International Conventions Applicable to the Trade in Illicit Medical Products: A political scientist’s view

Delphine Placidi-Frot (Pr. Dr.),
Permanent professor in Political Science & IR
pharmaceutical industry:
- emerged in the 19th century
- developed in 2 directions: patenting of medicines + gradually centralized manufacturing
- today, more than 20% of R&D across all sectors (following computers and electronics)
- 4th most IP intensive sector (> 4% of trademark applications every year) (OECD 2020)

illegal trade:
- extremely difficult to measure: between 1.3% and 4.2% of global trade in the medical sector (WTO 2022)
- 10% of drugs in circulation in developing countries apparently illegal
- 550 million doses of counterfeit medicines intercepted by customs in 2013

various health, social, economic impacts, especially in least developed countries, but a worldwide issue

a highly fragmented regulatory landscape, from the high number of actors implied in the supply chain (see map) to the multiple governance diplomacy (raising since the 2000s)
What are we/they taking about?

A worldwide challenge
MAP 3. Routes used for trafficking medical products to the Sahel

The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations. Final boundary between the Republic of Sudan and the Republic of South Sudan has not yet been determined.


What are we/they taking about?
A first glance at the topic through the definitions used by IOs

Trafficking in medical products includes (*WHO definitions*):

a) **falsified medical products**: medical products that deliberately/fraudulently misrepresent their identity, composition or source. They may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient;

b) **substandard medical products or “out of specification” products**: authorized medical products that fail to meet either their quality standards, or specifications, or both;

c) **unregistered/unlicensed medical products**: 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.

d) It can also involve forms of **disruption to or diversion of the legal supply chain** (including at the production, distribution, sale or dispensing stages)
Examples of disruptions to the regulated supply chain of medical products

- Manufacturers produce medical products
- Wholesalers import and distribute medical products
- Pharmacies, hospitals and clinics order and dispense medical products

Illegal disruptions:

1. Criminal actors may manufacture falsified medical products or export medical products without respecting export laws and regulations.
2. Criminal actors may import medical products that have not been authorized by the national regulatory authority, distribute them through unauthorized channels (street markets) or steal them from warehouses.
3. Criminal actors may bribe health officials to sell them medical products in bulk without prescription, or distribute falsified medical products through pharmacies, hospitals and clinics.

Pharmaceutical crime is a major global public health concern, with the trade of counterfeit and illicit medical products a truly global criminal phenomenon affecting all countries through source, transit or destination points. Patients across the world put their health and even their lives at risk by unknowingly consuming fake and unregulated medical products, or products that have been altered, diverted, badly stored or have passed their expiry date. Growing consumer demand, the COVID-19 pandemic and widespread use of the Internet has meant that the advertisement, sale and supply of illicit medical products from unauthorized and unregulated websites has become a growing problem in recent years. Source: Interpol, Pharmaceutical Crime, Jan 2022

Medical products are essential, highly regulated and often highly-priced, making them prone to illicit trade. The trafficking of substandard, unregistered, falsified and/or counterfeit medical products threatens human health and safety, endangers jobs and economic activity, stifles innovation and undermines trust in global supply chains, setting back efforts to use trade to support global health security and sustainable development. The costs of inaction are high. A multi-faceted response is required to tackle this complex, multi-dimensional problem. Source: WTO, launch of the report Tackling Illicit Trade in Medical Products: Better international co-operation for better health, July 2022 (see below)
Launch of the WTO Report in July 2022

In July 2022, the WTO convened a Global Review of Aid for Trade, which gathered top officials from 6 IOs to “call for greater coordination among relevant national and international bodies in the fight against illicit trade in medical products”. The WTO also launched a report called Tackling Illicit Trade in Medical Products: Better international co-operation for better health.

Although the report’s title refers to a « better international cooperation for a better health », the headline on the WTO website and on the video is slightly but notably different : « better trade for a better health ». 
See video of the WTO Aid for Trade Global Review 2022 – Session 9 on « Better Trade for Better Health », July 2022: https://www.youtube.com/watch?v=R01uOBICbMI
Taking a few steps backwards...

**Step 1:** Main causes of illnesses and deaths in the world, compared to the level of income per inhabitant


**Death by non-communicable disease, 2015**

Source: WHO, Global Health Observatory, www.who.int/gho

**Comment:** The world distribution of death by non-communicable disease shows marked contrasts. The countries with very ageing populations are more susceptible to neurodegenerative illnesses. Those suffering from a combination of unbalanced diets, high alcohol and tobacco consumption, sedentary lifestyles, and exposure to pollution are more affected by cardiovascular diseases and cancer. Mortality from diabetes now impacts the whole world, starting with the poorest.
Step 2:
Localisation of substandard and falsified medicines in the world

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FIG 2. Number of falsified products reported, by anatomical group and subregion, 2013–2022

Note: The total number of medical products is 623.

Step 3: World Top 20 Pharmaceutical Companies’ medical priorities

# Top 20 worldwide pharmaceutical companies in 2023


<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Sales 2022 (USD billion)</th>
<th>R&amp;D Spend 2022 (USD billion)</th>
<th>Top-Selling Drugs 2022</th>
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<td>Pfizer</td>
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<td>Cystine</td>
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<td>Bevacizum</td>
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<td>CSL</td>
<td>$13.123</td>
<td>$1.347</td>
<td>Humate (DAI)</td>
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Sources: EvaluatePharma, May 2023, Evaluate Ltd, www.evaluate.com

Notes:
- All figures represent prescription pharmaceutical sales from the named company only and exclude revenues from vaccines, OTC products, etc., as well as sales from non-prescription pharmaceuticals.
- Figures in parentheses are Evaluate Consensus Estimates and are included where actual reported sales data was not available at the time of preparation. Evaluate Sales estimates for generic companies are based on EvaluatePharma for assistance in the development of this year’s Pharma 50 listing.
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A various range of international and national actors

**Why international cooperation is necessary (although not sufficient)?**

Every country is concerned, not only the least developed ones:

*Most industrialized countries have effective market surveillance that keeps the share of counterfeit medicines below one per cent of total market volume. By contrast, according to WHO and OECD data, this figure exceeds 30 per cent in some countries in Latin America, Southeast Asia and Africa. Combatting the trade in counterfeit medicines and other falsified medical products requires therefore concerted action at international level. (WTO, 2022)*

**IOs:**

World Trade Organization (WTO), World Bank (WB)

Various UN agencies & programs, among which:
- UN Conference on Trade and Development (UNCTAD)
- UN Industrial Development Organization (UNIDO)
- UN Office on Drugs and Crime (UNODC)
- World Health Organization (WHO)
- World Intellectual Property Organization (WIPO)
- World Customs Organization (WCO)
- International Maritime Organization (IMO)
- Interpol
- etc.

Transnational Alliances or Coalitions:

ex: TRACIT = Transnational Alliance to Combat Illicit Trade (www.tracit.org)
A various range of international and national actors

At the regional level:
Organisation for Economic Co-operation and Development (OECD), European Union (EU), Europol, ... African Union, Afripol, ...

At the national level:
Health Ministries, Economic & Finance Ministries, national medicine security agencies

Private profit sector:
pharmaceutical industrials

Medical professionals:
hospitals, doctors, researchers

Civil society:
NGOs & patients’ associations
Diverging IO’s responses: WHO Global Surveillance and Monitoring System

Diverging IO’s responses: Interpol

Interpol’s Illicit Goods and Global Health Programme (IGGH):

Interpol’s IGGH programme aims at improving global cooperation and enforcement capability of both member countries and industries in the area of pharmaceutical crime.

Main actions:
- Collecting data and disseminating intelligence (e.g. analytical reports and threat assessments);
- Coordinating transnational law enforcement operations;
- Supporting multi-agency task forces to improve cooperation between police, customs, regulatory bodies and the private sector;
- Raising public awareness of pharmaceutical crime and helping consumers to make informed choices.

Interpol cooperates with national law enforcement agencies, IOs, industry and Interpol’s member countries, both at global and regional levels.

At global level: Operation Pangea

Since 2008, Operation Pangea has been combating the global trafficking of counterfeit pharmaceuticals marketed and sold online. Pangea also aims to raise public awareness of the risks associated with buying medicines from unregulated websites.

Operation Pangea XIV was launched in 2021.
**At regional levels:**

**Action against tramadol trafficking (Regional)**
This initiative was established in 2020 with the most affected countries of tramadol trafficking across Africa. The aim is to drive investigations between both source and destination countries, and also to raise awareness amongst the public about the dangers posed by the use of illicit goods.

**Operations Afya and Heera (Regional)**
Afya is an Interpol-led operation targeting criminal groups involved in the manufacture and distribution of illicit goods and pharmaceuticals in the Southern Africa region, and more broadly across Western Africa. 
*In 2021, Operation Afya led to the seizure of counterfeit products to the estimated value of USD 3,532,489, triggering over 300 criminal and administrative cases with 179 offenders apprehended.*

**Operation Qanoon (Regional)**
The Qanoon Initiative was launched in 2015 and covers the Middle East and North African region. In 2020, coinciding with the COVID-19 pandemic, the operation led to a number of significant seizures, including 63,418 facemasks in Jordan and 85,000 medical products (facemasks, gloves, thermometers, medical glasses) in Qatar.

**Operations targeting COVID-19 related crime**
Operation Vigilant Interdiction (OVI) was established as a global operation in 2020 to implement countermeasures against the emerging threat of COVID-19 related crime. Through engagement with member countries and partner organizations, Interpol’s IGGH programme developed and provided risk analysis, actionable intelligence and INTERPOL notices.

**Operation Flash – Illicit Pharmaceutical Products in Africa:**
The Operation was established in late 2021 between Interpol and Afripol, which will jointly launch the 1rst operation involving their common member countries. The operation will target counterfeit and illicit vaccines, medicines and medical devices and their use across Africa.
Medicrime Convention = **Council of Europe** Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health
came into force in 2016
It’s the first international agreement aimed at halting the illegal trade in therapeutic products and at preventing counterfeit therapeutic products from endangering people’s health.
The parties to the Convention undertake to **prosecute any acts linked to the manufacture or marketing of counterfeit therapeutic products or to the trade in such products.** The Convention also provides for national and international cooperation between the competent authorities.

**European Falsified Medicines Directive (FMD, 2011/62/EU) :**
adopted by the **European Union** (EU) in **2011**, implementation details (“delegated regulation”)
entered into force in **2019**
aims to **prevent counterfeit medicines entering the legal supply chain**
This Directive makes provision **inter alia** for safety features on the packs of medicinal products that are subject to prescription, making it possible to detect falsified medicines at the time they are given to the patient at the latest.
These safety features fall into two categories:
a) the first makes it possible to verify that medicines are authentic and to identify individual boxes (unique identifier)
b) the second detects whether packages have been opened (anti-tampering device)
Due to the clandestine nature of illicit transactions, the profits from illicit trade are hard to estimate. Data is accessed through seizures, law enforcement data and cross-comparisons with parallel legal markets.

OECD Task Force on Countering Illicit Trade, 2016, *Converging Criminal Networks*, Paris, OECD.
Concluding words / Sparking debate:

“a pharmaceutical fraud”, as analysed by Mathieu Quet (2018)?
Intergovernmental organizations:

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


Transnational Alliance to Combat Illicit Trade: https://www.tracit.org/pharmaceuticals.html


Scientific works:


Thanks for your attention!