

# **4**

## **Mapping the scale of the fake pharmaceutical challenge**

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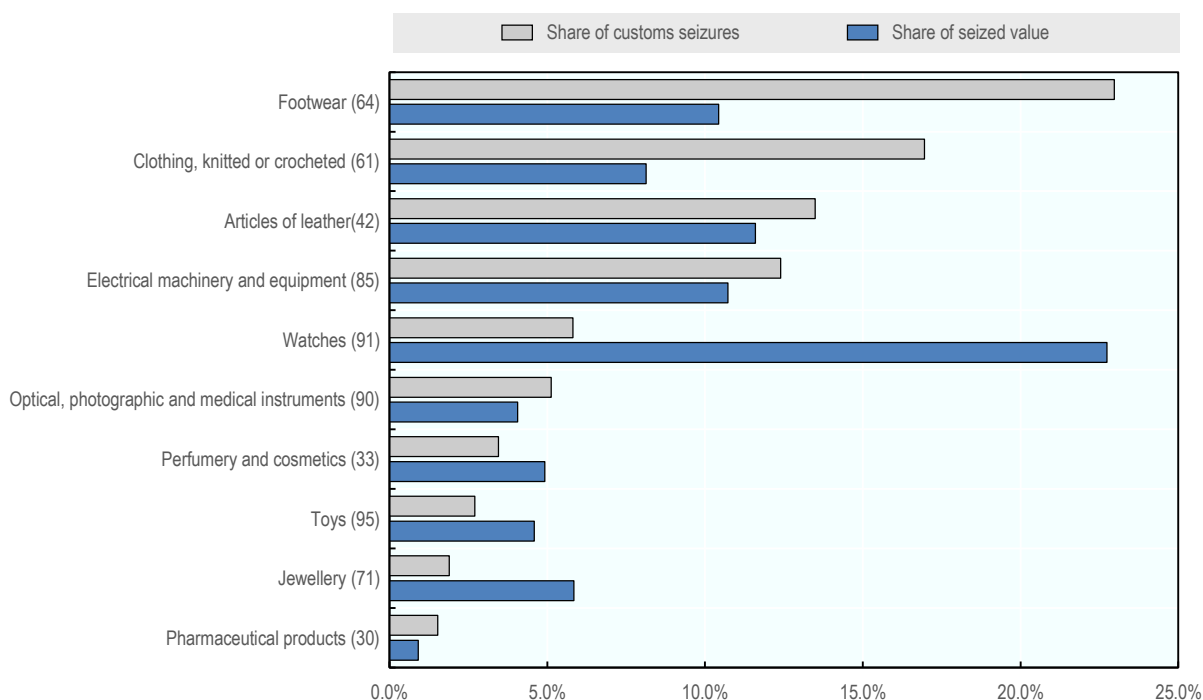
Pharmaceuticals are particularly vulnerable to counterfeiting. This chapter looks at the scale of the counterfeiting challenge, drawing on customs seizures and enforcement action data to track the recent growth in incidents. It also reveals the types of products most commonly counterfeited, and maps 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.

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### **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

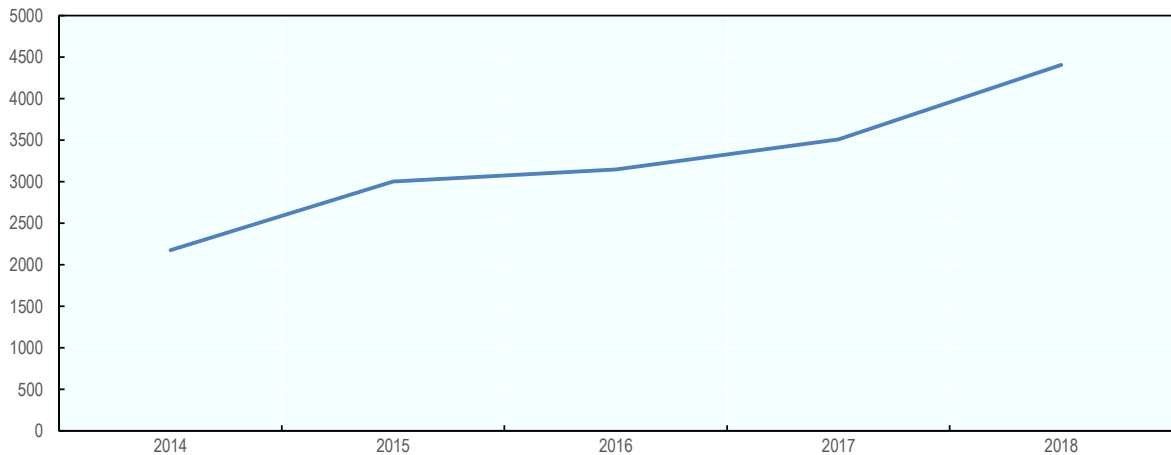


Note: Figures in parenthesis are Harmonized Systems (HS) codes. See WCO (2019) for a complete list of HS product categories.

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.<sup>1</sup> 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%).

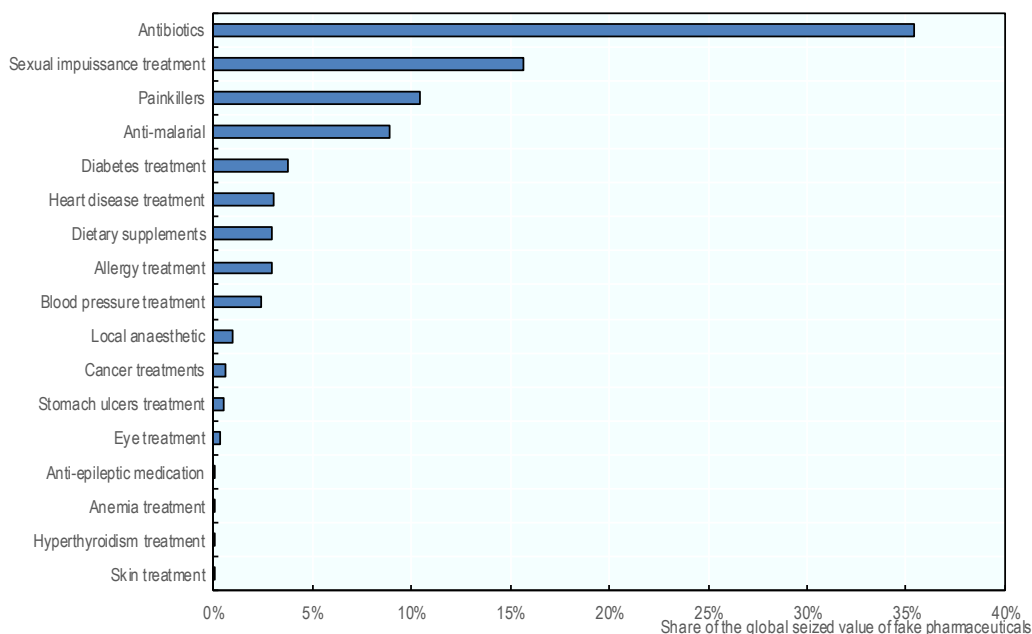
A study carried out by the UNODC in 2013 examining transnational crime in East Asia and the Pacific includes a close examination of the situation in pharmaceuticals (UNODC, 2013). Forensic testing revealed that one-third to two-thirds of the samples tested in the region were fraudulent. While counterfeiters 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**

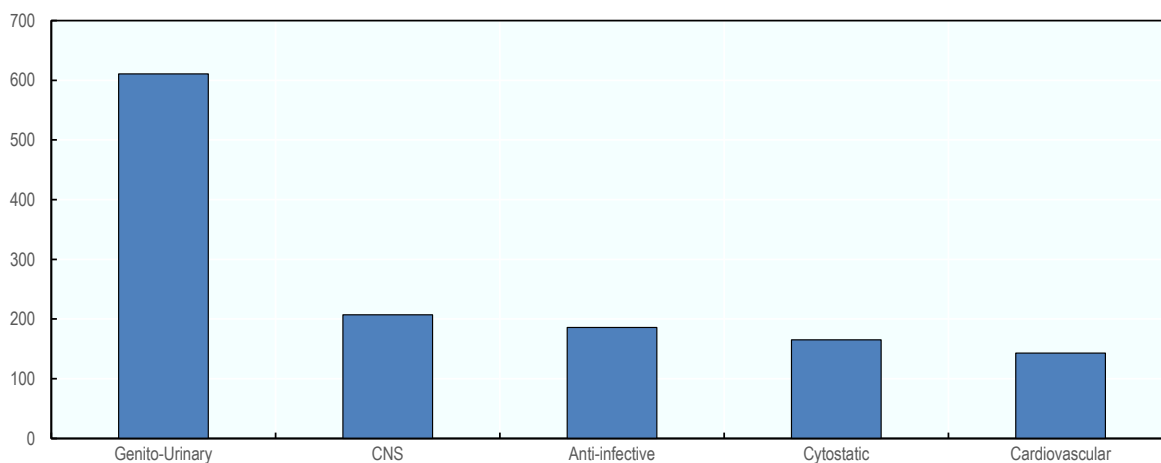


Source: OECD/EUIPO database.

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.

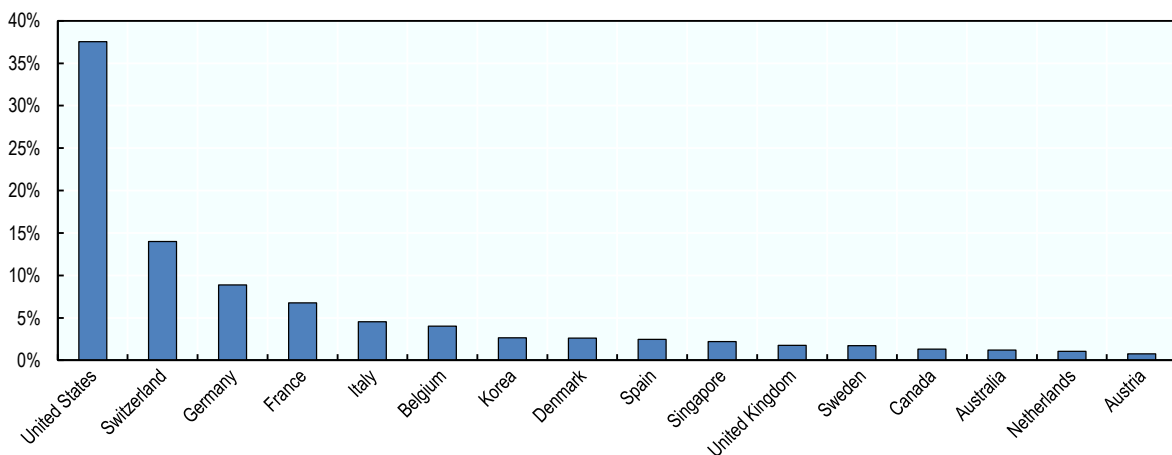
### Which IP right holders are most affected?

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.

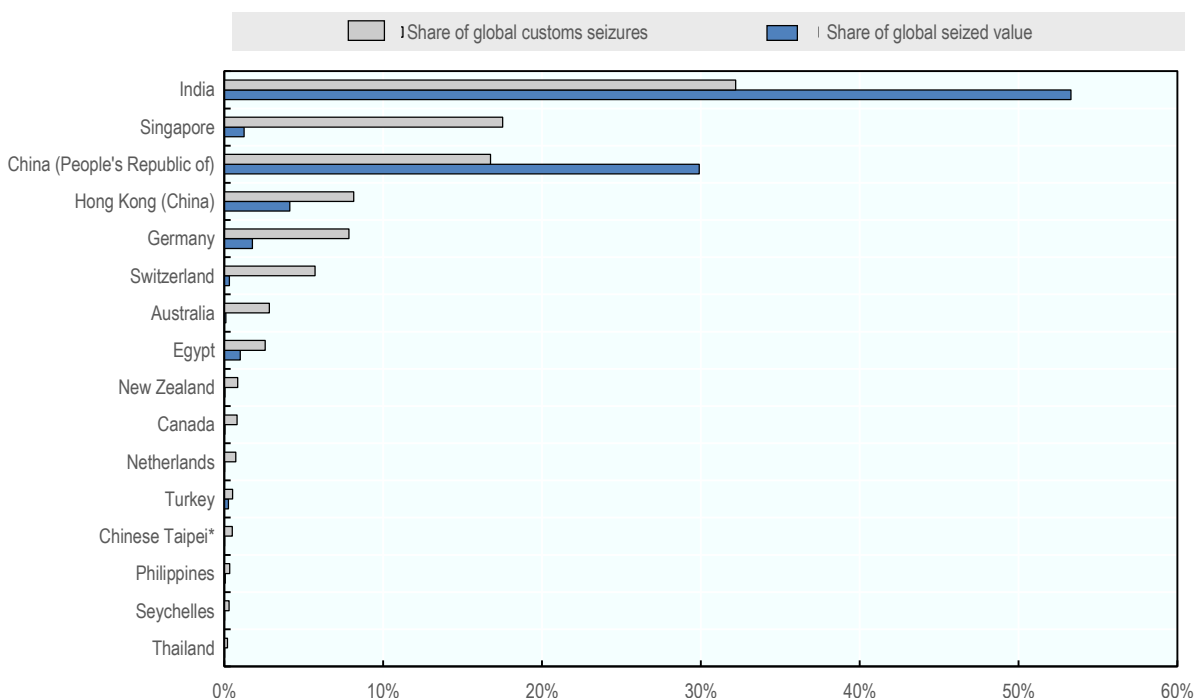
### Key provenance economies

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.

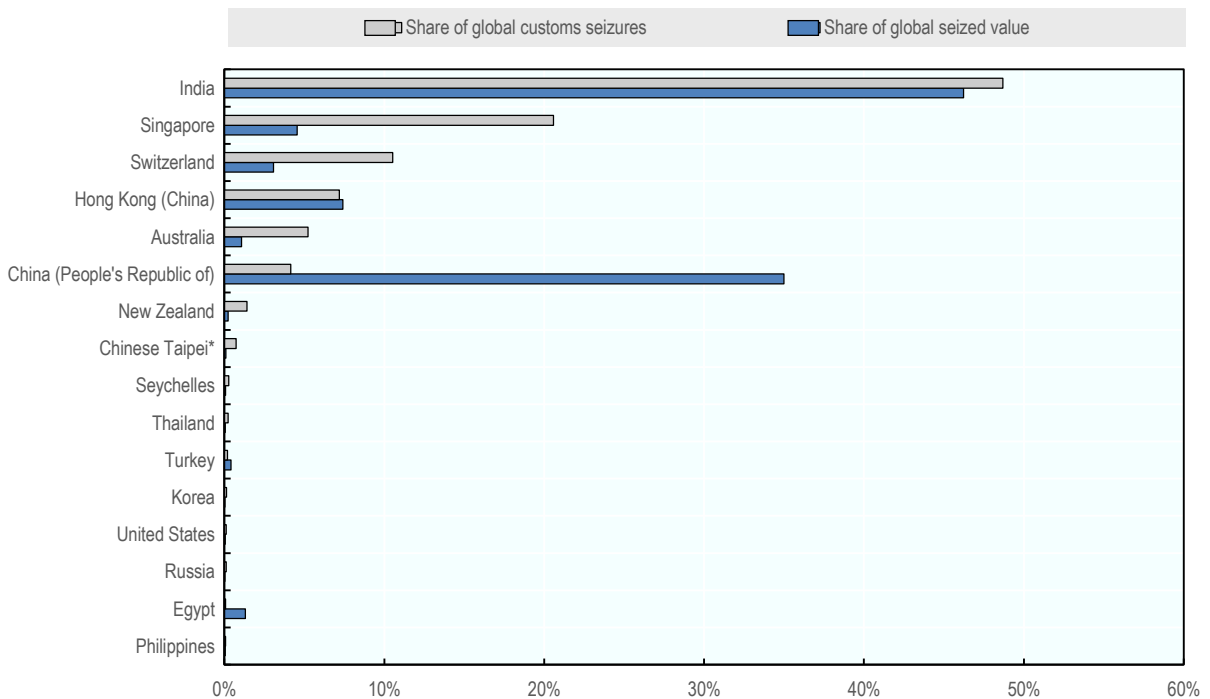
### Key sources: the case of the EU

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):<sup>2</sup>

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 are 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.<sup>3</sup>

**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

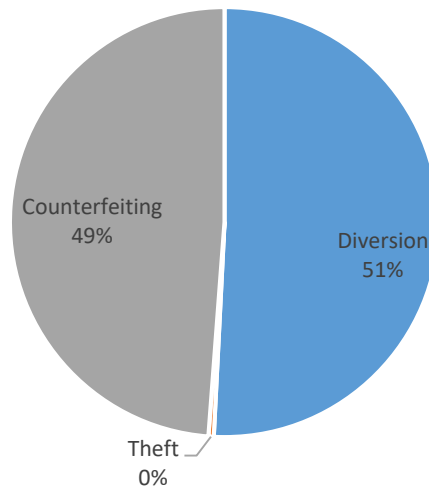
Note: Economies are listed in order of importance, measured by RCAP and RCAT index values, indicating a greater likelihood that the economy in question is a producer or a transit point of counterfeit medicines exported to the EU.

### **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

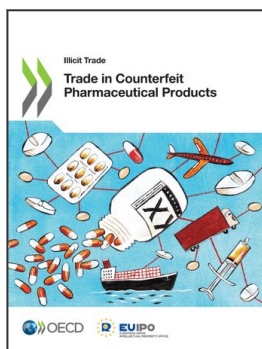
<sup>1</sup> See also [www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products](http://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products)

<sup>2</sup> 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.

<sup>3</sup> 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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