with the information on the place of seizure, this allows maps of trade in fake goods to be developed showing the key producer economies, main transit points and main destinations of fake pharmaceuticals.

Findings: producers and transit points in the global counterfeit pharmaceuticals trade

The RCAP and RCAT indices allow the main producers to be distinguished from the main transit points among the top provenance economies of counterfeit pharmaceutical products and medicines identified in Table 4.1. The details of the calculation of these indices and presented in Annex A.

India, China and some Far East Asian Economies, including Vietnam, Indonesia, Pakistan and the Philippines, appear to be the main producers of counterfeit pharmaceuticals traded worldwide (Table 4.3).

The role of Singapore is ambiguous given that it has both a large capacity for producing pharmaceuticals and a large capacity to re-export these products. Given that Singaporean customs have not reported any seizure of counterfeit pharmaceuticals, structured interviews with industry and enforcement experts were needed to conclude it is a transit point for counterfeit pharmaceutical products medicines .

Hong Kong (China) and the United Arab Emirates appear to be the main transit points for fake medicines and pharmaceutical goods shipped worldwide. They are followed by Egypt, Cameroon and Turkey.

Table 4.3. Main producing economies and transit points for counterfeit pharmaceutical products and medicines traded worldwide, 2014-2016

Producing economy	Transit point
India	Hong Kong (China)
China (People's Republic of)	United Arab Emirates
Philippines	Egypt
Viet Nam	Cameroon
Indonesia	Turkey
Pakistan	Singapore

Note: Economies are listed in order of importance, measured by RCAP and RCAT index values, indicating a greater likelihood that the economy in question is a producer or a transit point of counterfeit medicines in world trade.

Findings: producers and transit points in the counterfeit pharmaceuticals trade destined for the European Union

India and China are also identified as the main producers of counterfeit pharmaceuticals and medicines exported to the European Union (Table 4.4). Some Far East Asian economies, such as the Philippines and Thailand, also appear to be important producers/direct exporters of these products to the European Union, while the role of Singapore remains ambiguous.

Unlike its role in the global trade in fake pharmaceuticals, the United Arab Emirates is not an important transit point for counterfeit medicines and pharmaceutical goods shipped to the European Union. However, Hong Kong (China) and Turkey maintain their role as main transit points.

Finally, Iran, Switzerland and the United States are identified as specific transit points for fake pharmaceuticals shipped to the European Union.[3] .

Table 4.4. Main producing economies and transit points for counterfeit pharmaceutical products and medicines exported to the EU, 2014-2016

Producing economies	Transit points
India	Hong Kong (China)
China (People's Republic of)	Singapore
Philippines	Turkey
Thailand	Iran
	Switzerland
	United States

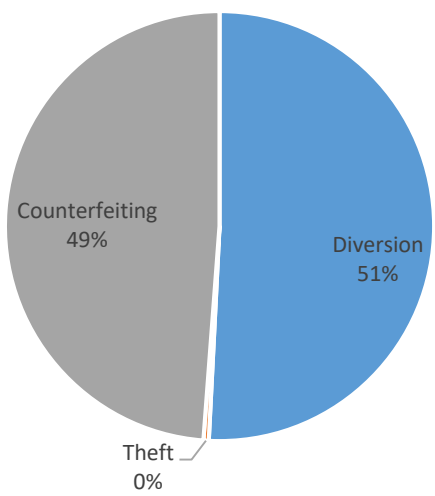
Note: Economies are listed in order of importance, measured by RCAP and RCAT index values, indicating a greater likelihood that the economy in question is a producer or a transit point of counterfeit medicines exported to the EU.

Using arrest data to identify main distributor and manufacturing countries

The second method for determining the main producing economies of fake pharmaceuticals and the key transit points involves using PSI data. Through liaison contacts, member reports and open source reports, PSI has documented the arrest of 2 253 people involved in counterfeiting, diversion or theft of pharmaceutical drugs worldwide during 2018. Due to a variety of considerations, including legal prohibitions against sharing of information, the identity of these arrested people is not always released by the authorities. Nevertheless, 33% of the reports, or 750 out of 2,253 arrests, contained adequate information for our analysis, including name, date of birth and/or address.

When examining the activity of those arrested, arrests for the diversion of medicines are slightly higher than those for counterfeiting (Figure 4.8). The institute notes however that this is a new development and may indicate that law enforcement worldwide is placing a higher priority on the illegal trade of medicines in general, not just counterfeits.

Figure 4.8. Percentage of arrests by crime, 2018



Note: For a definition of diversion, theft, and counterfeit pharmaceuticals see Chapter 2.
Source: PSI data

Based on the information available, PSI categorised the types of activity the subjects were engaged in when they were arrested. This analysis was designed to identify potential weaknesses in the organization where successful law enforcement interventions could be made. Five categories were identified:

1. Point of sale arrests: individuals working in pharmacies, hospitals, and those primarily associated with Internet sites selling suspected counterfeit or illegally diverted product.
2. Transporting arrests: individuals arrested at international borders and in airports while engaged in transporting counterfeit or diverted shipments.
3. Distributor arrests: wholesalers and individuals arrested at warehouses where counterfeit or illegally diverted goods were being stored.
4. Manufacturer arrests: arrests made at locations where equipment to manufacture counterfeit pharmaceutical drugs or labels was present.
5. Theft arrests: individuals involved in stealing pharmaceuticals; generally these were major thefts valued at more than USD 100 000.

Interestingly, between 2017 and 2018 the PSI has documented increases across all arrest activities, except for theft. Of particular note are the increased number of manufacturing (+73%) and point of sale (+163%) arrests recorded.

Distributors of illegal medicines continue to be the top category of arrests and are a particular law enforcement focus in Asia, Latin America and Europe. The majority of those engaged in the smuggling of counterfeit and diverted medicines were arrested in Asia and Eurasia. Overall, the arrests by activity findings for 2018 indicate that the authorities have continued to focus on major distribution and manufacturing operations.

Commenting specifically on manufacturing, Table 4.5 indicates that China arrested the largest number of individuals engaged in the manufacture of counterfeit medicines. It was followed by Spain, the United States, India, Pakistan and Indonesia. Note that almost all of these countries (except the United States and Spain) were identified as potential producers of counterfeit pharmaceuticals in the methodology developed by OECD/EUIPO and described in the previous section (see Table 4.1).

Table 4.5. Top ten countries for the number of arrests of individuals engaged in manufacturing counterfeit medicines, 2018

Economy	Number of arrests
China	233
Spain	52
United States	48
India	38
Pakistan	10
Indonesia	10
Canada	7
Colombia	6
Egypt	1

Source: PSI data.

Notes

[1] See also www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[2] The customs data identifies a set of EU member countries as provenances. However, these data refer in most cases to the points of entry of fake goods to the EU. Consequently these economies will not be included in the analysis.

[3] The roles of Switzerland and the United States as transit points have been refined through additional experts' interview, and taking into account their specific role as re-exporters.

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5 The supply chain: marketing, transport and distribution

Weak links in fragmented global supply chains allow counterfeiters of pharmaceuticals to succeed. This chapter analyses the nature of the fake pharmaceutical supply chain and describes the elements which allow this trade to go largely undetected. This includes a focus on the modes of transport chosen (small packets sent by post), and the sales channels – including the growing role of the Internet. Finally, it explores the role of free trade zones in helping counterfeiters to disguise their activities.

Counterfeiters of pharmaceuticals succeed in large part by exploiting weaknesses in supply chains, which are often fragmented (OECD, 2016). Medicines are prescribed by physicians who rarely come into contact with the medicines, and are delivered by pharmacists who commonly source from multiple wholesalers (Lybecker, 2008). In the United States, 90% of medicines are distributed by five major wholesalers. The remaining 10% comprise some 7 000 secondary wholesalers which specialise in purchasing and selling selected discounted products (OECD, 2016; Lybecker, 2008). The secondary suppliers fill demand in cases of spot shortages and also serve as an additional source of revenue for the primary wholesalers through pharmaceutical trading (OECD, 2016). The loosely regulated secondary suppliers purchase excess stock from wholesalers, pharmacies and sometimes unscrupulous brokers. The products are then re-sold to other large distributors or retailers (UNICRI, 2012). The secondary distributors acquire drugs at reduced prices derived from surpluses in production or storage on the part of producers or large distributors and pharmacies. Their small size allows them to exploit changes in the market and to concentrate on specific drugs that exhibit high demand at specific times and in specific areas.

Problems can arise when original pharmaceutical products cross the borders of various countries and numerous importers, retailers and distributors become involved (UNICRI, 2012). The repackaging that takes place throughout the distribution and shipment process offers opportunities for introducing counterfeit

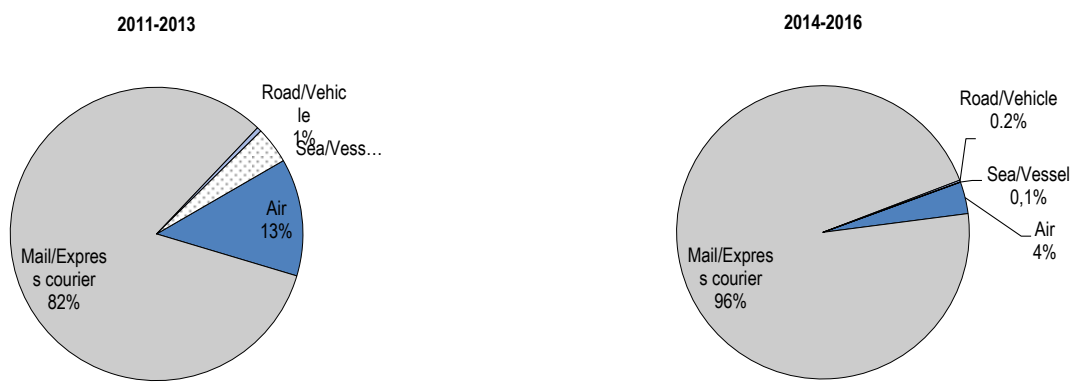
medicines into supply channels. The continuous change of hands can mask the provenance of counterfeit medicines, making tracing almost impossible and making it hard to identify who is making the counterfeit drugs. Repackaging can undermine the integrity of the products concerned, effectively foiling anti-counterfeiting mechanisms, such as product tracking mechanisms, used by the manufacturer of the genuine products. The counterfeiters disguised the activity by splitting the consignment, sending blister packs of tablets in one box and flat-packed cartons in which the blisters were to be packaged in another. Both were labelled as containing mobile phone covers, which was the case; the falsified tablets and packaging were buried underneath the phone covers. The seized medicine contained no active ingredient. Industry sources also indicate that counterfeiters engage in deceptive practices, marketing generic products as products manufactured by the original proprietary manufacturer. They are also known to remove and sell legitimate products from genuine packaging and replacing the products with counterfeit items. The legitimate products are then sold on grey markets.

Modes of transport

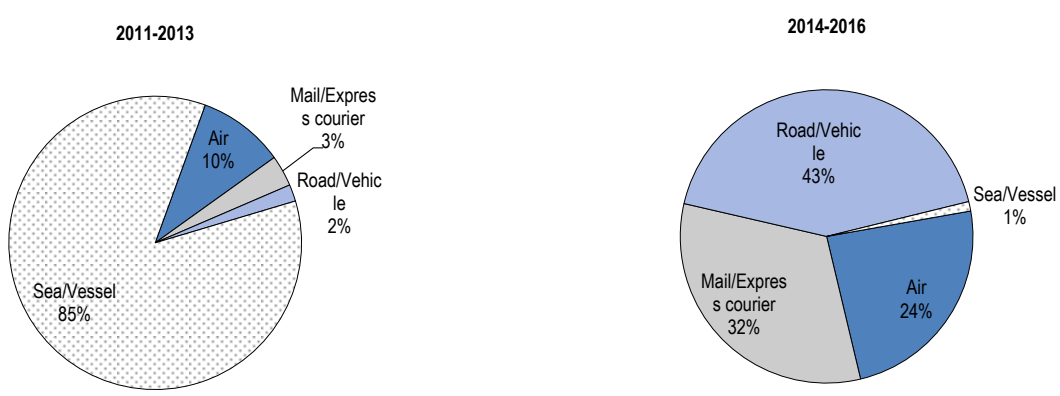
Mail and courier services are the main modes of transport for counterfeit pharmaceuticals traded worldwide, with their shares growing between 2011 and 2016 (Figure 5.1). In terms of volume, air is also an important means of transport in the global trade of fake pharmaceuticals. In terms of value, sea was the main transport mode for fake medicines and pharmaceutical products during 2011-2013, but was replaced by road transport and mail and postal services during 2014-2016.

Figure 5.1. Transport modes for counterfeit pharmaceuticals

a) In terms of the total number of customs seizures of fake pharmaceuticals worldwide



b) In terms of the global seized value of counterfeit pharmaceuticals

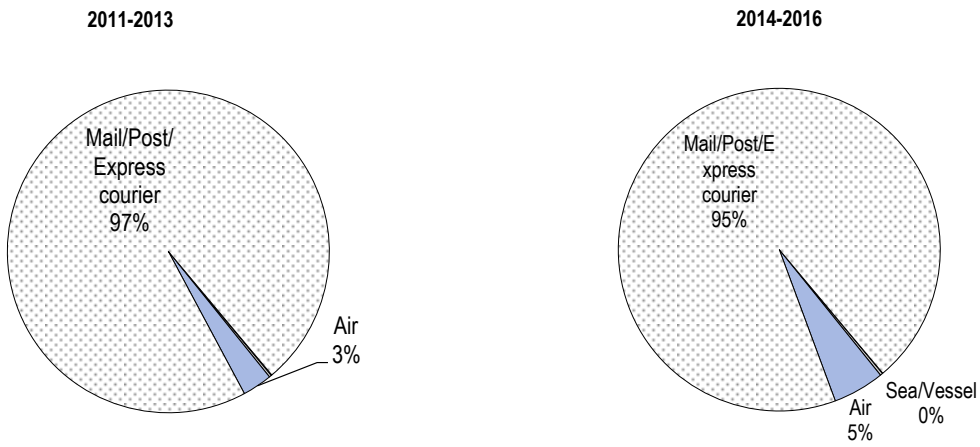


Source: OECD/EUIPO database.

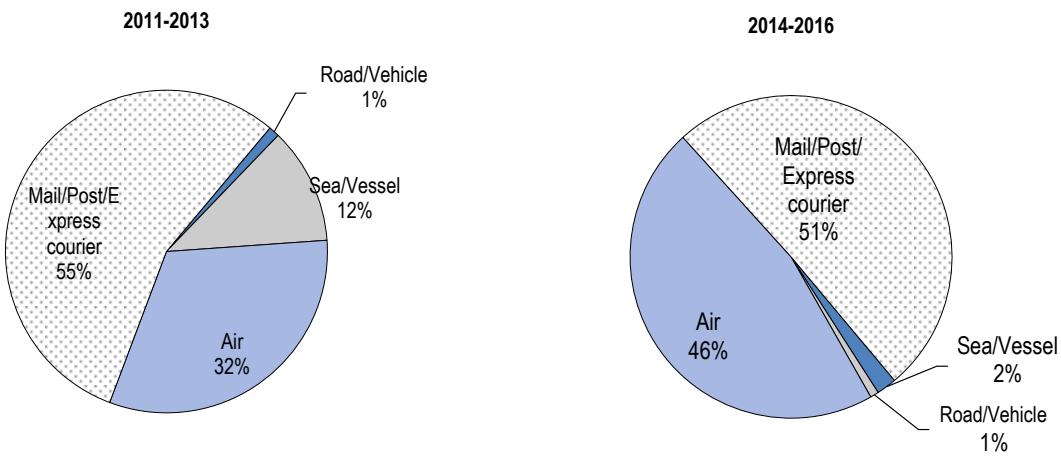
In 2014-2016, mail, postal services and express services were the main modes of transport for counterfeit pharmaceutical goods and medicines exported to EU economies, both in terms of value and volume (Figure 5.2). This was also the case for 2011-2013, and confirms the persistence of the problem of small parcels in the global trade in counterfeit goods (see OECD, 2018b).

Figure 5.2. Transport modes for counterfeit pharmaceuticals exported to EU economies

a) In terms of the total number of EU customs seizures of counterfeit pharmaceuticals



b) In terms of the seized value of counterfeit pharmaceuticals by EU customs



Source: OECD/EUIPO database.

The challenges of small parcels

The growing use by counterfeiters and other illicit traders of small shipments to cloak their activities has garnered increased attention (OECD/EUIPO, 2018b). Between 2014 and 2016, almost 57% of seizures of all product categories worldwide concerned postal shipments and 12% express courier. Air transport and sea transport followed, with slightly more than 15% and 10% of seizures respectively (OECD/EUIPO, 2019). Together, small parcels carried either by postal or express services account for 69% of customs seizures of IP-infringing products for the 2014-16 period, compared to 63% for the 2011-13 period (OECD/EUIPO, 2019).

The preference for using the post to send fake products in many instances reflects the fact that while the risk of detection may be low in sea transport, when interdiction occurs, losses on confiscated cargoes can

be very large (OECD/EUIPO, 2018b). Small shipments, however, allow counterfeiters to lower the potential losses that result from the discovery of an illicit trade movement as the ability to avoid detection is considerably higher, and only small volumes are confiscated each time.

The attractiveness of small shipments for counterfeiters has increased over time, benefitting from the explosive growth in e-commerce, and the accompanying rise in cross-border transactions by business and, even more importantly, consumers (OECD/EUIPO, 2018b). The sharp increase in items shipped directly to consumers by parcel post or letter packets has, in effect, ballooned the volume of legitimate trade, flooding the market with a growing number of items. The small shipments are handled primarily by postal authorities and express mail companies, with the active support of retail platforms such as Alibaba, Amazon and eBay. The large growth in legitimate trade in effect has likely made it more difficult to detect the illicit trade. The use of small parcels is well suited to counterfeiters of pharmaceutical products, as shipments of these products can be quite small, easily fitting in bubble wrap letter packets, as well as small parcel boxes.

The challenges posed by the growing volume of items have been significantly increased for the customs authorities responsible for handling items as they cross borders. The information that is available through ship manifests and the like, and the supporting role of customs brokers are absent in small volume trade (OECD/EUIPO, 2018b). In the case of small volume trade involving postal authorities, for example, only simplified documentation is required when items are sent. The information contained on the documents is certified by the sender, and is not typically verified, creating broad scope for both legitimate errors as well as fraud. Moreover, the customs information on postal forms is generally provided in paper form; and therefore not available electronically. In any case, it is generally only available to customs authorities in destination countries at the time a shipment arrives.

This creates a dilemma for customs as checking for suspicious imports has to be counterbalanced with the need for fast processing of all imports. A close review of so many small packages would cause unacceptable delays, and, given the difficulty in identifying counterfeit items, their low value (if contained in parcels or packets) and the relatively small share that they are likely to represent in total trade, the exercise would not be cost-effective. Efforts are being made to enhance the use of electronic forms in the post, in order to provide information to customs in destination countries in advance of arrival of shipments. This would facilitate risk assessment, which relies critically on data and other information to be successful. Problems associated with incomplete, misleading, incorrect or fraudulent information, however, would remain.

In the United States the STOP Act, enacted in October 2018, requires foreign postal authorities to provide advance electronic data (AED) on all packages or packets (under 2 kg) containing goods sent to the United States. The required data include the sender's name and address, the recipient's full name, weight and value of the package and its contents. The US Postal Service collects the data from the originating postal operator and passes it on to Customs and Border Protection (CBP) in order to help the CBP to better monitor and target goods moving by mail. Most foreign postal operators were obliged to transmit AED on up to 70% of packages by the end of 2018, though the rate for China, Hong Kong and Macau was 100%. All postal authorities will have to do so for 100% of packages by January 2021. In addition, in April 2019, the Federal Drug Administration (FDA) and CBP signed an agreement to maximise inspection and detection capabilities in order to prevent illegal and harmful products – such as unapproved fentanyl products, counterfeit prescription drugs and fake over-the-counter (i.e. non-prescription) medicines that look legitimate – from entering the United States through the nation's international mail facilities (IMFs) and ports of entry.[1] The two agencies will expand how information is shared to better identify trends which can target future entries. In fiscal year 2018, FDA staff posted at the IMFs around the country examined packages from more than 180 countries. Approximately 90% of the packages screened by the agency contained products that should not have been entering the country.

In the United Kingdom, since 1 January 2019 the Royal Mail has required shippers to provide electronic customs data when sending items (other than correspondence) to destinations outside the European Union (OECD/EUIPO, 2018b). The action was taken to make sure emerging and future legislative, security and customs requirements in overseas destinations would be met.

The situation with express companies is better, as the companies involved generally provide door-to-door services that are tracked and traced electronically. In these cases, other information – on the shipper, product and receiving party – is collected electronically, providing a potentially rich data source that, if available to customs authorities, would greatly assist in risk assessment. Co-operation on this front has advanced as express service providers and customs are working together to improve data and information exchanges. However, it appears that there is considerable scope for improvement as there are, among other things, privacy issues to be addressed, along with confidentiality concerns. As with postal transactions, there may be issues concerning the quality of the information as it is generally based on information provided by the sending party, providing scope for errors and, more importantly, deliberate misrepresentations or fraud.

The attractiveness of small shipments for bad actors is also affected by the special treatment that such shipments have been accorded for customs and tax. Under WTO trade facilitation, countries have established *de minimis* levels on imports, below which tariffs and taxes would not be collected. The existence and level of thresholds have a number of benefits: for governments, they reduce the scope of the imported items that need to be processed, freeing up resources for other work; for businesses and consumers, they simplify the importation of goods, lowering their cost. On the other hand, the reduced customs surveillance that occurs for items that are exempt from tariffs and taxes could also benefit parties involved in IP crime, allowing them to operate below the radar.

The challenge of tackling imports of small packages containing counterfeit and other illicit items is mounting. In the case of the United States alone, the volume of parcels and letter packets reached 498 million in 2017, with more than 60% entering in the form of packets. With e-commerce expected to continue to grow rapidly, the complexity of handling a growing number of potentially mislabelled shipments will grow.

Sales channels

The growing role of the Internet

The Internet is providing an increasingly viable option for distributing pharmaceutical products – both legitimate and counterfeit – to domestic and international consumers. The ability of sellers to hide their identity and misrepresent their products is particularly attractive to counterfeiters, providing criminals with a relatively easy point of entry into even the best regulated markets (WHO, 2017b). There are two distinct areas to purchase counterfeit pharmaceuticals online: the dark web and the freely accessible surface web.

The pharmaceuticals marketed on the surface web are mainly substance, for which legal controls differ between jurisdictions (Koenraadt and van de Ven, 2018). A 2016 study estimated the number of online pharmacies to be in the order of 30 000 to 35 000 in 2015, with an additional 600 launching every month (LegitScript, 2016). These pharmacies are serving a growing number of consumers. Surveys carried out in the United States, for example, show that the number of people buying medicines online more than quadrupled in less than a decade, rising to between 19 and 26 million people (WHO, 2017b). Based on a survey conducted in the Netherlands, (Koenraadt and van de Ven, 2018) estimate that approximately 10% of the Dutch population buys or has bought medicines online. Painkillers dominate the list of the most popular purchases (31.8%), followed by weight-loss pharmaceuticals (27%), sedatives and tranquillisers (14.2%) and sexual enhancers (14%). Financial motives, convenience and discretion were cited as the main motives for buying pharmaceuticals online (Koenraadt and van de Ven, 2018).

A 2017 survey of US consumers (ASOP Global, 2017) revealed that:

- Some 27% of respondents were very familiar with online pharmacies, while one-third were not familiar. Only 5% of respondents were familiar with available Internet resources to identify safe online pharmacies.
- One-third of respondents had used an online pharmacy to purchase medications for themselves or someone under their care. Of those individuals, 90% did not consult their healthcare provider prior to purchase. Those most likely to use the pharmacies were young, upper-income individuals.
- Some 40% of respondents mentioned price as a reason for using online pharmacies; another third indicated that there were insurance issues.
- Two in five respondents did not use online pharmacies, while a quarter of consumers did not think it was a good idea to purchase medicines online.
- A majority of respondents (55%) have or would consider purchasing at least one type of prescription or over-the-counter medication online.
- Some 11% of respondents were likely to use a Canadian online pharmacy. Interestingly, the FDA has reported that 85% of medicines that are sold to Americans by Canadian online pharmacies are not Canadian.

These statistics are echoed by recent data collected by the Alliance for Online Pharmacy in the EU (ASOP EU) from an online survey following a five country online educational campaign (France, Germany, Italy, Spain and the United Kingdom). Consolidated data (which varied from country to country) indicated that depending on the country, between 35% and 58% of respondents had bought medicine online. Importantly, between 35% and 65% of customers were not aware that most websites selling medicines online are operating illegally.

The LegitScript study referenced above indicated that 97% of online pharmacies failed to adhere to applicable legal requirements, and 92% of those operating illegally were doing so in a blatantly illicit manner (LegitScript, 2016). The United States was found to be far and away the primary focus of the illegal online drug industry, with 82% of Internet pharmacies in English and a similar percentage, 85%, targeting US consumers and offering shipment to the United States. A review of the movement of goods in 29 test purchases revealed that 100% of shipments were carried out using the post; none used courier services. The vast majority of products came from India, with Germany, Singapore, the United States, Canada and the United Kingdom also mentioned. The original source of the pharmaceuticals, however, could not be discerned. Other findings of the report include:

- None of the test buys that crossed borders were flagged by customs.
- Advertisements for illegal websites represented a tiny share of total online advertisements; those that were posted disappeared and never reappeared.
- The illegal online pharmacies avoided registering their domain names with registrars that enforced policies prohibiting illegal online pharmacies. Approximately 45%-52% of illicit online pharmacies were with 10 domain name registrars that either did not have, or did not adequately enforce, policies prohibiting illegal prescription drug sales.
- All five of the major payment networks operate rigorous programmes designed to prevent purchases related to illegal online drug sellers. Illicit pharmacies, however, often did not identify themselves as selling prescription drugs to inquiring banks and were usually coded as selling other types of products, thereby undermining the payment providers' efforts.
- As criminals seek to expand the use of the Internet they are now using all types of platforms including social media to reach their audiences

The counterfeiters often promote their business through direct solicitations to potential customers using email and online advertising. The most popular medicines for sale online are so-called “lifestyle” medicines (EAASM, 2008). At the same time, counterfeiters are taking advantage of a rising “self-prescribing culture” on the part of individuals. Moreover, online purchases can appeal to consumers because of 1) the speed and convenience of purchases; 2) the possible lower cost of products; 3) the ability to avoid discussing sensitive conditions with healthcare professionals, family or employer/authorities; and 4) the frequent absence of a need for a prescription.

According to the pharmaceutical company Pfizer, over the 2015-18 period, more than 10 000 Facebook accounts or profiles selling counterfeit Pfizer medications were identified and reported (Reddy, 2018). Moreover, they referred more than 1 000 Instagram accounts selling counterfeit Pfizer products between April and October 2018 to Facebook, Instagram’s parent company. The company notes it is working to find and remove drug sales by blocking and filtering terms associated with them, and it quickly shuts down suspicious accounts that people report to them. It is also working on developing new technology to identify when someone is trying to sell drugs. Pfizer also reported that in 2017, authorities from 49 countries seized more than 12 million counterfeit doses of Pfizer products. More than 5 000 vendors were advertising Xanax for sale on the dark web. The company conducted a pilot programme with law enforcement and bought 138 Xanax samples on the dark web; they tested them and found only seven, or 5%, were authentic. The Pharmaceutical Security Institute reports that it receives roughly 15 000 to 17 000 cases of counterfeit drugs reported globally from its members, which include security directors from 35 pharmaceutical companies. The number of new reported cases was 1 178 from 134 countries in 2017, up 7% from 2016. The bulk of counterfeits appear to be from China, India and the United States.

The scale of online counterfeit trade has been assessed by a number of organisations. The WHO has estimated that over half of medicines purchased over the Internet from illegal sites that conceal their physical address are counterfeit.[2] A 2008 report by the European Alliance for Access to Safe Medicines concludes that (EAASM, 2008):

- 62% of medicines purchased online during the study were fake or substandard
- 95.6% of online pharmacies researched were operating illegally
- 94% of websites did not have a named, verifiable pharmacist
- 84.5% of online pharmacies were virtual (i.e. did not operate brick and mortar establishments)
- 78.8% of the sites appeared to be violating trademarks
- 90.3% of websites supplied prescription-only medicines without a prescription.

The experts analysing purchases of online pharmaceuticals to determine their authenticity noted that the vast majority of consumers were unlikely to be able to detect counterfeit products on their own (EAASM, 2008). They concluded that while some counterfeiters made efforts to ship products in ways which would deceive consumers, others did not; the latter shipped products in the wrong packaging, with incorrect or poorly copied manufacturer or product logos or unorthodox box size. A few of the products were shipped merely as loose tablets wrapped inside several sheets of newspaper, while others were delivered in envelopes or paper folded over to form an insecure, make-shift packet. One delivery was simply an envelope containing some loose, unidentified tablets inside a small transparent plastic bag.

According to the EAASM, there is evidence that counterfeiters have used Oceania and the Bahamas as an intermediate destination for fake medicines sent from China and the Middle East (EAASM, 2008). From there, the products are distributed to Europe and other regions via online traders masquerading as legitimate pharmacies based in Europe, the United States and Canada.

A report prepared by the National Association of Boards of Pharmacy (NABP) summarises research carried out during 2019 which identified more than 11 500 online pharmacies that could not be recommended by the association (NABP, 2019). Nearly a third of these pharmacies offered or facilitated

the sale of opioids or other. Many of the online pharmacies did not list an address; these pharmacies were most likely to be selling counterfeit products.

The challenge is illustrated further by a simple web search carried out on a popular lifestyle medicine, which returned 147 million results in 0.38 seconds. The overwhelming majority of sites were believed to be from unregistered pharmacies (ASOP EU, 2013). To gain insights into the return on counterfeit sales, a project was launched by the EAASM, which involved setting up a bogus online pharmacy in Germany (EAASM, 2012). Over a nine-week period in 2011, the site attracted 360 532 visitors, of whom 182 602 were unique, from 112 countries. Pay-per-click (PPC), in which the web host pays the search engine a fee for each click, proved to be the most effective way to attract traffic (responsible for 95% of visits), followed by email advertising (4%) and banner advertising (sponsored visual advertisement placed on selected websites) (1%). The study concluded that had the website been actually trading, it would have netted EUR 12-35 million per year.

The involvement of criminal organisations in illicit pharmacies has been demonstrated on a number of occasions (Guerra and Mackey, 2017). In 2007, US federal law enforcement charged 18 members of the Affpower organisation for operating an online pharmaceutical distribution network involving domestic and foreign entities. The organisation included 1) merchant websites for the purchase of drugs; 2) affiliated websites that marketed and promoted sales; 3) a network of physicians who issued prescriptions for the pharmaceuticals; (4) a network of pharmacies that dispensed the drugs; and (5) credit card processors to process the sales. Affpower's administrative headquarters and customer service department were located in Costa Rica while servers that hosted merchant websites were located in Cyprus.[3] The owner and operator of Affpower resided in the United States but had bank accounts in Panama, Cyprus and Costa Rica, which were used to further the illegal activity. Affpower used a credit card processor in Israel and bank accounts and an accounting firm in Cyprus. The company recruited licensed physicians throughout the United States and Puerto Rico to review and approve orders for prescriptions illegally. The global operation generated over 1 million prescription orders in two years, generating more than USD 126 million. Similar operations were carried out by the Bansal organisation, which sold more than 11 million prescription pills to more than 60 000 purchasers in the United States, grossing at least USD 8 million in just over a year. The Juan Gallinal network set up sham corporations and used a server in Switzerland. The network made approximately USD 9.8 million over a three-year period.

Street markets

In some developing countries, street markets are often used to sell medicines. The uncontrolled nature of such sales enables counterfeiters to engage in illicit trade with low risk of detection. In Ghana, for example, drug inspectors found tablets purporting to be antimalarial medicines in a rural dispensary (WHO, 2017b). The tablets contained less than 2% of the expected active ingredients. The dispensary had purchased the medicines from a licensed wholesaler, who had, in turn purchased the falsified medicines at a discounted price from a travelling salesman, who was selling the product cheaply from the back of a truck. The wholesaler apparently did not question the legitimacy of the product, which was accepted without any paperwork.

Free trade zones

Originally established hundreds of years ago as means to facilitate goods in transit by relieving traders of many customs formalities that would otherwise apply to goods entering into a country for consumption, free trade zones (FTZs) have evolved and developed into an important tool for attracting foreign investment and promoting economic development and growth, particularly in developing countries (OECD/EUIPO, 2018a). The number of zones has expanded rapidly through the years, rising from 79 zones located in 25 economies in 1975 to over 3 500 zones in 130 countries in recent years. For businesses, zones provide numerous benefits; these can include savings in taxes and customs duties; labour and immigration rules

that are more flexible than those applicable in the customs territory of host countries; lighter regulation and oversight of corporate activities; fewer restrictions on corporate activities; and opportunities to improve the distribution of goods to diverse markets.

Lightly regulated zones are, however, also attractive to parties engaged in illegal and criminal activities. These zones have facilitated trade in counterfeit products, smuggling and money laundering, often providing bad actors a relatively safe environment for carrying out their illicit activities. The problem is aggravated in instances where governments do not police zones adequately; this can occur when zones are deemed to be foreign entities that are outside the scope of domestic policing activities. It can be further aggravated when zones are operated by private parties. These parties' main interests are likely to be in finding ways to expand zone occupancy and provide profitable services to zone businesses. They may therefore have little direct interest and/or capacity in law enforcement, nor may they have the capacity or authority for scrutinising zone operations. Even where government authorities are actively involved in overseeing zone activities, there is evidence that co-ordination between these authorities and zone operators, particularly those that are private parties, can be weak, providing further scope for bad actors to exploit zones for their illicit activities.

As noted by the WCO, FTZs are a very important element in global value chains (WCO, 2018). However, from the supply chain security perspective, they still largely remain outside customs control and supervision; there are in fact not many customs administrations that have a mandate to enforce law within the zones.

An example of how zones have been used to facilitate trade in counterfeit pharmaceuticals is found in a 2006 case involving a number of countries (ICC, 2013). In May 2006, UK customs agents seized eight pharmaceutical products, seven of which were counterfeit. The products included infringements involving products made by Merck, Novartis, AstraZeneca, Pfizer and Procter & Gamble (Bogdanich, 2007). The shipment was in transit from the Oyster Corporation, established in the Sharjah FTZ, Dubai, to Personal Touch Pharmacy, established in the FTZ of Freeport, Bahamas (ICC, 2013). A search warrant by the Royal Bahamas Police Drug Unit resulted in the seizure of several counterfeit drugs and uncovered a fulfilment centre for Internet drug orders placed with an illegal on-line pharmacy based in Canada.

The day after the raid in the Bahamas, suspect pharmaceuticals stored in the Sharjah FTZ were moved to an unrelated facility in the Jebel Ali Free Zone in Dubai, in an attempt to avoid further detection. The investigation would eventually unravel a complex supply chain of fake drugs that ran from China through Hong Kong, the United Arab Emirates, UK, and the Bahamas, ultimately to be sold online to customers as Canadian medicines. The Bahamas served as the place where prescriptions were filled and packaged (Bogdanich, 2007). The products would then be sent to the United Kingdom for final shipment to customers in the United States, with the UK postage intended to enhance the credibility of the products. Individuals were charged and, in some cases, imprisoned in the three areas involved: Dubai, Bahamas and Canada. In the case of Canada, the owner of the online pharmacy involved was eventually sentenced to four years in prison in 2013, when 90% of one shipment was found to contain counterfeit drugs.[4] The person involved was arrested in the United States following deportation from the Bahamas, while on the way to Canada.

A second case occurred in 2006, in which Pfizer International discovered counterfeit products in the Euro Gulf Trading Co., located in the Jebel Ali Free Trade Zone (ICC, 2013). A complaint was filed, prompting an inspection by the General Inspection Department and the Investigations and Smuggling Control Section of the Dubai Seaports and Customs Authority. At the warehouss, inspectors found quantities of counterfeit goods, including pharmaceuticals, along with equipment used to print false production and expiration dates.

Notes

[1] See www.fda.gov/news-events/press-announcements/fda-and-cbp-bolster-collaboration-protect-public-health-and-safety.

[2] See www.who.int/bulletin/volumes/88/4/10-020410/en/.

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[3] Note by Turkey:
The information in this document with reference to "Cyprus" relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Turkey recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the "Cyprus issue".

Note by all the European Union Member States of the OECD and the European Union:
The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus.

[4] See www.safemedicines.org/2013/01/fake-online-pharmacy-founder-andrew-strempler-guilty-of-mail-fraud-508.html.

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6 The push factors behind counterfeit pharmaceuticals

Why is the pharmaceutical market so attractive for counterfeiters? This chapter explores this question, analysing how the profitability of this criminal venture – combined with low risk of detection, low risk of prosecution and weak penalties – have contributed to its steady growth.

The decision of what counterfeit product to produce and which markets to target is driven by factors related to: 1) the characteristics of the market, which determine market potential; 2) technological and logistical considerations, which determine the feasibility of counterfeiting; and 3) the institutional environment, which determines the risks of being caught.

Table 6.1 assesses the situation for pharmaceuticals, based on a general framework and analysis presented in OECD (2008). As shown, the pharmaceutical market can be highly attractive for counterfeiters.

Table 6.1. Framework for assessing the attractiveness of counterfeiting pharmaceuticals

Driving factor	Conditions favouring counterfeiting pharmaceuticals	Situation for pharmaceuticals
Market characteristics		
Profitability	High unit profitability and/or large volume	Can be very large, especially if cheap ingredients are used
Market size	Large potential market	Pharma market is large (more than USD 1 trillion) and growing
Brand power	High level of brand recognition	Strong brand power
Production, technology and distribution		
Investment required	Simple, low cost equipment	Cost of making crude fakes can be modest; a pill press may suffice

Technology required	Not sophisticated; easy to acquire	Production technology, packaging and labeling challenges vary; can be easy, or a significant challenge
Logistics	Simple and cheap	Shipping costs are low; free trade zones have facilitated trade in fakes
Marketing and sale of products	Easy to establish/infiltrate distribution channels	Difficult to infiltrate principal supply chains; easier if second tier wholesalers targeted; Internet has facilitated trade in fakes
Ability to conceal operations	Easy to hide illicit operations	Can be easy if operations are on a small scale
Ability to deceive consumers	Easy to deceive consumers	Easy to deceive visually; anti-counterfeiting technology can complicate significantly
Institutional characteristics		
Legal and regulatory framework	Weak laws	Complicated situation in many countries makes it difficult to prosecute
Enforcement	Weak enforcement	Enforcement levels vary across countries; clever counterfeiters often succeed in avoiding enforcement efforts
Penalties	Weak sanctions	Criminal sanctions provided for in many countries; fines are generally a manageable cost of business in many countries

Source: Based on OECD (2008), *The Economic Impact of Counterfeiting and Piracy*, https://doi.org/10.1787/9789264045521-en.

Profitability

The sale of counterfeit medicines can be highly profitable and highly attractive to organised crime groups, especially when the amount of expensive active ingredients used in the counterfeits are reduced. For some products the active ingredients can account for 80% of the cost of a generic medicine (WHO, 2017b). According to the pharmaceutical company Pfizer, who produced the innovative medicine, Viagra (one of the most counterfeited medicines worldwide), the production of 1 kilogramme of heroin has higher costs and lower street value than the respective costs and profit entailed by the production and distribution of 1 kilogramme of Viagra, meaning that the profit margins for Viagra are much higher (UNICRI, 2012). In one case investigated by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, 100 000 counterfeit pills imported at the price of about GBP 0.25 each were being sold for up to GBP 20 each, which translates into a profit margin of 7,900%.

Low risk of detection

In international trade, customs officials are most likely to encounter potentially low-quality medicines before they enter a country, and health care workers are most likely to spot them once they do (WHO, 2017b). It is rare, however, for either of these groups to have access to simple field tests that would help them to triage suspect products. Moreover, where field testing equipment is available, staff do not always have the training or the time to use it correctly.

In an assessment of the regulatory capacity of 26 countries in Africa published in 2010, the WHO concluded that these countries did not generally have the capacity to control the quality, safety or efficacy of the medicines circulating on their markets or passing through their territories. Detection of counterfeit medicine by custom officers is difficult due to the limited time for analysis of the shipments. Additionally, many criminals engaged in pharmaceutical counterfeits use original packaging but manipulate the pharmaceuticals. Of 20 samples of seized suspected counterfeit pharmaceuticals analysed by Dégardin and Roggo (2016), all packaging was found to be authentic with the exception of one vial, which was a different shape and size. In three samples, pharmaceuticals have been found to be genuine and in 17, they have been confirmed to be counterfeits. Five samples consisted of genuine chemical composition but manipulated packaging. In one case chemical content was totally counterfeited. In case of 11 counterfeits,

the samples were of genuine origin but the medicines had been diluted with water, with the dilution factors ranging from 1.5 to 200. Half of the samples had a different batch number on the vial than on the box. While the counterfeit was confirmed within one to two days of detection of suspected shipments, one week was needed for the full forensic analysis of the composition (Dégardin & Roggo 2016).

Low risk of prosecution

The risk of prosecution for counterfeiting pharmaceuticals is low (WHO, 2017b). Most counterfeits are only detected when they reach retailers or patients and it is frequently difficult to trace them back through complex supply chains, or to prove where criminal activity occurred. Moreover, in most countries, investigation of criminal activity is the work of the police, who may not have extensive expertise in the specialised techniques sometimes needed to investigate pharmaceutical crime. The situation is further complicated because the international nature of trade in counterfeits often requires cross-border investigation, which can be difficult, especially if the criminal parties involved have complex ownership structures and use foreign bank accounts. Difficulties in following paper trails of investigated products to trace their point of origin can be significant as the location of evidence necessitates forensic examination of computers and smartphones, some of which may be in foreign jurisdictions. Language barriers can also affect cross-border co-operation.

Weak penalties

In most countries, sentences for falsification of medical products are far less than those applicable to, for example, drug smugglers, who can be imprisoned for lengthy terms and can have the proceeds of their crimes confiscated (WHO, 2017b).

Table 6.2 compares information on maximum prison terms in selected countries for trademark infringement and narcotics trafficking (OECD, 2018c).

Table 6.2. Maximum incarceration for trademark infringement and narcotics trafficking

In years

	Brazil	Canada	France	United Kingdom	United States	Average
Trademark infringement	1	5	4	10	10	6
Narcotics trafficking	15	10	10 (or life sentence in certain cases)	Up to life sentence	Up to life sentence	25[1]

Note: [1]Life sentence is approximated at 50 years.
Sources: OECD, 2018c and www.inhouselawyer.co.uk/wgd_question/are-there-criminal-sanctions-for-infringement-of-any-intellectual-property-rights-and-if-so-what-are-they-and-how-are-they-invoked/#France.

Table 6.3 shows the sanctions and maximum incarceration periods for trademark infringement in the BRICS countries.

In addition to criminal sanctions, rights holders can sue for damages. Alternatively, as shown in Table 6.3, they can seek compensation through statutory penalties; such penalties are not available in all countries. Other fines can also be applied. In the case of statutory damages, the amounts that can be recovered, when provided for, vary significantly among countries. In the case of the United States, they can reach up to USD 2 million (OECD, 2018).

Table 6.3. Selected features of trademark regimes in Brazil, China, India, Russian Federation and South Africa, 2016

Item	Brazil	China	India	Russian Federation	South Africa
Statutory damage	x	≤ USD 430,000	x	≤ USD 72,000	x
Administrative civil fines	x	≤ 5x illicit gain (1)	x	≤ USD 2,900(2)	x
Criminal sanctions: imprisonment up to …	1 year	7 years (3)	3 years	6 years (4)	5 years (5)
Other fines	✓	x	≤ USD 2,900	≤ USD 14,000((6)	≤ USD 650 (7)

Notes: National currency amounts have been translated into USD, based on average exchange rates in 2016 (see, www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates). (1) If the illicit revenue is less than USD 7 200, or is not known, a fine ≤ USD 36 000 can be imposed. (2) Applicable to legal entities. (3) Applicable to cases which are deemed to be serious in nature. (4) Applicable when a group of persons or organised group of infringers is involved. (5) For repeat offenders; first offence is for up to 3 years. (6) Applicable to groups; fine can also be calculated on the basis of an amount equal to up to 5 years wage or salary, or other income, of a convicted person. (7) For repeat offenders; first offence is up to USD 376.
Source: OECD, 2018c.

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7 Impact of counterfeit medicines

Why are counterfeit medicines such a problem and who is affected? This chapter explores in depth the multiple ways in which fake pharmaceuticals cause damage – to individuals' health, to the bottom line and reputation of producers, to government budgets and to the environment.

Counterfeit medicines affect economies in a number of areas:

- Individuals who fall victim to low quality counterfeit products that may not adequately treat their medical needs.
- Legitimate producers, who can lose sales to counterfeiters, and need to take steps to ensure that counterfeiters do not infiltrate their supply chains, and to mount efforts to combat counterfeiters.
- Governments, which are actively involved in managing health care in countries.
- Entire economies, in the form of the impact on crime levels, the environment and the possible effects on jobs and foreign investment.

It is often assumed that high-income countries with strong regulatory systems can effectively exclude substandard and falsified medical products from their markets, but WHO analysis shows that this is not necessarily the case, as reports on these products have been submitted by countries in Western Europe and North America as well as other high-income settings (WHO, 2017b). In an analysis of cases of counterfeit incidents involving penetration of legitimate supply chains and reported to PSI CIS database between 2009 and 2011, Mackey et al. (2015) revealed that upper and lower-middle income countries comprised 93% of all the cases. Analysis of the health consequences of falsified medicines performed by Rahman et al. (2018) showed that the 48 reported incidents involving health damage due to falsified medicines were almost equally distributed among developing (27 cases, 56.3%) and developed countries (21 cases, 43.7%).

Impact on individuals

Bad quality counterfeit medicines can affect individuals in a variety of ways (WHO, 2017c):

- Adverse effects (for example toxicity) from incorrect active ingredients.
- Failure to cure or prevent future disease, thereby increasing mortality, morbidity and the prevalence of disease.
- Contributing to the progression of antimicrobial resistance and drug-resistant infections.
- A loss of confidence in health care professionals, health programmes and health systems.
- Increasing out-of-pocket and health system spending on health care.
- Lost income due to prolonged illness or death.
- Lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy.

As indicated above, people taking counterfeit medicine may be putting their lives at risk. Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malarial medication might be responsible for an additional 116 000 deaths (WHO, 2017c). Renschler et al. (2015) estimate that each year over 120 000 under-five malaria-positive children may die across 39 sub-Saharan countries due to taking poor-quality anti-malarials, including counterfeit and substandard pharmaceuticals. In their rather conservative review of the published literature on the health consequences of falsified medicines, Rahman et al. (2018) analysed 48 reported incidents in which falsified medicines caused serious adverse effects to patients. These incidents involved approximately 7 200 casualties, including 3 604 deaths. The results of the study indicate that a similar number of incidents affect developing and developed countries alike, and the counterfeiters target all types of medications (Rahman et al. 2018).

Forensic tests of suspect samples performed by the pharmaceutical industry also demonstrate that counterfeit medicines, in 90% of those cases tested, could cause harm to the patient (Novartis in Society Report, 2019).

While many incidences of patient harm will likely go undetected, numerous examples have nevertheless been recorded.[1] For example, a recent UK survey carried out by Sapio research and commissioned by a private company INCOPRO, concludes that almost one-third (32%) of those who have bought one or more counterfeit medicines have suffered a health issue as a result (INCOPRO, 2020). There are numerous other documented cases in which patients have died or suffered harm due to an online purchase. As just one example, in 2013 people died after taking a counterfeit diet pill bought through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences for humans.[2]

Impact on producers

The impact of counterfeits on legitimate producers are multiple, including lost sales, costs of protecting brands, loss of reputation, the potential cost of managing the disposal of counterfeits and litigation costs involving counterfeiters and possibly people who were unknowingly victimised by counterfeits. The challenges are alluded to in corporate reports, albeit in a general manner. For example, one of the five largest pharmaceutical companies – Pfizer – mentioned counterfeiting in its 2019 annual financial report , although not in its general annual report.

In the financial report, the company includes a section on counterfeit products, containing general information on the challenges it faces, and noting the efforts it has taken to address the situation (Pfizer Inc., 2019a; 2019b):

> *"We undertake significant efforts to counteract the threats associated with counterfeit medicines, including, among other things, working with the FDA and other regulatory authorities and multinational coalitions to combat the counterfeiting of medicines and supporting efforts by law enforcement authorities to prosecute counterfeiters; assessing new and existing technologies to seek to make it more difficult for counterfeiters to copy our products and easier for patients and healthcare providers to distinguish authentic from counterfeit medicines; implementing business practices designed to protect patient health; promoting public policies intended to hinder counterfeiting; working diligently to raise public awareness about the dangers of counterfeit medicines; working collaboratively with wholesalers, pharmacies, customs offices, and law enforcement agencies to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and repackagers, and using data analytics and risk assessment tools to better target the factors that give rise to the counterfeiting problem in the first place. However, our efforts and the efforts of others may not be entirely successful, and the presence of counterfeit medicines may continue to increase."*

Novartis includes an identical paragraph on counterfeits in both its annual report and its annual financial report, describing the dangers that the practice could have on patients and the firm's reputation (Novartis AG, 2019a; Novartis AG, 2019b). It notes that the industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. It indicates that counterfeiting of their products could result in substantial reputational and financial harm.

In its most recent annual report, Roche Group includes a section on counterfeiting that details the effects that fakes can have on patient health (Roche Group, 2019). It indicates that the global trading system opens up possibilities for introducing counterfeit products into the regular supply chain, and that it collaborates on international criminal investigations to address problems. The firm uses its internal analytical skills to examine samples of counterfeiting. Besides identifying the composition of counterfeits, analyses comprise also the ink on packaging and leaflets, blisters and paper. Counterfeits from different parts of the world are examined to determine whether they originated from the same source. In 2018, the company closed 377 suspected cases of counterfeiting, of which 142 were confirmed.

Merck addresses the challenges associated with counterfeiting in its annual report (Merck KGaA, 2019):

> *"To combat product-related crime, an internal coordination network covering all functions and businesses (the Merck Anti-Counterfeiting Operational Network) was set up several years ago. In addition, security measures are in use to protect products against counterfeiting. Innovative technical security solutions and defined preventive approaches are used to ward off dangers relating to cybercrime and espionage. Measures to prevent risks and to prosecute identified offenses are conducted in all the relevant crime areas in close and trustworthy cooperation with the responsible authorities. The impact of these risks on business operations depends on the respective individual case, product-specific factors, the value chain and regional aspects in particular. Our Corporate Security department is responsible for the overall coordination of all measures in this area. Overall, the threat resulting from crime in general is seen as being possible and is classified as a medium risk."*

Although counterfeiting is not mentioned in the MSD annual financial report it does however document certain trademark infringement litigation (Merck & Co., Inc, 2019). The term counterfeit does not appear as such in either the annual report or the annual financial report of Johnson & Johnson (Johnson & Johnson, 2019a; Johnson & Johnson 2019b).

Loss of revenue

The sale of counterfeit products in many instances displaces sales from legitimate pharmaceutical companies. The most recent EU Status Report on Infringement (EUIPO, 2019) estimates that the European pharmaceutical industry[3] was losing EUR 9.6 billion in sales due to counterfeits during the period 2012-2016, which represent 3.9% of total sales. In China, unauthorised production of a drug produced by an international pharmaceutical company resulted in a drop in sales to about USD 242 000 (OECD, 2016). When the counterfeiting ceased in 2003, sales grew to USD 1.2 million. In 2003, the turnover from India's pharmaceutical industry was estimated at USD 4.2 billion; of this, counterfeiters produced an estimated USD 1 billion (OECD, 2016).

Increased costs of security measures

Incorporating anti-counterfeiting technologies into their products and packages raises the costs for legitimate pharmaceutical manufacturers (OECD, 2016). The costs of introducing a unique identifier for manufacturers and parallel importers have been estimated by European Commission at EUR 50 to 320 million annually. These costs relate to adapting production and packaging lines and investing in software systems to upload the unique identifier information onto the repository system. The estimation of costs for the entire sector (including manufacturers, wholesalers, retailers and repositories systems) ranges between EUR 200 and 800 million.[4] Firms incorporate overt, covert and forensic technologies depending on the risk and sophistication of counterfeiters; many also monitor their products in the markets of counterfeit-prone countries and conduct their own investigations into reported counterfeiting incidents. As noted in a recent report by the Institute of Medicines of the National Academies, multinational pharmaceutical companies have invested in security departments that work globally with regulators and law enforcement agencies. These departments collect 80% of the evidence used in criminal prosecution (IOM, 2013).

Damage to brands

As with other forms of counterfeiting, fake medicines risk damaging a firm's brand and the products involved when those products do not meet expectations. Moreover, the firm's reputation for safety and quality are put at risk, and the firm may be subject to liability if consumers are harmed by counterfeit versions of their drugs (OECD, 2016).

Undermining innovation

Innovation is key to the success of pharmaceutical companies and to improving health outcomes. In recent decades, new medicines have improved survival rates and the quality of life for many patients around the world, while improving treatment of diseases such as HIV and certain cancers (OECD, 2018b). R&D is central to innovation; however, it is risk-prone, costly and, as indicated earlier, time consuming, with much of the risk and costs borne by private enterprises and investors. R&D is promoted in large measure by the protection of intellectual property rights, without which innovators would be hard pressed to profit from the sizeable investments required to develop new products. Infringement of IP through counterfeiting undermines innovation by reducing incentives to invest and innovate, and by depriving pharmaceutical companies of revenues, thereby lowering the amount of money available for further R&D (Tracit, 2019).

The impact of counterfeiting on pharmaceutical innovation can be particularly significant for developing countries (OECD, 2016). Less than 10% of global health research expenditures are directed to conditions that account for more than 90% of preventable mortality – conditions that are prevalent in developing economies.

Impact on governments

Counterfeit pharmaceuticals can result in squandered health resources, not only for individual patients, but also for international humanitarian organisations, NGOs and national government programmes (OECD, 2016). Counterfeiters divert resources away from genuine treatment, robbing limited health budgets of already scarce resources. At the same time, counterfeits can mean losses in corporate taxes and VAT, increased regulatory and enforcement costs for securing the supply chain, and higher health care costs to treat the adverse effects of fake drugs. With respect to taxes, EUIPO (2016) estimates that the cost to EU governments of revenues foregone from counterfeit medicines was in the order of EUR 1.7 billion.

Greater regulatory and enforcement costs

The total costs of regulatory and enforcement measures in the pharmaceutical area are not generally available as they are combined in overarching budgets of the agencies involved (OECD, 2016). While there are tools available to detect counterfeits, they can be costly. Much depends on the nature of the counterfeit products, which can be classified as follows (IOM, 2013):

- Category 1: Completely fraudulent products with unknown content and therapeutic effects significantly different from the genuine drug.
- Category 2: Look somewhat similar to the drug being imitated, but the drug composition is not known.
- Category 3: Look very similar or identical to the genuine product but contain an entirely different drug, if any.
- Category 4: Look very similar or identical to the actual product but contain an alternative drug or synthetic analogue providing similar therapeutic value to that of the authentic product, and intended to create repeat business.
- Category 5: Visually identical, highly sophisticated copies or synthetic analogues with some therapeutic value that cannot be detected using most field and laboratory methods.

In some instances, visual inspection will suffice; in others tests may be needed for physical properties such as disintegration, using reflectance spectroscopy, and refractive index; and chemical tests including colorimetry and dissolution, chromatography, spectroscopic techniques and mass spectrometry (IOM, 2013). Modern science has opened up immensely powerful and expensive forensic chemistry techniques that can give investigators information on the unique fingerprints that manufacturers leave on their products. This analysis can give prosecutors the evidence necessary to link falsified drugs to particular sources. Such analysis, however, can be too costly to apply in a general manner. Forensic chemistry assays cost between USD 5 000 and USD 15 000 per test on average. While extremely accurate, they are therefore not practical for routine product quality market surveillance in any country and may be out of reach entirely in many of the low- and middle-income countries most affected by counterfeiting problems.

Loss of confidence/trust in governments and public health programmes

Genuine harm, even among a small number of patients, can lead to a loss of confidence in government programmes and health care systems (OECD, 2016). Incidents of therapeutic failure and drug resistance can destroy the credibility and success of health programmes; counterfeit and substandard medicines will only undermine consumers' trust further and can have future knock-on effects, such as the decrease in the quality of contraceptive pills in Brazil in the late 1990s. IOM (2013) reports that rumours about contraceptive quality linger, showing the type of long-term damage that can occur.

Increased health care costs

Counterfeit medicines may also result in higher health care costs, as patients may require additional treatment to deal with potential adverse effects of ineffective or damaging drugs. Physicians and health care providers rarely suspect counterfeit or substandard drugs as the reason for a patient's poor therapeutic response. Accordingly, they most frequently respond by ordering more tests or repeating the course of treatment (OECD, 2016).

Economy-wide effects

In addition to the direct effects on consumers, producers and governments, counterfeits can have broader, economy-wide effects in a number of areas, including on the environment, foreign investment and crime. There may also be impacts on economic performance; EUIPO (2019) reports that counterfeits result in an estimated EUR 16.5 billion of lost sales and affect more than 80 000 jobs in the pharmaceuticals sector and other sectors that sell goods and services to it.

Environmental pollution

While the pharmaceutical industry is required to meet environmental protection standards and reduce chemical waste and other hazardous materials in their production processes, the same does not hold true for manufacturers of counterfeit drugs, who can reap the financial benefits of dirty production by taking environmental shortcuts (Tracit, 2019; OECD, 2016). Producers of illicit pharmaceuticals disregard the impact that chemical compounds may have on the environment, disposing of toxic dyes and chemicals without regulatory oversight, while ignoring the treatment of wastewater streams (OECD, 2016). Authorities note that seized counterfeit electronic goods and counterfeit chemicals and pharmaceuticals are particularly difficult to dispose of in an environmentally friendly manner, as the core ingredients of fake drugs are in most cases unknown, hence the environmental damage they can pose is also difficult to assess ex ante.

Lost foreign investment

The prevalence of counterfeit medicines on a national market may reduce or discourage foreign investment, as potential investors judge that their interests will not be protected (OECD, 2016). The consequences may constitute significant lost opportunities for economic growth and development as well as for improvements in the national health care system.

Costs of tackling complex criminal networks

Criminal involvement in the manufacture and distribution of counterfeit pharmaceutical products is of concern as it provides those involved with a source of revenue to support a wider range of illicit activities and can undermine confidence in public institutions, such as law enforcement. Investigations have uncovered significant evidence that organised criminal groups (OCGs) have expanded their illicit activities into the field of counterfeit medicines (UNICRI, 2012). A 2014 INTERPOL report examines the role of OCGs in pharmaceutical crime, finding involvement ranging from small clusters of 3 to 10 members, to larger well-established hierarchical groups and sophisticated international networks with elusive structures (Table 7.1) (INTERPOL, 2014). Analysis by Hall et al. (2017) showed that actors involved in the illicit supply of medicines "often belong to loosely structured networks. These networks straddle what are often presented as the dichotomies of licit/illicit, online-offline and global/local." Often legitimate companies serve as a shield for trade in counterfeit pharmaceuticals. "Suppliers on all levels can operate under the guise of a legitimate company and sell illicit medicines for extra income, while using it to expand their network and launder profits" (Hall et al., 2017). The increasing use of the Internet to sell counterfeit and illicit medicines has resulted in growth in the latter form of criminal enterprises. The networks are difficult to target due to the ease with which they can move and establish new websites, the high level of anonymity offered in the virtual world, and the difficulty in piecing together the different criminals involved in wide-ranging affiliate networks.

Table 7.1. Pharmaceutical cases possibly involving organised crime groups, 2013

Region	Case
Africa	**Nigeria**. One person was arrested for smuggling counterfeit medicines from China to Lagos, Nigeria. The illicit medicines included Coartem, Ibuprofen and Maloxine. The scale of the smuggling operation indicates that there was involvement of an OCG.
Asia	**Philippines**. Philippine authorities arrested traffickers attempting to ship slimming pills, pain relief medication and antibiotics which had been shipped from Singapore. Customs authorities confiscated a 40-foot container loaded with 20 pallets of fake medicines. Connections to a trading company indicates that the case is tied to an OCG.
	Japan. Between 2011 and 2013, an OCG called Azuma-Gumi was running a counterfeit medicine operation selling Viagra, Cialis and Levitra in Japan. Six people were arrested.
Europe	**Russian Federation**. Russian authorities reported that they had dismantled a counterfeiting operation which had been ongoing for several years in Russia. Fake medicines such as Herceptin, Meronem, Cefobit, Mantera and Sulperason were manufactured and distributed by an OCG. Seven suspects were arrested.
Oceania	**New Zealand**. Three suspected counterfeiters were arrested with doping substances and Tadalafil in New Zealand. The three suspects were part of an OCG which distributed fake medicines in the country. The investigation revealed that the group's leader was operating a sophisticated ring of distributors and using a pill press to make tablets, as well as an improvised lab in a garage.
South America	**Colombia**. Police arrested 21 suspects in an operation in which a total of 89 754 units of fake medicines were confiscated. The OCG involved falsified expiration dates and batch numbers of medicines.
	Guatemala. Ten people were arrested as part of an operation to take down an OCG. The group had a leader and operated from a legitimate pharmaceutical company, which was licensed to produce medicines. The OCG used the company to cover production of illegal medication in order to increase the company's revenues.

Source: INTERPOL (2014), *Pharmaceutical Crime and Organized Criminal Groups: An analysis of the involvement of organized criminal groups in pharmaceutical crime since 2008*, www.reajetus.com/wp-content/uploads/2016/04/Pharma-Crime-Sub-Directorate.pdf

Authorities are also addressing related issues, including corruption within the legitimate pharmaceutical community and a lack of dedicated national enforcement units to tackle the issue (INTERPOL 2014). The challenge is heightened by the fact that criminals are increasingly using the Internet to carry out their activities and are, in turn, developing sophisticated techniques to avoid detection. Some INTERPOL member countries face legislative challenges in thwarting those responsible for pharmaceutical crime, as few countries appear to possess specific legislation to target this type of crime. Furthermore, many countries cited weak penalties as a contributing factor to the proliferation of criminal networks, who are willing to continue to take risks as the rewards outweigh the potential penalties.

Key findings from the INTERPOL report are:

- Criminals involved in pharmaceutical crime are operating through informal networks, but traditional organised crime groups across the globe are also involved throughout the supply chain.
- An increase in pharmaceutical crime occurred in some countries during 2008-13, especially in South and Central America.
- Both informal networks and organised crime groups seem to be trafficking in the same types of illicit medicines: erectile dysfunction medication; slimming pills; as well as pain and anxiety relief medication.
- An important trend in many countries is the increased use of illicit online pharmacies, operated by both informal networks and organised criminal groups.
- Large amounts of money are involved in the transnational criminal enterprises: one illicit online pharmacy network earned USD 55 million during two years of operations.
- Other crimes, such as money laundering, human trafficking for sexual exploitation and weapons smuggling, can be tied to criminals involved in pharmaceutical crime.

Cases pursued in the United States provide further insights into the role of criminal organisations in marketing counterfeit medicines:

- In April 2019, six people were charged in the US Federal Court with operating a wide-ranging drug conspiracy that included importation of large amounts of drugs which were then used to produce counterfeit Xanax pills, using Alprazolam as the main ingredient and binding agents. The illicit ingredients were purchased on the Dark Web using cryptocurrency, with the counterfeit Xanax likewise sold on the Dark Web or through conventional illegal drug distribution channels.[5] If convicted on multiple charges (conspiracy to possess with intent to distribute controlled substances, using or maintaining a drug premises, possession with intent to distribute controlled substances, possession of a firearm in furtherance of a drug trafficking crime, possession of an unregistered firearm and conspiracy to commit money laundering) two of the defendants could face life imprisonment.
- In January 2019, the president of a medical company was sentenced to 26 months in prison for conspiring to smuggle misbranded pharmaceuticals into the United States and for the unlicensed wholesale distribution of prescription drugs.[6] The individual concerned instructed subordinates to smuggle misbranded prescription drugs and devices into the United States, including oncology drugs, orthopedic injections, and cosmetic devices. These products were not approved by the Federal Drug Administration (FDA) and did not contain the labels, warnings, and instructions required by the FDA. In order to smuggle these products into the United States, the company used false names and false customs forms, and broke large shipments into multiple smaller shipments. The products were stored in private residences, often in violation of safety regulations requiring the pharmaceuticals to be stored at cool temperatures.
- In March 2018, a US federal grand jury returned a 28-count indictment charging four individuals with mail and wire fraud conspiracy, mail fraud, trafficking in counterfeit goods, introducing misbranded articles into interstate commerce, distribution of a controlled substance, international money laundering, and smuggling.[7] The individuals sought to enrich themselves by purchasing from overseas suppliers FDA-regulated products that were counterfeit and/or misbranded, illegally importing them into the United States from the People's Republic of China and subsequently selling them to US consumers. In an effort to evade detection by law enforcement, the defendants had the packages shipped to a trans-shipper located in Miami, Florida, who would then re-package and/or re-label the parcels and send them to defendants in Puerto Rico, where they were warehoused. The products were then marketed through online stores platforms such as eBay.com and Bonanzo.com, and then shipped by post to individuals and wholesale buyers. The products sold included counterfeit and misbranded male-enhancement pills, some of which contained drugs that the consumers were not aware of and could cause danger to their health, including heart attacks or strokes. If indicted, the defendants were facing a forfeiture allegation of USD 3.7 million, six properties or homes, two bank accounts, one Pay Pal account, and three certificates of deposit plus a maximum possible sentence of 30 years' imprisonment for the conspiracy charges, 10 years for trafficking counterfeit goods, and 3 years for introducing and receiving misbranded products in interstate commerce. One of the defendants also faced up to 20 years in prison for international money laundering and 20 years for smuggling.
- In July and August 2017 and March and June 2018, five individuals involved in a scheme to traffic steroids were sentenced in the United States.[8] From approximately May 2015 until April 2017, the conspirators involved in the scheme manufactured steroid products made from raw materials that they purchased overseas and marketed as Onyx steroids using Onyx labels that were also ordered from overseas suppliers. The defendants sold the steroids to customers across the United States using email and social media platforms, collected payment through money remitters, such as Western Union and MoneyGram, and used false identifications and multiple remitter locations to pick up the proceeds. Some of the defendants laundered proceeds from the steroid sales through a tanning business, which they owned and operated specifically to launder the proceeds of the steroid operation.

- In April 2018, an individual was sentenced to 36 months' imprisonment for conspiring to distribute counterfeit, misbranded, and adulterated Botox into the United States. The individual concerned owned and operated a sophisticated wholesale drug distribution business involving individuals in Canada, Panama and Turkey. The Botox was sourced from Turkey and shipped to doctors in the United States. The drugs were adulterated because they were not kept at required constant cold temperatures, and sometimes the drugs were shipped and stored with no refrigeration or insulation. Further, some of the Botox had counterfeit exterior packaging, and the manufacturing lot numbers on the exterior of the drugs' cartons did not match the lot numbers on the drug vials inside the cartons.
- In March 2017, an individual pleaded guilty in the United States to engaging in a conspiracy to manufacture counterfeit Xanax pills and to launder the proceeds gained by the illegal scheme.[9] The parties involved used imported equipment and components to support their operations. The two counts to which he pleaded guilty were subject to sentences of 5 years and 10 years.

In February 2016, a Pakistani national appeared in court after being extradited to the United States to answer charges related to the illegal importation and sale of misbranded and unapproved drugs, some of which were further alleged to have been counterfeit or controlled substances, and all of which were manufactured overseas and shipped to the United States.[10] The company involved claimed to be, among other things, a leading and long-standing exporter of branded and generic pharmaceutical drugs and surgical products. The illegal drugs imported by the defendants included counterfeit or unapproved versions of Viagra, Lorazepam, Alprazolam, Diazepam, Zolpidem, and Phentermine. The defendants filled US drug orders by procuring brand name and generic drugs that they knew to be unapproved for the US market by the FDA from suppliers whose drug manufacturing facilities were not approved by the FDA and whose packaging and patient literature for their drugs were also not approved by the FDA. As part of the conspiracy, the defendants, using a series of email addresses, would forward the drug orders to a network of drug suppliers in Pakistan, India, the United Kingdom, and the People's Republic of China. To evade detection by customs authorities the drugs were concealed, in loose format, in plastic vitamin bottles and plastic water bottles. They would also use customs declarations that inaccurately or misleadingly described the contents of the shipments, or would not use customs declarations altogether. The drugs would often be shipped in mail parcels without packaging, without labels, and without patient safety leaflets or other written instructions and information. Penalties for these offences range from not more than 3 years in federal prison per count, to not more than 20 years in federal prison, per count. Each count also carries a penalty of up to USD 250 000.

Notes

[1] ASOP Global consolidated research collected over a number of years https://buysaferx.pharmacy/for-the-media/examples-of-people-harmed-by-medications-bought-online/

[2] Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable" The Daily Mail, United Kingdom (April 22, 2013); available at http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html. This medicine was misused. The patient took both anti-depressants and a pill marketed as a weight loss aid containing lethal ingredient.

[3] At the manufacturing and wholesale levels.

[4] Commission Staff Working Document SWD(2015) 189 final https://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2015/swd_2015_0189_en.pdf

[5] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/april-23-2019-six-indicted-drug-conspiracy-included-production-and-distribution-powerful-synthetic.

[6] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-18-2019-medical-company-executive-sentenced-smuggling-18-million-misbranded-pharmaceuticals.

[7] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-8-2018-four-individuals-indicted-trafficking-counterfeit-goods.

[8] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/june-20-2018-fitchburg-woman-and-saugus-man-sentenced-roles-counterfeit-steroid-conspiracy; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-30-2018-lynn-man-sentenced-over-10-years-prison-role-counterfeit-steroid-conspiracy; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/july-17-2017-gloucester-woman-pleads-guilty-her-role-counterfeit-steroid-trafficking-scheme; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/august-28-2017-shrewsbury-man-pleads-guilty-operating-counterfeit-steroid-scheme.

[9] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-28-2017-oakland-man-pleads-guilty-role-conspiracy-manufacture-counterfeit-drugs.

[10] See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/february-1-2016-pakistani-man-makes-appearance-us-district-court-denver-following-indictment-and.

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8 Efforts to combat counterfeit pharmaceuticals

Many initiatives are underway to tackle the growing problem of counterfeit pharmaceuticals. This chapter summarises the main global efforts, including crime-fighting programmes run by INTERPOL and the World Health Organization. It also outlines the various legislative measures in place to protect consumers and producers from fake medicines.

Governments and industry have been working hand-in-hand to combat counterfeit, substandard and falsified pharmaceuticals. Some of these efforts have been described earlier in this report. Here we describe more global initiatives taken by international organisations.

INTERPOL

A number of initiatives are in place at the international level to combat counterfeit and illicit drugs, co-ordinated by INTERPOL. Operation Pangea has been carried out since 2008, with the number of countries participating rising from 8 to a record 123 in 2017.[1] The operation targets the online sale of counterfeit and illicit medicines and medical devices. Participating agencies carry out co-ordinated operational activities against illegal websites during the same week in order to identify the criminal networks behind the trafficking (Table 8.1). During Pangea XI, which was carried out in 2018, police, customs and health regulatory authorities from 116 countries targeted the illicit online sale of medicines and medical products, resulting in 859 arrests worldwide and the seizure of USD 14 million worth of potentially dangerous pharmaceuticals.[2] Almost one million packages were inspected during the week of action, with 500 tonnes of illicit pharmaceuticals seized worldwide. Seizures included anti-inflammatory medication, painkillers, erectile dysfunction pills, hypnotic and sedative agents, anabolic steroids, slimming pills and medicines for treating HIV, Parkinson's and diabetes. More than 110 000 medical devices including syringes, contact lenses, hearing aids and surgical instruments were also seized.

Table 8.1. Operation Pangea 2008-2018

Year (Pangea number)	Number of countries	Seizures		Number of arrests	Number of websites closed
		Quantity	Value (millions of USD)		
2008 (I)	10	NA	NA	NA	NA
2009 (II)	24	167 000 items	NA	221	72
2010 (III)	45	1 million	2.6	NA	290
2011 (IV)	81	2.4 million items	6.3	551	13 500
2012 (V)	100	3.75 million items	10.5	80	18 000
2013 (VI)	100	9.8 million items	41	58	9 000
2014 (VII)	111	9.4 million items	31	237	10 600
2015 (VIII)	115	20.7 million items	81	156	2 414
2016 (IX)	103	12.2 million items	53	393	4 932
2017 (X)	123	25 million items	51	400	3 584
2018 (XI)	116	500 tonnes	14	859	3 671

Notes: [1]Arrested or under investigation. NA: Not available.
Source: INTERPOL news releases at www.interpol.int/News-and-Events

One of the main trends identified during the decade of Pangea operations is the continuous growth of unauthorised and unregulated online pharmacies, which are capitalising on increasing consumer demand worldwide.[3] It has also observed that criminals are shipping packages containing smaller numbers of pills and tablets to try to avoid the more stringent checks which have become routine in many countries.[4] In the 2018 Pangea operation, authorities in Poland discovered counterfeit contraceptive pills hidden inside DVD packages, while in Ireland illicit sleeping pills were found concealed inside a hollowed-out book. Criminals also attempted to evade detection by falsely labelling shipments. In Argentina for example, more than 4 million unmarked ibuprofen pills were seized after they were declared as sample items, and the United Kingdom recovered some 150 000 powerful sleeping pills in shipments labelled as clothing, bedding and food.

In addition to the global Pangea campaigns, INTERPOL has overseen a number of regional initiatives to intercept counterfeit pharmaceuticals.[5] These include Operation Rainfall, which focused on Asia; Operation Qanoon, which focused on the Middle East and North Africa; and Operation Heera, which focused on West Africa. The results of these campaigns for 2018 are shown in Table 8.2.

Table 8.2. Selected Interpol operations involving pharmaceutical products, 2018

Operation	Number of units seized	Estimated value (USD)	Suspects identified
Rainfall	295 000	122 400	15
Qanoon	1.4 million	1.5 million	39
Heera	95 800	3.8 million	41

Source: https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

World Customs Organization

The WCO manages an IPR, Health and Safety Programme that focuses on capacity building, co-ordinating efforts of its members and related international organisations, working with the private sector and developing enforcement tools.[6] The capacity building includes accreditation of experts, organising regional and national seminars for customs officers and conducting diagnostic missions that include the review of national legislation, analysis of country-specific risks, engagement of rights holders and national competent authorities. Co-ordinating efforts by all stakeholders through simultaneous enhanced border controls focuses on improving information sharing in real time among different countries, providing customs officers with tools and instruments for more efficient risk analysis and targeting, enhancing co-operation with the rights holders and learning more about the phenomenon of counterfeiting flows and concealment methods. Partnership with the private sector focuses on developing real-time access to the commercial data and strategic information needed to detect counterfeit goods.

In its 2018 report on the situation in illicit trade, the WCO notes that the high volumes and increasingly sophisticated nature of trade in counterfeit goods were serious concerns, and that organised criminal groups were heavily involved in disseminating and selling such products (WCO, 2018). It notes further that the WCO prioritises combating IPR infringements by capturing the attention of customs officers and industries worldwide and ensuring sufficient vigilance in efforts to combat the counterfeiting. The report distinguishes medical products from “IPR products”, which are defined to include clothing and accessories, cosmetics and electronic appliances. Medical products are defined more broadly to include counterfeit, genuine products that lack either the appropriate authorization or licences, and products that are undeclared.

Trends

While seizures of IPR products have declined, seizures of medical products have surged by 167%, rising from 2 862 in 2016, to 7 629 in 2017. Seizures of metabolic agents (e.g., steroids, and antidiabetic products) and urogenital agents (e.g., erectile and kidney dysfunction medicine) top the list. Most of the seizures occurred by intercepting products sent via the post, which accounted for 72% of the total of all seizures (WCO, 2018). Seizures from vessels, however, accounted for the largest number of items seized, accounting for close to 75% of the 270.9 million items seized.

An examination of trafficking flows reveals that North America and Western Europe were the top destinations for fake medical products in 2017, receiving 50% and 26% respectively of the total cases with known trafficking information (WCO, 2018). According to the available data, 74% of all cases originated in the Asia-Pacific region, followed by Western Europe (13%). Unlike the Asia-Pacific region, however, the predominant recipient of Western European cases was Western Europe itself.

Operations

WCO’s operations primarily entail applying risk analysis techniques and targeting across regions. A significant number of suspect containers are targeted during the pre-operational phase and are subsequently inspected during the operational phase (WCO, 2018). In June 2017, the WCO carried out Operation ACIM 2 (Action against Counterfeit & Illicit Medicines), in co-operation with the International Institute of Research against Counterfeit Medicines (IRACM). The operation mobilised the resources of 18 customs administrations in Africa that conducted simultaneous inspections of consignments potentially containing certain types of counterfeit and/or illicit pharmaceutical products. The operation took place in 18 ports over an eight-day period and was intended to provide a deeper insight into the flow of pharmaceutical goods entering the African mainland. Accredited experts in IPR offered training in new and practical targeting techniques to enhance interdiction capabilities. During the operational phase, authorities intercepted some 258.9 million units of fake medicines across 840 cases.

WCO also co-ordinated two operations a number of years ago, targeting counterfeits shipped through the post and courier services (OECD/EUIPO, 2018b). Operation Global Hoax, which took place in 2010, resulted in the seizure of tens of thousands of counterfeit products, including pharmaceuticals, at international mail facilities and express courier depots. Operation Global Hoax II, which took place from November 2011 to January 2012, also focused on postal and courier channels. More than 30 000 parcels were detained and over 150 000 counterfeit items seized, including pharmaceuticals.

World Health Organization

In 2012 the World Health Assembly established a mechanism to provide oversight, strong commitment and political will from member states and the WHO to tackle issues concerning substandard, spurious, falsely-labelled, falsified or counterfeit medical products (WHO, 2017b). The mechanism brings together WHO member states in a voluntary, self-governing body. It was formed to increase member state collaboration on the prevention and control of the areas covered. Efforts were initially hampered by discussions over whether protection of public health should include consideration of intellectual property rights. This was resolved in 2017 when it was decided that the threat to lives and well-being posed by substandard and falsified medical products could be dealt with most effectively by focusing exclusively on issues of public health concern, and that consideration of IPR was outside the scope. The overall aim of the initiative is to establish an environment that is effective in preventing, detecting and responding to the threats posed by substandard and falsified products. In support of this, technical work carried out under the mechanism aims at:

- identifying factors that drive the emergence of substandard and falsified medical products
- developing recommendations for health authorities to detect and deal with substandard and falsified medical products
- developing a national action plan to prevent, detect and respond to substandard and falsified medical products
- creating a global regulatory focal point network
- implementing track and trace systems
- understanding authentication technologies
- reaching a global common understanding on the definitions of substandard, unregistered/unlicensed and falsified medical products.

This has translated into a programme that focuses on:

- training and supporting a network of nationally designated focal points within national and regional regulatory agencies who act as a channel of communication between national and global authorities around medicine quality
- developing tools and systems that countries can adapt to make reporting of suspected products easier and more efficient
- supporting countries in appropriate public-health focused investigation and response to incidents involving substandard and falsified medical products
- developing and maintaining a global database of reports relating to the discovery of substandard or falsified medicines, for use by regulatory agencies globally
- analysing global data to provide evidence-based recommendations for appropriate decision-making and effective action.

The system includes a Rapid Alerts mechanism, which provides details of confirmed cases that might pose a public-health risk to another country. The alerts are intended to help guide post-market surveillance, and sometimes lead to the detection of more falsified products.

A blueprint for responding effectively to the challenges posed by substandard and falsified medicines, while not aimed at IP issues, is nevertheless relevant to those issues as one can presume that a large share of counterfeit products are also falsified (Table 8.3). The Guidance was developed at the WHO, for use in developing national responses.

Table 8.3. Actions to implement the WHO's "prevent, detect and respond" approach in tackling substandard and falsified medicines

Prevent	
Education and awareness	There are focused education, media and awareness programmes, for non-health professionals, the general public and civil society groups on substandard and falsified medical products.
	The issue of substandard and falsified medical products is integrated as part of the core medical, pharmacy and regulatory curriculum.
Comprehensive legal framework	There are legal provisions in place enabling the national medicines regulatory authority (NMRA) to seize, quarantine, sample, analyse, recall and destroy substandard and falsified medical products.
	There are legal provisions in place for the inspection, investigation, enforcement and proportionate sanctioning of those engaged in the manufacture, distribution, storage, supply and sale of substandard and falsified medical products.
	There is a documented strategy and guidelines in place and implemented relating to the prevention, detection and response to substandard and falsified medical products.
Multi-stakeholder engagement	There is clear and regular communication with civil society groups, health care professional organizations, the pharmaceutical industry and actors within the supply chain, specifically focusing on substandard and falsified medical products.
	There are documented and implemented procedures for regular engagement with the relevant government departments and agencies, including national pharmacovigilance centres, national poison centres and national quality control laboratories
Supply chain integrity	A track and trace system with an authentication process has been implemented for medical products.
	The supply chain has been mapped from point of manufacture or importation through to public outlets, pinch points identified and staff trained to identify, report and respond to suspected substandard and falsified medical products.
Detection	
Border control	There are designated ports for the importation and export of medical products, and a regulatory presence at those ports.
	There are documented and implemented procedures for allowing the exchange of information concerning suspected substandard and falsified medical products between customs, police and the regulatory agency.
Reporting systems	Effective public reporting systems exist, enabling the reporting of suspected substandard and falsified medical products and adverse drug reactions to the NMRA.
Risk-based inspection and surveillance	A risk-based strategy is documented and implemented for conducting regular targeted and random market surveillance for substandard and falsified medical products within the regulated and unregulated supply chains.
	There is a documented and implemented risk-based inspection programme for those entities engaged in the manufacture (including relabelling/repackaging), importation, distribution/wholesale and supply/sale of medical products.
Access to laboratories and screening technologies	There is access to an externally accredited national quality control laboratory and documented procedures are in place and implemented regarding the analysis and reporting of substandard and falsified medical products.
	There is access to field screening equipment (and relevant reference material), which staff have been trained to use, and procedures are documented and implemented for the use of such equipment.
Response	
Alerts and recalls	A documented and implemented procedure exists concerning the issuing, receipt and response to Rapid Alerts concerning substandard and falsified medical products.
	A designated and trained focal point(s) within the NMRA has been established to receive and respond to reports of suspected substandard and falsified medical products and has access to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products.
Regulatory strengthening	Regulatory personnel are designated and trained in the response to substandard and falsified medical products and documented procedures have been established and implemented.
	The prevention, detection and response to substandard and falsified medical products has been embedded in core regulatory responsibilities across departments and government agencies and is

	included in regulatory assessment indicators.
Transparent legal process	The use of regulatory or criminal law sanctions is justified and applied in a consistent and proportionate way. The application and use of sanctions is published by the national or regional regulatory authority.
Evidence-based policy and procedures	Each incident involving substandard and falsified medical products has been reviewed with a view to identifying weaknesses in the system, vulnerabilities in the supply chain and making appropriate changes to improve the safety of patients.
	There is clear use of data from a wide range of sources in developing evidence-based policy and procedures to prevent, detect and respond to substandard and falsified medical products.

Source: WHO (2017b). *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products*, www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1.

Legislative measures

A number of international instruments have been developed to support efforts to combat counterfeit and substandard pharmaceutical products, including the MEDICRIME Convention and the EU's Falsified Medicines Directive. Similar efforts have also been pursued at the national level, and by industry groups.

MEDICIRIME Convention

The Council of Europe has developed the MEDICRIME Convention, which provides countries with a model legal framework for dealing with falsified medicines and other types of pharmaceutical crime that threaten public health (WHO, 2017b). The aim is, in part, to provide a framework that will allow for more international co-ordination in the investigation of suspect falsified medicines, and in the prosecution of criminals. Under the convention, which entered into force in January 2016, intentionally manufacturing, supplying, offering to supply and trafficking of falsified medicines is considered a criminal act. This treaty calls for multilateral collaboration across nations, disciplines and sectors, and lays the ground for co-operation with and between international bodies such as INTERPOL, Europol, UNODC, the WCO and WHO, in order to put a stop to this international threat to public health.[7] The convention has been ratified by 15 countries.[8]

Supply Chain Security

In the European Union, the Falsified Medicines Directive (FMD) is legislation passed by the Council of European Union and European Parliament in 2011. It aims at increasing the security of the manufacturing and delivery of medicines across Europe and to protect patients and prevent falsified medicines from entering the supply chain.[9] The Directive 2011/62/EU came into force in January 2013; delegated regulation of the directive was implemented in February 2019. The directive requires:[10]

- a unique identifier and an anti-tampering device on the outer packaging of medicines
- a common, EU-wide logo to identify legal online pharmacies
- tougher rules on the import of active pharmaceutical ingredients
- stronger record-keeping requirements for wholesale distributors.

Pharmacies, and others who are authorised to supply medicines to the public, will be required to authenticate products, which means visually checking the anti-tamper device and performing a verification and decommissioning scan, "at the time of supplying it to the public".[11]

With respect to Internet sales, the FMD obliges Member States to make non-prescription products available "at a distance" via the Internet (EAASM, 2018). Prescription products are not subject to the same requirement but may be made available in accordance with Member State legislation. Internet retailers are obliged to display a logo (mentioned above), often referred to as the Common Logo, in order to market products online. Government agencies overseeing the market are responsible for the registration process of those entities wanting to sell medicines over the Internet, and also inspections to ensure that such pharmacists or retailers are operating legally and displaying the logo in accordance with the directive. The logo is encrypted to enable a visitor to the site to click on the logo which then routes through to a list of

registered sellers (normally pharmacies). The visitor is therefore able to check the validity of the website. Under the directive, Member States, in co-operation with the EU Commission, are further obliged to conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products.

In the United States, the Drug Supply Chain Security Act, passed in 2013, outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs that are distributed in the United States.[12] The aim is to enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system is also aimed at improving detection and removal of potentially dangerous drugs from the drug supply chain. The act outlines requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners). The requirements, development of standards, and the system for product tracing are to be phased in by November 2023.[13] By that time, manufacturers will be required to encode their products with a unique identifier at the product unit level, and provide for electronic track and trace of units.[14] The aim is to have complete unit traceability throughout the supply chain by 2023.[15]

In Turkey the pharmaceutical track and trace system (ITS) has been used by the Ministry of Health since January 2010. Every transaction of pharmaceuticals is registered in the ITS, which ensures traceability of medicines from manufacturing to the final user.

Online pharmacy authentication

The Royal Pharmaceutical Society of Great Britain (RPSGB) has created an Internet pharmacy logo which is displayed on the front page of participating online pharmacy sites; individuals are linked to a page on the RPSGB website where they can make checks to assess authenticity of what claims to be a *bona fide* registered online pharmacy (EAASM, 2008). The Verified Internet Pharmacy Practice Sites (VIPPS) seal of approval is an international system, operating in parts of the United States, Canada, South Africa and Australia, which aims to protect online consumers in a similar way to the RPSGB initiative. The VIPPS logo links consumers to the National Association of Boards of Pharmacy (NAPB) VIPPS site, where information is stored which helps identify genuine online pharmacies from rogue traders. PharmacyChecker is a free-to-consumer online service which produces reports on the credentials, prices and customer feedback of online pharmacies, focusing mainly on the United States and Canada. It is designed to help users identify reputable and trustworthy businesses. The site publishes a list containing the web addresses and business names of what it considers to be disreputable, dishonest and/or illegal online medicine trade sites.

A similar initiative was developed in the EU, where the common logo was introduced for legally operating online pharmacies and retailers in EU countries as one of the measures to fight against falsified medicines. The common logo was first introduced by Falsified Medicines Directive.[16] It consists of a national flag in the middle left side of the logo which corresponds to the EU country where the pharmacy or retailer is registered or authorised, and it leads to the website of the national competent authority listing all legally operating online pharmacies and retailers in this country.

As a complementary measure, the National Association of Boards of Pharmacy (a non-profit organisation comprised of state pharmacy regulators in the US, Canada, and the Bahamas) has acquired the top level domain name .pharmacy from ICANN (Internet Corporation for Assigned Names and Numbers).[17] The .Pharmacy Verified Websites Program is an international system that verifies websites operating or doing business in the United States, Canada, South Africa, Spain, the United Kingdom, Australia, Ireland, and other countries, which aims to protect online consumers in a similar way to the RPSGB initiative. Pharmacies wanting to offer the protection and gain the credibility of using a verified top-level domain name .pharmacy have to pass stringent regulatory criteria. Thus if a visitor searches on the web and finds a .pharmacy website, they can be assured it is genuine and that it is selling medicines in accordance with the in-country laws.

Notes

[1] See www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations.

[2] See www.interpol.int/en/News-and-Events/News/2018/Illicit-online-pharmaceuticals-500-tonnes-seized-in-global-operation.

[3] See www.europol.europa.eu/newsroom/news/millions-of-medicines-seized-in-largest-operation-against-illicit-online-pharmacies.

[4] See www.interpol.int/en/News-and-Events/News/2018/Illicit-online-pharmaceuticals-500-tonnes-seized-in-global-operation.

[5] See www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations.

[6] See www.wcoomd.org/en/topics/enforcement-and-compliance/activities-and-programmes/ipr.aspx.

[7] See https://rm.coe.int/medicrime-convention-questionsanswers-en-2019/1680925cc2.

[8] See www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures?p_auth=Ur9r4Oos.

[9] See www.abpi.org.uk/what-we-do/working-with-government-and-parliament/falsified-medicines-directive-fmd/.

[10] See https://ec.europa.eu/health/human-use/falsified_medicines_en.

[11] See www.abpi.org.uk/what-we-do/working-with-government-and-parliament/falsified-medicines-directive-fmd/.

[12] See www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

[13] See www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/are-you-ready-drug-supply-chain-security-act.

[14] See www.pharmacytimes.com/publications/issue/2017/november2017/what-are-the-drug-supply-chain-security-acts-key-provisions.

[15] See https://adents.com/usa-dscsa-serialization-requirements-deadlines.

[16] See Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011.

[17] See https://nabp.pharmacy/programs/dotpharmacy/.

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EAASM (2018), *Falsified Medicines and the Common Logo – Raising Public Awareness*, European Alliance for Access to Safe Medicines, Leigh-on-Sea, http://fightthefakes.org/wp-content/uploads/2018/02/Fighting-Facts-By-Member-States-WEB.pdf.

OECD/EUIPO (2018b), *Misuse of Small Parcels for Trade in Counterfeit Goods: Facts and Trends*, OECD Publishing, Paris, https://doi.org/10.1787/9789264307858-en.

WCO (2018), *Illicit Trade Report 2017*, World Customs Organization, Brussels, www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr_2017_en.pdf?db=web

9 Concluding remarks

This study has compiled and analysed a unique international set of customs seizure data and other enforcement data, combined with structured interviews with industry, trade and customs experts, to quantitatively assess the value, scope and trends of the trade in counterfeit pharmaceutical products. It finds that world trade in counterfeit pharmaceuticals accounted for as much as USD 4.4 billion in 2016, which represents 0.84% of world trade in pharmaceuticals. Furthermore, the range of affected medicines is growing.

Counterfeiters target a wide and growing range of pharmaceuticals including antibiotic, lifestyle treatments, cancer treatments, pain killers and anti-malaria drugs. Counterfeiters also target diabetes treatments, and central nervous systems medicines.

India and China are the largest identified producers of counterfeit pharmaceuticals. The products are shipped worldwide, with a special focus on African economies, Europe and the United States. In addition, Singapore and Hong Kong (China) are among the most important transit points for counterfeit products, mainly exporting them in small parcels to the United States, Europe, Japan and some South American economies. Other relevant transit points for fake pharmaceuticals include Yemen, the United Arab Emirates and Iran. From these countries, fake pharmaceuticals are reshipped either to African economies such as Egypt or to Ethiopia by air and sea, or to Europe and the United States, by mail. As law enforcement and regulatory pressure has increased within China, key aspects of production may be moving elsewhere, to selected other South-East Asian economies.

Express courier and postal parcels – driven by the rising popularity of e-commerce – are the most popular ways of shipping counterfeit medicines, significantly complicating the screening and detection processes and lowering the risk of detection and penalties.

Companies registered in the United States are hit the hardest by this trade in counterfeits, but those in other OECD countries are also strongly affected (notably Switzerland, Germany and France). Almost 38% of all seized counterfeit medicines infringe the intellectual property (IP) rights of firms registered in the United States.

Counterfeit medicines have a wide range of negative consequences. Legitimate producers lose sales to counterfeiters, while governments lose taxes and face long term issues related to managing health care in countries. Importantly, there are of course effects on the individuals who are very often unaware of the issue, and who fall victim to low quality counterfeit products that do not treat their medical needs, and which can adversely affect their health.

Producers and governments have been active in combatting counterfeiting as it threatens their considerable investment in developing new products, while introducing uncertainty about the effectiveness and value of their products. Producers, for example, have been developing techniques to improve the tracking and tracing of their products, to make it more difficult for counterfeiters to penetrate markets, and they have worked closely with governments to support efforts to disrupt illicit trade in their products.

Next steps

This quantitative assessment of trade in counterfeit medicines provides a foundation on which to formulate policy responses. It also feeds into existing discussions on policies and governance frameworks to counter illicit trade. Issues identified include the lack of deterrent penalties, the emergence and role of e-commerce, and frameworks and factors related to misuse of small parcels in trade in counterfeit medicines.

The unique dataset of trade in counterfeit medicines developed for this study could also be used in a set of follow-up exercises, such as a more detailed mapping of the trade routes of fake drugs, and the analysis of the impact on governments, industry and consumers. This would provide additional information on the actual harm caused by counterfeiting and could guide the development and strengthening of risk-based enforcement practice.

Annex A. Data and methodology

The data

The main producing economies of fake pharmaceuticals and the key transit points are determined using statistical "filters" (see below). This is done based on three sources of information:

- data on seizures of counterfeit pharmaceuticals.
- international trade statistics on the pharmaceutical sector, and
- industrial activity data for the pharmaceutical sector.

An important data limitation should be highlighted in this context. While the quality of data on customs seizures of infringing pharmaceutical products received from member countries of the EU and from the US is very high, the data from South American, African, Middle Eastern and Asian customs authorities are of insufficient quality. Hence the mapping exercise for the EU and the US as destinations is relatively precise, but a precise charting of trade routes and the modes of transport for the other regions is not possible. For transparency purposes, all data gaps were highlighted throughout the analysis.

In addition, the datasets identify a set of EU member countries as provenances. However, these identifications are based on data from the European Commission's Directorate-General for Taxation and Customs Union (DG TAXUD), and refer to goods coming from outside the EU that were seized in a different member state to the country where it entered the EU. This is because DG TAXUD data refer only to imports to the EU from third countries, and do not include internal EU trade.

Data on seizures of counterfeit goods

The database on customs seizures is the critical quantitative input to this study. It was constructed from three separate datasets received from the WCO, from DG TAXUD of the European Commission, and from the US Department of Homeland Security. The database includes detailed information on seizures of IPR-infringing goods made by customs officers in 99 economies around the world between 2014 and 2016. For each year, there are more than 100 000 observations in the database; in most cases one observation corresponds to one customs seizure.

The database contains a wealth of information about IPR-infringing goods 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, general statistical category of seized goods as well as their detailed description, name of legitimate brand owner, number of seized products and their approximate value.

Concerning valuation of seized goods, there are two principles 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 (2016) revealed that the declared values are reported in most cases.

International trade statistics

The trade statistics are based on the United Nations (UN) Comtrade database (landed customs value). With 171 reporting economies and 247 partner economies (76 economies in addition to reporting economies), the database covers the largest part of world trade and is considered the most comprehensive trade database available. Products are registered on a six-digit Harmonized System (HS) basis (see WCO, 2019), and can then be aggregated.

This study uses two different types of trade statistics provided by the UN Comtrade database. First, the calculations of the General Trade Related Indices (GTRIC) are based on import data. Second, the identification of potential transit points is based on re-export data. Re-exports are exports of foreign goods in the same state as previously imported, i.e., that have not acquired domestic origin through processing.

In most economies, import statistics are compiled from the records filed with local customs authorities. This is particularly important in the context of this report as data on customs seizures of infringing products originate from the same source – customs offices at the destination. This reinforces the choice for import statistics as the reference point for the calculation of the GTRIC indices, as both imports data and seizure data refer to the same observed incoming trade flows.

Industrial activity data

The identification of potential producer points of fake pharmaceutical goods and medicines is based on data on industrial activity provided by the UNIDO Industrial Statistics Database (UNIDO, 2019). This study takes advantage of the cross-country comparability of the data on industrial output and value-added included in the UNIDO's Industrial Statistics Activity database (UNIDO, 2019) to distinguish a producing economy from a potential transit point for the pharmaceutical sector. The database contains seven principal indicators of industrial statistics (number of establishments, number of employees, wages and salaries, output, value added, gross fixed capital formation, and number of female employees) at the 4-digit level of the International Standard Industrial Classification of All Economic Activities (ISIC).

The main producing economies and key transit points for counterfeit pharmaceuticals were identified following several steps:

1. Economies were ranked according to their propensity to be an economy of provenance for counterfeit pharmaceuticals. The resulting index is called GTRIC-e. These indices are calculated in Chapter 4, and economies more likely to export counterfeit pharmaceuticals are presented in Table 4.1.
2. An indicator of the relative comparative advantage for producing pharmaceuticals was calculated for each economy (RCAP-e) based on UNIDO (2019) data. This is the first "filter" to be used in the analysis. The methodology is described in the next subsection of this annex.
3. For each economy an indicator of the relative comparative advantage for being a transit point in global trade in pharmaceuticals was calculated (RCAT-e) based on re-export data (UN Trade Statistics Division, 2019). This is the second "filter" to be used in the analysis. The methodology is described in the next subsection of this annex.
4. Both filters (RCAP-e and RCAT-e indicators) were applied for every economy with a high GTRIC-e score. This indicates whether the given economy is a producing one, or a potential transit point for fake pharmaceuticals.
5. Some additional descriptive statistical analysis checked the modes of transport and the size of shipments on the selected trade routes.

It should be highlighted that the framework presented below relies on a set of methodological assumptions. For transparency purposes all are spelt out in the text.

Construction of GTRIC-e for pharmaceuticals

The first step was to rank all the known provenance economies by their relative intensity of exporting fake pharmaceuticals. This distinguished the key provenances in trade with fake pharmaceuticals. Each of these key points then was investigated further to determine its exact role in trade in fake pharmaceutical products and medicines.

The most intense provenance economies were identified using an index that ranked them according to their relative propensity to be an economy of provenance for counterfeit pharmaceuticals (GTRIC-e). The index is based on the data on global customs seizures and data on imports (OECD/EUIPO, 2019). It takes into account: 1) the absolute value of exports of fake pharmaceuticals from a given economy (in USD); and 2) the share of fakes in total exports of fake pharmaceuticals from a given economy.

The construction of GTRIC-e directly relied on the methodology introduced in the OECD/EUIPO (2019) study. A detailed description of the methodology used to calculate the GTRIC-e is provided below.

Importantly, two assumptions are made to calculate the GTRIC vectors. The first is that the volume of seizures of a given product or from a given source economy is positively correlated with the actual intensity of trade in counterfeit goods in that product category or from that economy. The second assumption acknowledges that this relationship is not linear, as there might be some biases in the detection and seizure procedures. For instance, the fact that infringing goods are detected more frequently in certain categories could imply that differences in counterfeiting factors across products merely reflect that some goods are easier to detect than others, or that some goods, for one reason or another, have been specially targeted for inspection.

GTRIC-e was constructed in four steps:

1. For each reporting economy, the seizure percentages for provenance economies were calculated.
2. For each provenance economy, aggregate seizure percentages were formed, taking the reporting economies' share of sensitive imports as weights.
3. From these, each economy's counterfeit source factor was established, based on the provenance economies' weight in terms of global trade.
4. Based on these factors, the GTRIC-e was formed.

Step 1: Measuring reporter-specific seizure intensities from each provenance economy

v_{epi} is economy *i*'s registered seizures of all types of infringing goods included in a given product category *p* that originate from economy *e* at a given year in terms of value.

γ_{epi} is economy *i*'s relative seizure intensity (seizure percentage) of all infringing items within the product category that originate from economy *e*, in a given year:

$$\gamma_{epi} = \frac{v_{epi}}{\sum_e v_{epi}}, \text{ such that } \sum_e \gamma_{epi} = 1 \ \ \forall i$$

Step 2: Measuring general seizure intensities of each provenance economy

The general seizure intensity for economy *e* within the product category *p*, denoted Γ_{ep}, is then determined by averaging seizure intensities, γ_{epi}, weighted by the reporting economy's share of world imports from known counterfeit and pirate origins.[1] Hence:

$$\Gamma_{ep} = \sum_i \varpi_{pi} \gamma_{epi}$$

where the weight of reporting economy *i* is given by

$$\varpi_{pi} = \frac{m_{epi}}{\sum_i m_{epi}}$$

with m_{epi} is economy *i*'s imports of goods in a given product category *p* from economy *e* at a given year in terms of value, so that $\sum_i \varpi_{pi} = 1 \ \forall p$

Step 3: Measuring partner-specific counterfeiting factors

$m_{ep} = \sum_i m_{epi}$ is defined as the total registered world imports of all sensitive goods in the product category *p* from provenance economy *e*.

$m_p = \sum_e m_{ep}$ is defined as the total registered world imports of all sensitive goods in the product category *p* from all provenance economies.

The share of provenance economy *e* in world imports of all sensitive goods in the product category *p*, denoted s_{ep}, is then given by:

$$s_{ep} = \frac{m_{ep}}{m_p}, \text{ such that } \sum_e s_{ep} = 1, \ \forall p$$

From this, the economy-specific counterfeiting factor is established by dividing the general seizure intensity for economy *e* with the share of world imports from *e* within the product category *p*:

Step 4: Establishing GTRIC-e

Gauging the magnitude of counterfeiting and piracy from a provenance economy perspective can be done in a similar fashion as for sensitive goods. Hence, a general trade-related index of counterfeiting for economies (GTRIC-e) is established along similar lines and assumptions:

- The first assumption (A3) is that the intensity by which any counterfeit or pirated article from a particular economy is detected and seized by customs is positively correlated with the actual amount of counterfeit and pirate articles imported from that location.
- The second assumption (A4) acknowledges that assumption A3 may not be entirely correct. For instance, a high seizure intensity of counterfeit or pirated articles from a particular provenance economy could be an indication that the provenance economy is part of a customs profiling scheme, or that it is specially targeted for investigation by customs. The importance that provenance economies with low seizure intensities play regarding actual counterfeiting and piracy activity could therefore be under-represented by the index and lead to an underestimation of the scale of counterfeiting and piracy.

As with the product-specific index, GTRIC-e is established by applying a positive monotonic transformation of the counterfeiting factor index for provenance economies using natural logarithms. This follows from assumption A3 (positive correlation between seizure intensities and actual infringement activities) and assumption A4 (lower intensities tend to underestimate actual activities). Considering the

possibilities of outliers at both ends of the GTRIC-e distribution – i.e. some economies may be wrongly measured as being particularly susceptible sources of counterfeit and pirated imports, and vice versa – GTRIC-e is approximated by a left-truncated normal distribution as it does not take values below zero.

The transformed general counterfeiting factor across provenance economies on which GTRIC-e is based is therefore given by applying logarithms onto economy-specific general counterfeit factors (see, for example, Verbeek, 2000):

$$cf_{ep} = \ln(CF_{ep} + 1)$$

In addition, it is assumed that GTRIC-e follows a truncated normal distribution with $cf_{ep} \geq 0$. Following Hald (1952), the density function of the left-truncated normal distribution for cf_{ep} is given by

$$g_{LTN}(cf_{ep}) = \begin{cases} 0 & if\ cf_{ep} \leq 0 \\ \dfrac{g(cf_{ep})}{\int_0^{\infty} g(cf_{ep})\partial cf_{ep}} & if\ cf_{ep} \geq 0 \end{cases}$$

Where $g(cf_{ep})$ is the non-truncated normal distribution for cf_{ep} specified as:

$$g(cf_{ep}) = \frac{1}{\sqrt{2\pi\sigma_{cf}^2}} \exp\left(-\frac{1}{2}\left(\frac{cf_{ep} - \mu_{cf}}{\sigma_{cf}} \right)^2 \right)$$

The mean and variance of the normal distribution, here denoted μ_{cf} and σ_{cf}^2, are estimated over the transformed counterfeiting factor index, cf_{ep}, and given by $\widehat{\mu}_{cf}$ and $\widehat{\sigma}_{cf}^2$.

This enables the calculation of the counterfeit import propensity index within each product category *p* (GTRIC-e) across provenance economies, corresponding to the cumulative distribution function of cf_{ep}.

Methodology to identify producers from transit points of counterfeit pharmaceuticals

Construction of RCAP-e and RCAT-e

Relative comparative advantage for production of a given good (RCAP-e)

The first statistical filter that can be used to tell producers from transit points looks at the production capacities of a given economy in the pharmaceutical sector. The rationale behind this test is simple: production activity often relies on certain skills, or resources. It also exhibits certain returns to scale properties that results in specialisation of this particular economy in the production of pharmaceuticals. Hence, production of counterfeit medicines and pharmaceutical goods is more likely to occur in a known provenance economy that specialises in the legitimate production of pharmaceuticals, than in a country without production capacity in the pharmaceutical sector.

This specialisation of a given trading economy in production of pharmaceuticals is captured by an indicator of the relative comparative advantage for production (RCAP-e). The indicator looks at the share of industrial activity in the pharmaceutical sector with the total industrial activity in a given economy.

Construction of this indicator is based on industry statistics. Importantly, these statistics are based on a different taxonomy than the trade statistics, hence a matching exercise was performed (see Box 5). A detailed description of the methodology used to calculate the RCAP-e is provided below.

Formally, the revealed comparative advantage in production for an economy *e* in the pharmaceutical sector (RCAP) measures whether this economy produces more pharmaceuticals as a share of its total production than the "average" country:

$$RCAP_{ep} = \frac{y_{ep} \Big/ \sum_p y_{ep}}{\sum_e y_{ep} \Big/ \sum_e \sum_p y_{ep}}$$

where y_{ep} is the output of product p by economy e in a given year.

Relative comparative advantage for being a transit point (RCAT-e)

The relative comparative advantage for being a transit point in global trade (RCAT-e) is the second filter used to determine the actual role of a provenance economy. This indicator represents the degree to which a given economy specialises in re-exporting pharmaceuticals, e.g. through development of advanced logistical infrastructure, or by its convenient geographical location. Consequently, it is assumed that such factors that facilitate transiting of genuine pharmaceutical products and medicines will also facilitate transit of fake pharmaceuticals.

The RCAT-e indicator is calculated by comparing relative volumes of re-export of pharmaceuticals to the shares calculated for other exporting economies. This is done based on re-export data that come from the UN Comtrade database (UN Trade Statistics Division, 2019).

Formally, the revealed comparative advantage in transit for an economy *e* within the pharmaceutical sector (RCAP-e) measures whether this economy re-exports pharmaceuticals as a share of its total manufacturing re-exports than the "average" country:

$$RCAT_{ep} = \frac{x_{ep} \Big/ \sum_p x_{ep}}{\sum_e x_{ep} \Big/ \sum_e \sum_p x_{ep}}$$

where x_{ep} is re-exports of product p by economy e in a given year.

Application of both filters

A complete list of RCAP-e and RCAT-e indices by economy can be found in Annex B.

Once the statistical filters (RCAP-e and RCAT-e indicators) are constructed, they are applied to distinguish the producing economies from the key potential transit points. Both filters are applied for every economy on the top provenance list for counterfeit pharmaceuticals, i.e. economies with a high GTRIC-e score (see Table 4.1 and Table 4.2).

The rationale for using the filters is as follows: if an economy is *not* a significant producer of fake pharmaceuticals (i.e. its RCAP is low) and/or is a large re-exporter of this good in legitimate trade of pharmaceuticals (i.e its RCAT is high), then it is likely to be a transit point.

On the other hand, if this top listed provenance economy of counterfeit pharmaceutical products and medicines is a significant producer (i.e. has a high RCAP score) or is a small re-exporter (i.e. has a low RCAT score), it is likely to be a producer of fake pharmaceuticals.

This exercise results in a list of producers and a list of transit points. Together with the information on the place of seizure, this will allow the development of maps of trade in fake pharmaceuticals, showing key producers, main transit point and main destination points.

Notes

[1] This is different to the economy's share of total imports of sensitive goods used to calculate GTRIC-p.

References

OECD/EUIPO (2016), *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264252653-en.

Annex B. Additional Tables

Table B.1. Description of the HS 30 product category, pharmaceutical products

3001 Glands and other organs (extracts, secretions thereof) for organo-therapeutic uses, dried, powdered or not; heparin and its salts; other human or animal substances for therapeutic or prophylactic uses n.e.c.	300120 Glands and other organs; extracts of glands or other organs or of their secretions, for organo-therapeutic uses
	300190 Glands and other organs; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, n.e.c. in heading 3001
3002 Human blood; animal blood for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, immunological products, modified or obtained by biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) etc	300211 Blood, human or animal, antisera, other blood fractions and immunological products; malaria diagnostic test kits
	300212 Blood, human or animal, antisera, other blood fractions and immunological products; antisera and other blood fractions
	300213 Blood, human or animal, antisera, other blood fractions and immunological products; immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale
	300214 Blood, human or animal, antisera, other blood fractions and immunological products; immunological products, mixed, put up in measured doses or in forms or packings for retail sale
	300215 Blood, human or animal, antisera, other blood fractions and immunological products; immunological products, put up in measured doses or in forms or packings for retail sale
	300219 Blood, human or animal, antisera, other blood fractions and immunological products; n.e.c. in heading 3002.1
	300220 Vaccines; for human medicine
	300230 Vaccines; for veterinary medicine
	300290 Toxins, cultures of micro-organisms (excluding yeasts) and similar products
3003 Medicaments; (not goods of heading no. 3002, 3005 or 3006) of two or more constituents mixed together for therapeutic or prophylactic use not in measured doses or in forms or packings for retail sale	300310 Medicaments; containing penicillins, streptomycins or their derivatives, for therapeutic or prophylactic uses, (not in measured doses, not packaged for retail sale)
	300320 Medicaments; containing antibiotics other than penicillins, streptomycins and their derivatives, for therapeutic or prophylactic uses, (not in measured doses, not packaged for retail sale)
	300331 Medicaments; containing insulin, for therapeutic or prophylactic uses, not packaged for retail sale
	300339 Medicaments; containing hormones (excluding insulin), (but not containing antibiotics), for therapeutic or prophylactic uses, not packaged for retail sale
	300341 Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts, for therapeutic or prophylactic uses, (not packaged for retail sale)

Table B.1. Description of the HS 30 product category, pharmaceutical products

3003 Medicaments; (not goods of heading no. 3002, 3005 or 3006) of two or more constituents mixed together for therapeutic or prophylactic use not in measured doses or in forms or packings for retail sale	300342 Medicaments; containing alkaloids or their derivatives, containing pseudoephedrine (INN) or its salts, for therapeutic or prophylactic uses, (not packaged for retail sale)
	300343 Medicaments; containing alkaloids or their derivatives, containing norephedrine or its salts, for therapeutic or prophylactic uses, (not packaged for retail sale)
	300349 Medicaments; containing alkaloids or their derivatives; other than ephedrine, pseudoephedrine (INN) or norephedrine or their salts; for therapeutic or prophylactic uses, (not packaged for retail sale)
	300360 Medicaments; containing antimalarial active principles described in subheading note 2 to this chapter, for therapeutic or prophylactic uses, (not packaged for retail sale)
	300390 Medicaments; (not containing antibiotics, hormones, alkaloids or their derivatives), for therapeutic or prophylactic uses, (not packaged for retail sale)
3004 Medicaments; (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale	300410 Medicaments; containing penicillins, streptomycins or their derivatives, for therapeutic or prophylactic uses, packaged for retail sale
	300420 Medicaments; containing antibiotics (other than penicillins, streptomycins or their derivatives), for therapeutic or prophylactic uses, packaged for retail sale
	300431 Medicaments; containing insulin, for therapeutic or prophylactic uses, packaged for retail sale
	300432 Medicaments; containing corticosteroid hormones, their derivatives or structural analogues (but not containing antibiotics), for therapeutic or prophylactic uses, packaged for retail sale
	300439 Medicaments; containing hormones (but not insulin), adrenal cortex hormones or antibiotics, for therapeutic or prophylactic uses, packaged for retail sale
	300441 Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts, for therapeutic or prophylactic uses, packaged for retail sale
	300442 Medicaments; containing alkaloids or their derivatives, containing pseudoephedrine (INN) or its salts, for therapeutic or prophylactic uses, packaged for retail sale
	300443 Medicaments; containing alkaloids or their derivatives, containing norephedrine or its salts, for therapeutic or prophylactic uses, packaged for retail sale
	300449 Medicaments; containing alkaloids or their derivatives; other than ephedrine, pseudoephedrine (INN) or norephedrine or their salts; for therapeutic or prophylactic uses, packaged for retail sale
	300450 Medicaments; containing vitamins or their derivatives, for therapeutic or prophylactic use, packaged for retail sale
	300460 Medicaments; containing antimalarial active principles described in Subheading Note 2 to this Chapter, for therapeutic or prophylactic uses, packaged for retail sale
	300490 Medicaments; consisting of mixed or unmixed products n.e.c. in heading no. 3004, for therapeutic or prophylactic uses, packaged for retail sale

Table B.1 Description of the HS 30 product category, pharmaceutical products

3006 Pharmaceutical goods	300610 Pharmaceutical goods; sterile surgical catgut, suture materials, tissue adhesives, laminaria, laminaria tents, absorbable surgical or dental haemostatics, and surgical or dental adhesion barriers
	300620 Pharmaceutical goods; blood-grouping reagents
	300630 Pharmaceutical goods; opacifying preparations for x-ray examinations, diagnostic reagents designed to be administered to the patient
	300640 Pharmaceutical goods; dental cements and other dental fillings, bone reconstruction cements
	300650 Pharmaceutical goods; first aid boxes and kits
	300660 Pharmaceutical goods; chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides
	300670 Pharmaceutical goods; Gel preparations designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments
	300691 Pharmaceutical goods; appliances identifiable for ostomy use
	300692 Pharmaceutical goods; waste pharmaceuticals

Source: WCO (2019)

Table B.2. RCAP indices for counterfeit pharmaceuticals, 2014-2016

Provenance economy	RCAP	Provenance economy	RCAP
Algeria	0.538	Japan	1.192
Armenia	0.324	Jordan	3.179
Australia	1.119	Kazakhstan	0.654
Austria	1.029	Kenya	0.495
Azerbaijan	0.015	Korea	0.466
Belarus	0.390	Kyrgyzstan	0.056
Belgium	2.862	Lithuania	0.372
Bosnia and Herzegovina	0.583	Malaysia	0.168
Brazil	0.825	Mexico	0.795
Canada	0.740	Moldova	0.648
Chile	1.157	Mongolia	0.712
China	1.103	Montenegro	0.684
Chinese Taipei*	0.268	Netherlands	0.668
Colombia	1.091	New Zealand	0.356
Costa Rica	0.636	Oman	0.050
Croatia	2.115	Panama	0.470
Cyprus*	3.455	Peru	0.505
Czech Republic	0.395	Philippines	0.603
Denmark	5.639	Poland	0.591
Ecuador	0.550	Portugal	0.582
Egypt	1.584	Qatar	0.011
Estonia	0.168	Romania	0.543
Finland	0.749	Saudi Arabia	0.227
Former Yugoslav Republic of Macedonia	1.205	Serbia	0.795
France	1.842	Singapore	2.524
Georgia	0.964	Slovak Republic	0.137
Germany	1.124	Slovenia	3.750
Greece	0.891	Spain	1.358
Hong Kong (China)	3.683	Sri Lanka	0.099
Hungary	1.434	Switzerland	10.338
India	1.641	Tanzania	0.267
Indonesia	0.361	Turkey	0.466
Iraq	0.025	Ukraine	0.757
Ireland	17.117	United Arab Emirates	0.444
Israel	3.155	United Kingdom	1.168
Italy	1.286	United States	1.551

Note: A high RCAP index indicates that the share of the pharmaceutical sector in the total output of the corresponding economy is higher than the average share of this economy in the global manufacturing output. *Note by Turkey:*
The information in this document with reference to "Cyprus" relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Turkey recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the "Cyprus issue".
Note by all the European Union Member States of the OECD and the European Union:
The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus.
Source: Authors' own calculation based on data from UNIDO (2019).

Table B.3. RCAT indices for pharmaceuticals, 2016

Provenance economy	RCAT	Provenance economy	RCAT
Albania	0.039	Former Yugoslav Republic of Macedonia	0.588
Algeria	0.001	France	2.219
Andorra	0.019	French Polynesia	0.047
Antigua and Barbuda	0.153	Georgia	1.309
Argentina	0.445	Germany	1.903
Armenia	0.233	Greece	1.381
Aruba	0.317	Greenland	0.000
Australia	0.379	Guatemala	0.865
Austria	1.957	Guinea	0.002
Azerbaijan	0.020	Guyana	0.108
Bahamas	0.008	Honduras	0.070
Bahrain	0.002	Hong Kong (China)	1.235
Barbados	3.555	Hungary	1.586
Belarus	0.161	Iceland	0.579
Belgium	3.776	India	1.314
Belize	0.028	Indonesia	0.105
Benin	0.053	Iran	0.063
Bermuda	0.000	Ireland	7.904
Bolivia	0.009	Israel	3.222
Bosnia and Herzegovina	0.426	Italy	1.707
Botswana	0.036	Jamaica	0.091
Brazil	0.249	Japan	0.151
Brunei Darussalam	0.003	Jordan	2.808
Bulgaria	1.246	Kazakhstan	0.010
Burkina Faso	0.016	Kiribati	0.036
Burundi	0.002	Korea	0.092
Cabo Verde	0.010	Kuwait	0.009
Cambodia	0.014	Kyrgyzstan	0.032
Cameroon	0.008	Lao People's Democratic Republic	0.000
Canada	0.532	Latvia	1.057
Chile	0.098	Lebanon	0.413
China (People's Republic of)	0.101	Lesotho	0.010
Colombia	0.342	Lithuania	0.758
Costa Rica	0.736	Luxembourg	0.296
Côte d'Ivoire	0.015	Macau (China)	0.009
Croatia	1.354	Madagascar	0.001
Cyprus*	3.416	Malawi	0.021
Czech Republic	0.541	Malaysia	0.035
Denmark	3.931	Malta	2.378
Dominican Republic	0.994	Mauritius	0.440
Ecuador	0.062	Mexico	0.166
Egypt	0.470	Moldova	1.914
El Salvador	0.750	Mongolia	0.000
Estonia	0.176	Montenegro	0.600
Ethiopia	0.006	Montserrat	0.119
Fiji	0.226	Morocco	0.158
Finland	0.558	Mozambique	0.005

Table B.3. RCAT indices for pharmaceuticals, 2016 *(continued)*

Provenance economy	RCAT	Provenance economy	RCAT
Myanmar	0.000	Serbia	0.587
Namibia	0.006	Seychelles	0.040
Nepal	0.373	Sierra Leone	0.000
Netherlands	1.612	Singapore	0.623
New Caledonia	0.034	Slovak Republic	0.234
New Zealand	0.207	Slovenia	3.652
Nicaragua	0.036	Solomon Islands	0.000
Niger	0.006	South Africa	0.166
Nigeria	0.003	Spain	1.424
Norway	0.224	Sri Lanka	0.023
Oman	0.039	Suriname	0.012
Pakistan	0.287	Swaziland	0.004
Palau	0.012	Sweden	1.650
Palestinian Authority*	0.375	Switzerland	7.196
Panama	4.673	Tanzania	0.012
Paraguay	0.183	Thailand	0.068
Peru	0.048	Togo	0.118
Philippines	0.034	Tonga	0.011
Poland	0.599	Trinidad and Tobago	0.005
Portugal	0.612	Tunisia	0.103
Qatar	0.005	Turkey	0.183
Romania	0.582	Uganda	0.154
Russia	0.044	Ukraine	0.170
Rwanda	0.007	United Arab Emirates	0.086
Saint Kitts and Nevis	0.003	United Kingdom	2.349
Saint Lucia	0.115	United States	0.972
Saint Vincent and the Grenadines	0.000	Uruguay	0.557
Samoa	0.003	Viet Nam	0.025
Sao Tome and Principe	0.001	Yemen	0.058
Saudi Arabia	0.044	Zambia	0.002
Senegal	0.179	Zimbabwe	0.027

Note: A high RCAT index indicates than the share of the corresponding economy in global reexports of pharmaceutical products is higher than the average share of this economy in global manufacturing reexports. *Note by Turkey:*
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Source: Authors' own calculations based on UN Trade Statistics Division (2019).

Illicit Trade

Trade in Counterfeit Pharmaceutical Products

This report, one in a series of studies by the OECD and the European Union Intellectual Property Office (EUIPO), enhances understanding of the issues and challenges facing governments, businesses and society posed by the trade in fake pharmaceutical products. Illicit markets for fake pharmaceuticals are attractive for counterfeiters, given the high profit margins, low risks of detection and prosecution, weak penalties, and the ease with which consumers can be deceived into believing that the counterfeit products are genuine. Counterfeit medicines not only cause economic damage for the sector, but are also a significant threat to public health, since fake medicines are often not properly formulated and may contain dangerous ingredients. Fake pharmaceuticals include antibiotics, lifestyle treatments, pain killers, anti-malarial drugs, diabetes treatments and central nervous system medicines.

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