Topic 2: Trafficking of falsified medical products

Falsified medical products pose a considerable public health threat as they can fail to cure, may harm and even kill patients. These threats to public health have led the international community to call for a stronger and more coordinated response. Compounding this public health risk is the fact that the supply chain for medicines operates at a global level, and therefore, a concerted effort at the international level is required to effectively detect and combat the introduction of falsified medical products along this supply chain.

Statement of the problem

The growing phenomenon of the falsification of medical products threatens the right to life, as enshrined in different international human rights instruments. In its resolution 20/6, the Commission on Crime Prevention and Criminal Justice urged Member States to prevent trafficking in fraudulent medicines by introducing legislation, as appropriate, covering, in particular, all offences related to fraudulent medicines, such as money-laundering, corruption and smuggling, a well as the confiscation and disposal of criminal assets, extradition and mutual legal assistance, to ensure that no stage in the supply chain of fraudulent medicines was overlooked.

Glossary of terms

Additional explanations are provided in the glossary for certain definitions having particular importance for this Guide. Those definitions are set out in green boxes and are supplemented by a brief commentary to help clarify their meaning.

Accessory to a medical device means any article that is not a medical device but is intended by its manufacturer to be used together with a particular medical device to specifically enable or assist the device to be used following its intended purpose.

Active substance means any substance or mixture of substances that is designated to be used in the manufacture of medicine for human or veterinary use and that, when used in such manufacture, becomes an active ingredient of the medicine.

Document includes any document, whether physical or digital, that travels with, in advance of or following the movement of the medical product for demonstrating the legitimacy of that product or supporting a representation of its legitimacy, including records, packaging, patient information leaflets, invoices and delivery dockets, customs-related documents for importation and exportation, and sales documentation.

Market and trends

Monitoring System for substandard and falsified medical products, the types of products that are falsified include malaria medicines, antibiotics, lifestyle products, including products for cosmetic use, erectile dysfunction, bodybuilding and dieting, anesthetics and painkillers, cancer medicines, heart medicine, mental health medicine, vaccines, diabetes medicine and more. Both innovator medical products and generics are falsified. The falsified products are also not confined to high-value medicines or well-known brand names.

It is nearly impossible to estimate the true level of substandard and falsified medical products globally. According to a WHO study, the observed failure rate of substandard and falsified medical products in low and middle-income countries is approximately 10,5 %. In other words, in low and middle-income countries, 1 in 10 medical products is either falsified or substandard. The value of this market is estimated at US$ 30 billion.

Challenges and opportunities

Falsified medical products represent a significant public health threat. They fail to cure diseases of patients who often do not realize the reason for their deteriorating condition. Toxicity in falsified medical products can potentially cause greater harm to patients or even kill them. Besides, as a consequence of falsified medical products, drug resistance progresses.

Falsified medical products also have a socio-economic impact as a large number of users often buy them because they have not access to safe medical products, for instance, because they cannot afford them. Patients who consume falsified medical products lose faith in medicine and, often, the health system in general. Moreover, falsified medical products result in economic loss. Medicines that fail to protect or cure patients strain the budgets of households and health systems. Legitimate manufacturers of both generic and innovator pharmaceutical products suffer both from a financial and reputational point of view while attention has been focused on the health and regulatory aspect of this problem, far less has been given to the issue from a criminal justice perspective. As with other forms of crime, organized criminal groups abuse gaps in national and international legal frameworks, lack of resources of regulatory, enforcement and criminal justice officials, as well as difficulties in international cooperation.

At the same time, as it continues to be difficult to identify falsified medical products, the prospect of the comparatively low risk of detection and prosecution concerning the potential income makes the manufacturing and trafficking in falsified medical products an attractive commodity to organized criminal groups. Prevention of falsified medical products is another area of work that is often overlooked. Prevention would include awareness-raising on the risks of falsified medical products, as well as on how to avoid and spot them. In the heart of the matter lies lack of access to safe, affordable and quality medical products, which is at the very core of public health's interests. The adoption of a definition through the World Health Assembly is an encouraging step towards more action to prevent and combat the manufacturing and trafficking of falsified medical products.

public health challenge

Fighting falsified medical products represents a major public health challenge. The extent of this pharmaceutical crime is impossible to quantify. However, the WHO estimates that falsified medical products account for 10% of the worldwide market and more than 30% in some countries. In markets with powerful and effective regulatory systems (such as Australia, Canada, most EU countries, etc.), falsified medical products are estimated to represent less than 1% of the market value. The Internet is a perfect hiding place for counterfeiters. It provides an international channel for sales, as well as anonymity and ease of concealment.

Falsified medical products give rise to multiple risks because of they:

-Endanger patients’ health (according to the WHO, Falsified medical products may be responsible for a large number of deaths worldwide),

-Feed a parallel and freeloading economy, which is contrary to sustainable development and may present risks to safety, hygiene, the environment, ethics, human rights, etc.

We can also note the economic cost of counterfeit medicines for industry, government, and society as a whole. Each year in the European Union alone it causes1 the:

- Loss of 4.4% of legitimate sales;

- Loss of €10.2 billion in revenue for the sector;

-Destruction of 90,900 direct and indirect jobs;

Loss of €1.7 billion in government revenue (taxes and social contributions).

Global mobilization

The fight against falsified medical products mobilizes an increasing number of stakeholders, governments and healthcare authorities as well as police organizations and customs officials.

-Last WHO fact sheets of January 2018 estimated that 1 in 10 medical products in low- and middle-income countries is substandard or falsified.

- (WHO) Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in vitro diagnostic tests (GSMS) during its first four years of operation, up to 30 June 2017, contains more than 1,500 product reports.

Ex: The Indonesian Ministry of Health believes that around 5,000 children received falsified vaccines in 2016 alone.

Actions

Sanofi organizes a wide range of initiatives in support of a single, critical goal: contributing to the fight against falsified medical products and, whenever possible, preventing the phenomenon. Our approach simultaneously pursues a large number of different objectives: protecting the patient, preserving trust in the supply chain, cooperating with national and international organizations, using cutting-edge technology to ensure product quality and operating our own dedicated Anti-Counterfeit Laboratory.

Resources

https://www.unodc.org/documents/treaties/publications/19-00741\_Guide\_Falsified\_Medical\_Products\_ebook.pdf

https://www.unodc.org/e4j/en/organized-crime/module-3/key-issues/falsified-medical-products.html

https://www.unodc.org/unodc/en/fraudulentmedicines/introduction.html