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