

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

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Trade in Illicit Medical Products: A complex, global and multifaceted problem

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 ?

FIG. 2: A MEDICINE'S JOURNEY



Source : WHO, 2017, *WHO Global Surveillance and Monitoring System for substandard and falsified medical products*. Geneva, World Health Organization.

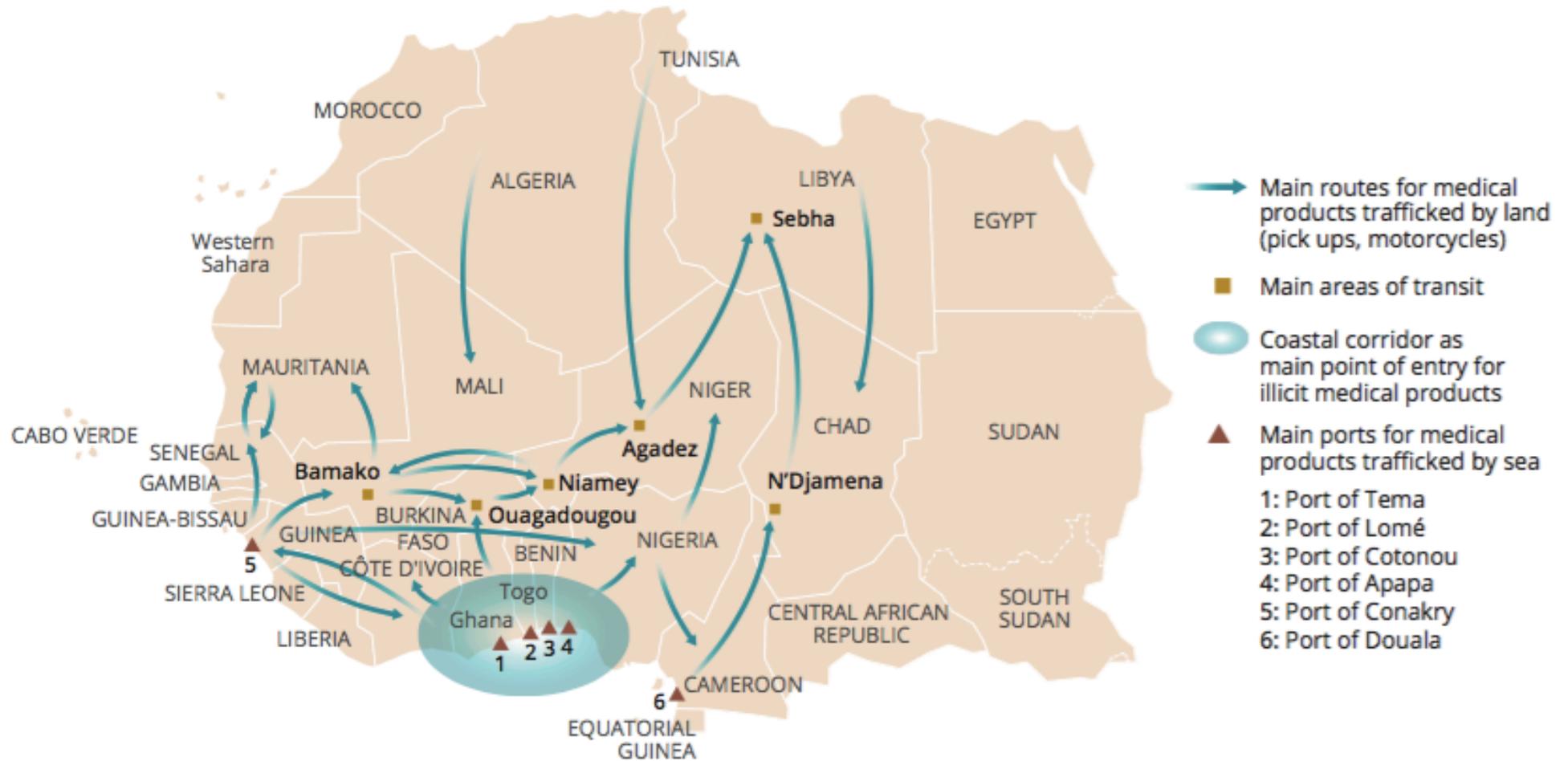
A worldwide challenge

FIG. 6: MAPPING THE SUPPLY CHAIN OF FALSIFIED AVASTIN



Source : WHO, 2017, *WHO Global Surveillance and Monitoring System for substandard and falsified medical products*. Geneva, World Health Organization.

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.

Source: Interviews with law enforcement officials in the Sahel, 2018–2021.

Source : UNODC / TOCTA - Sahel (Transnational Organized Crime Threat Assessment), 2022, *Trafficking in Medical Products in the Sahel*, Vienna : https://www.unodc.org/documents/data-and-analysis/tocta_sahel/TOCTA_Sahel_medical_2023.pdf

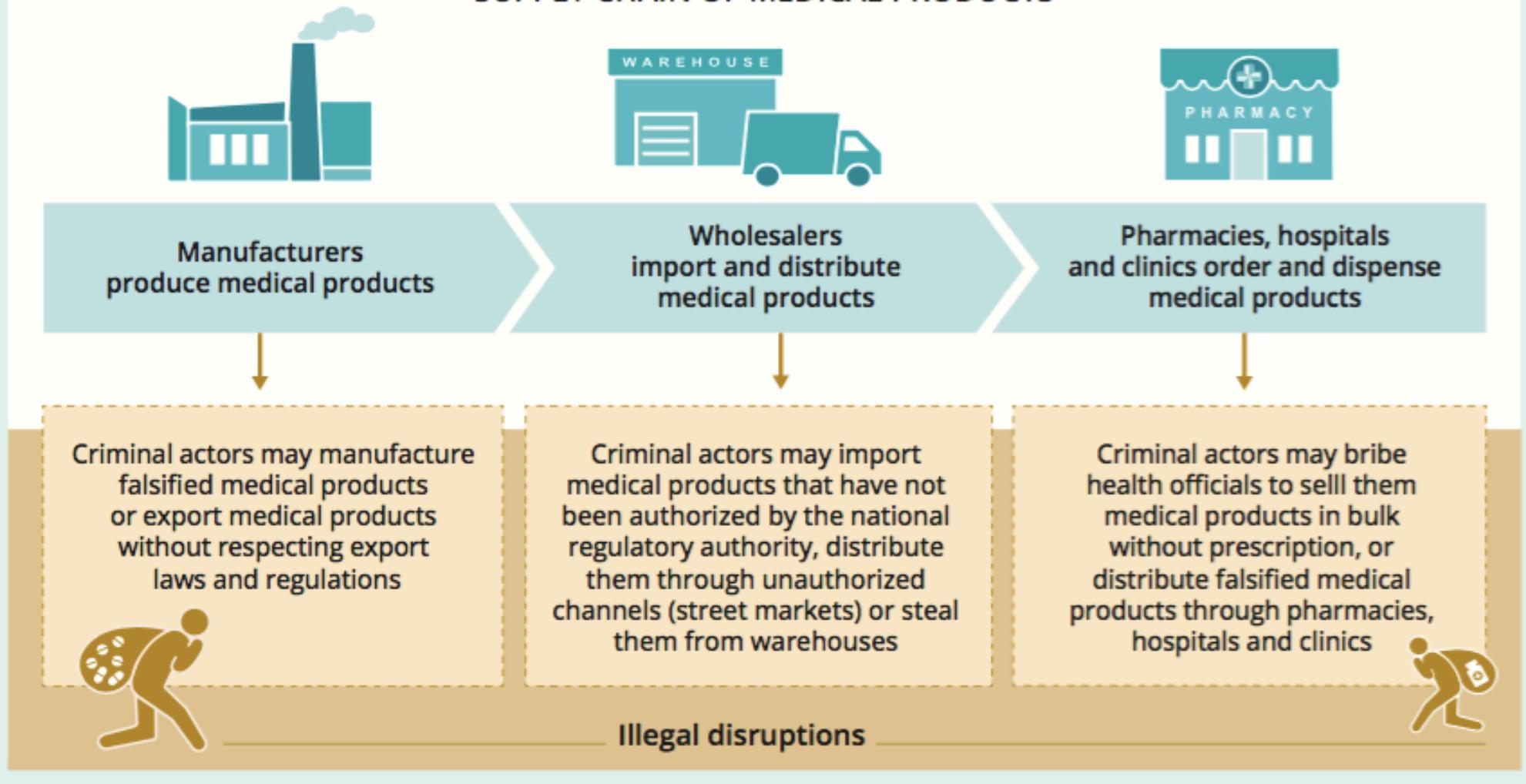
What are we/they taking about ?

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



Source : UNODC / TOCTA - Sahel (Transnational Organized Crime Threat Assessment), 2022, *Trafficking in Medical Products in the Sahel*, Vienna : https://www.unodc.org/documents/data-and-analysis/tocta_sahel/TOCTA_Sahel_medical_2023.pdf

What are we/they taking about ?

A first glance at the topic through the analyses made by IOs

*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 ».



Tackling illicit trade in medical products

Better international cooperation for better health



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Better Trade for Better Health: Strengthening cooperation to tackle illicit trade in medical products

Zoom and Room S1 [Summary](#)

27 July 2022, 11:30-12:30 (CEST)

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.

Convened by the WTO at the 2022 Global Review of Aid for Trade, heads of international organizations will share perspectives on the impact of illicit trade, with a focus on medical products. They will collectively identify the resources, interventions and innovative tools needed to fight illicit trade and create new opportunities for legal trade in medical products with a view to protecting people's health. Areas to be explored include harnessing trade facilitation, ensuring compliance with applicable quality standards and promoting the balanced and effective enforcement of intellectual property rights. On this occasion, the Director-General will launch the WTO report: 'Tackling Illicit Trade in Medical Products: Better international co-operation for better health'.



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[Leveraging WTO Rules to Combat Illicit Trade in Medical Products \(WTO Secretariat working paper\)](#)

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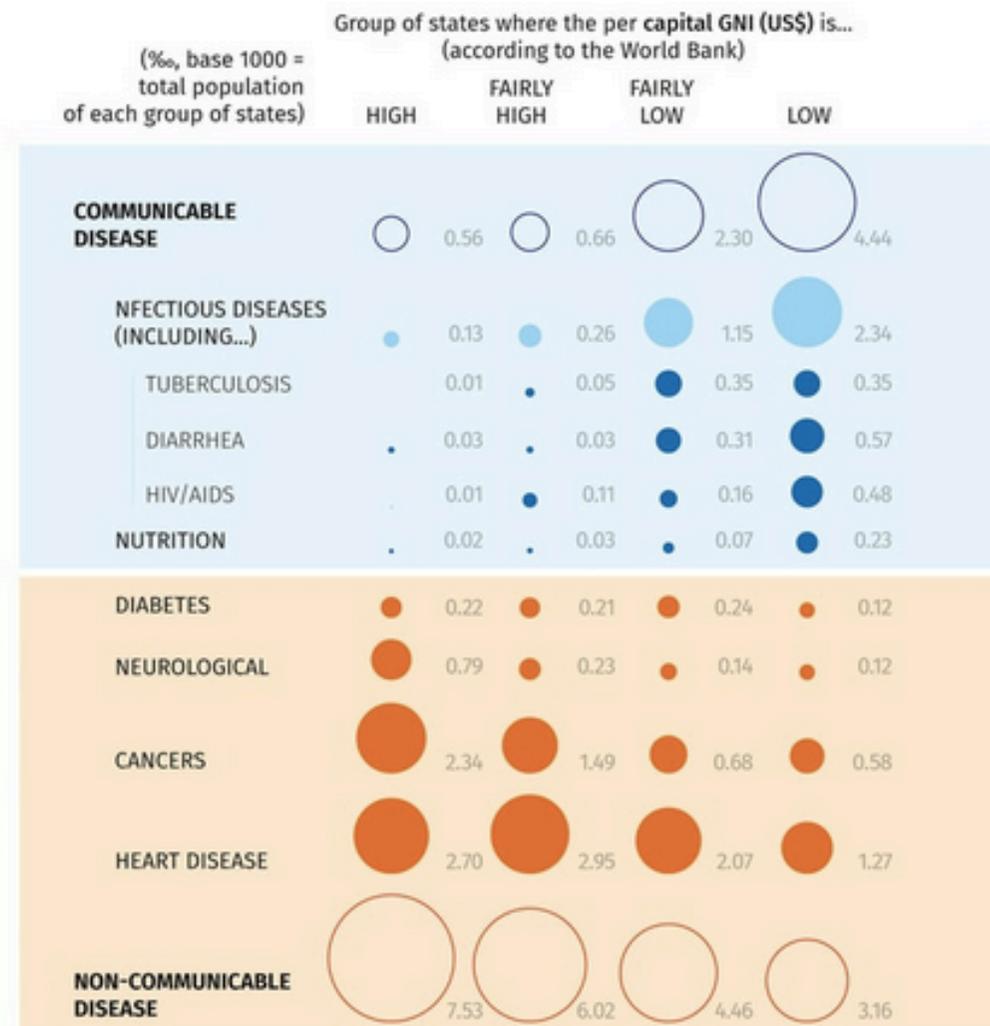


See video of the WTO Aid for Trade Global Review 2022 – Session 9 on « Better Trade for Better Health », July 2022: <https://www.youtube.com/watch?v=R01uOBICbMI>

Taking a few steps backwards...

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

Main causes of death by income level, 2015



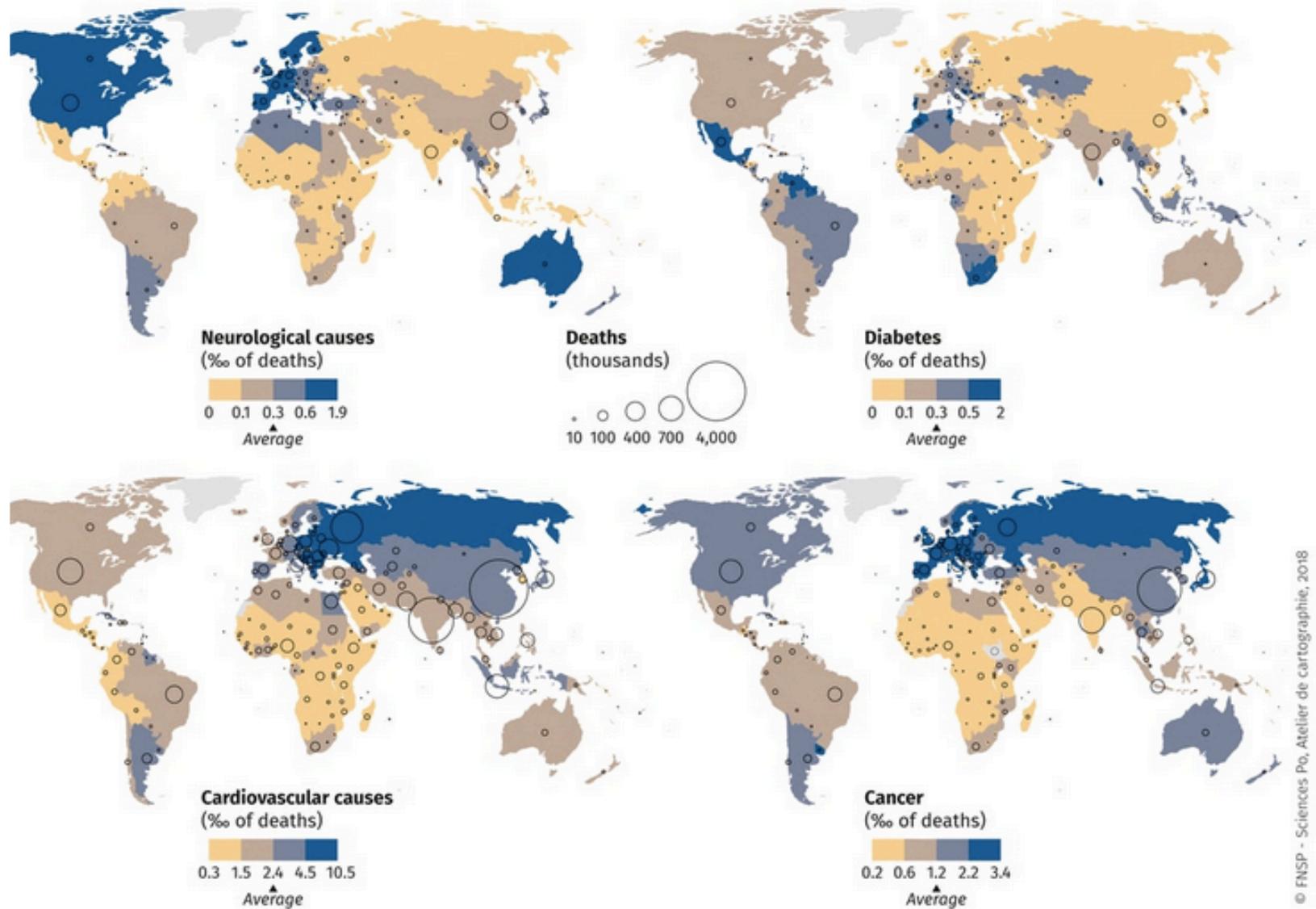
Source: WHO, Global Health Observatory, www.who.int/gho

Info & download

Comment: The table reveals the links between the main causes of mortality and the average level of income per inhabitant in 2015. The populations of high-income countries are more liable to die from non-communicable diseases (neurological causes and cancer in particular) while in low-income countries, people die from infectious diseases (tuberculosis, diarrhea, HIV/aids) or malnutrition. This reverse gradient is less marked in the case of diabetes (due to there being two types) and heart disease.

"Global Diseases" *World Atlas of Global Issues*, 2018, [online], accessed on 19/06/2023 : <https://espace-mondial-atlas.sciencespo.fr/en/topic-contrast-and-inequalities/article-1A07-EN-global-diseases.html>

Death by non-communicable disease, 2015

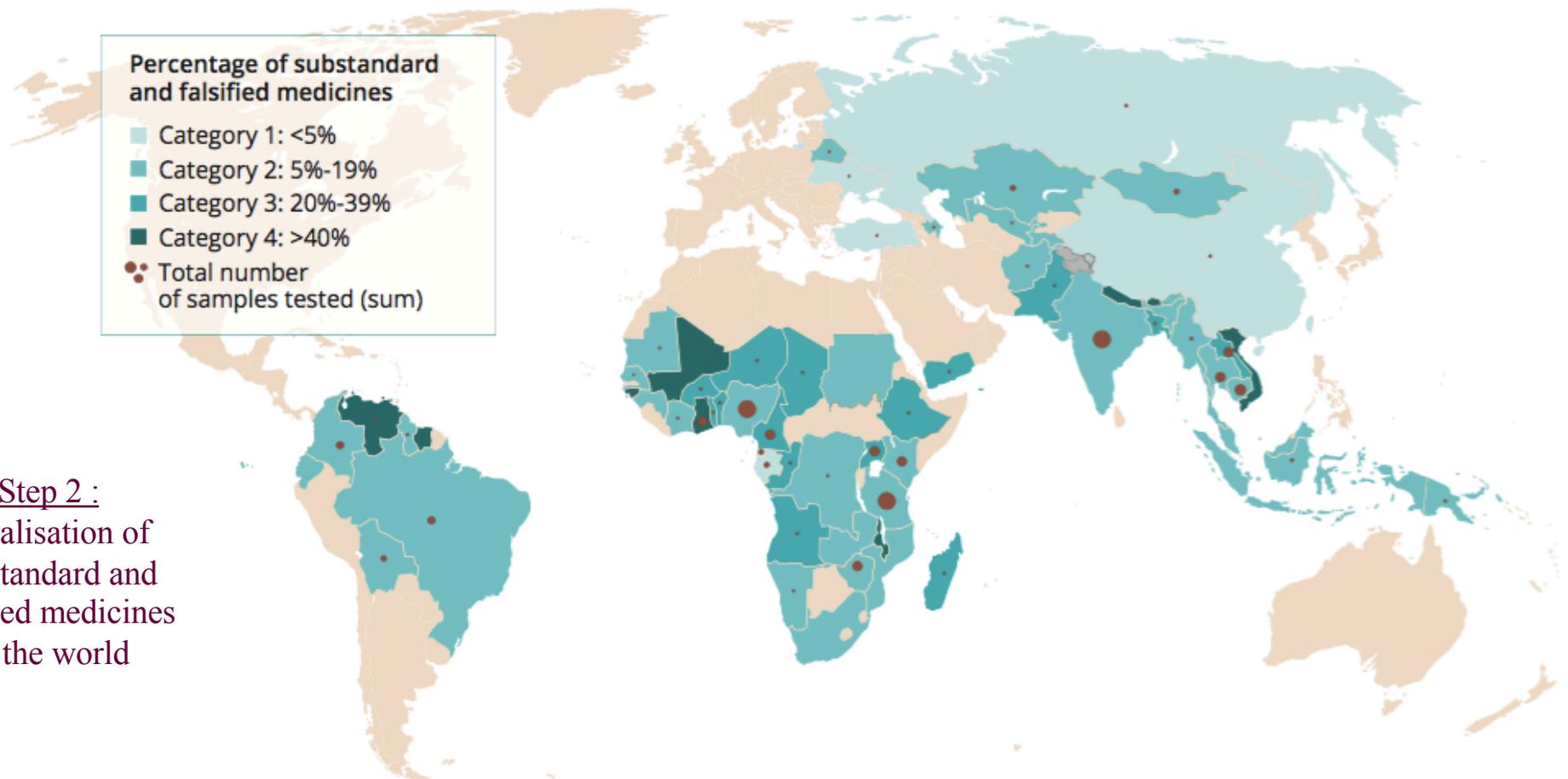


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<https://espace-mondial-atlas.sciencespo.fr/en/topic-contrasts-and-inequalities/article-1A07-EN-global-diseases.html>

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

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.

MAP 2. Reported national percentage of substandard and falsified medicines in the medical market, 2018



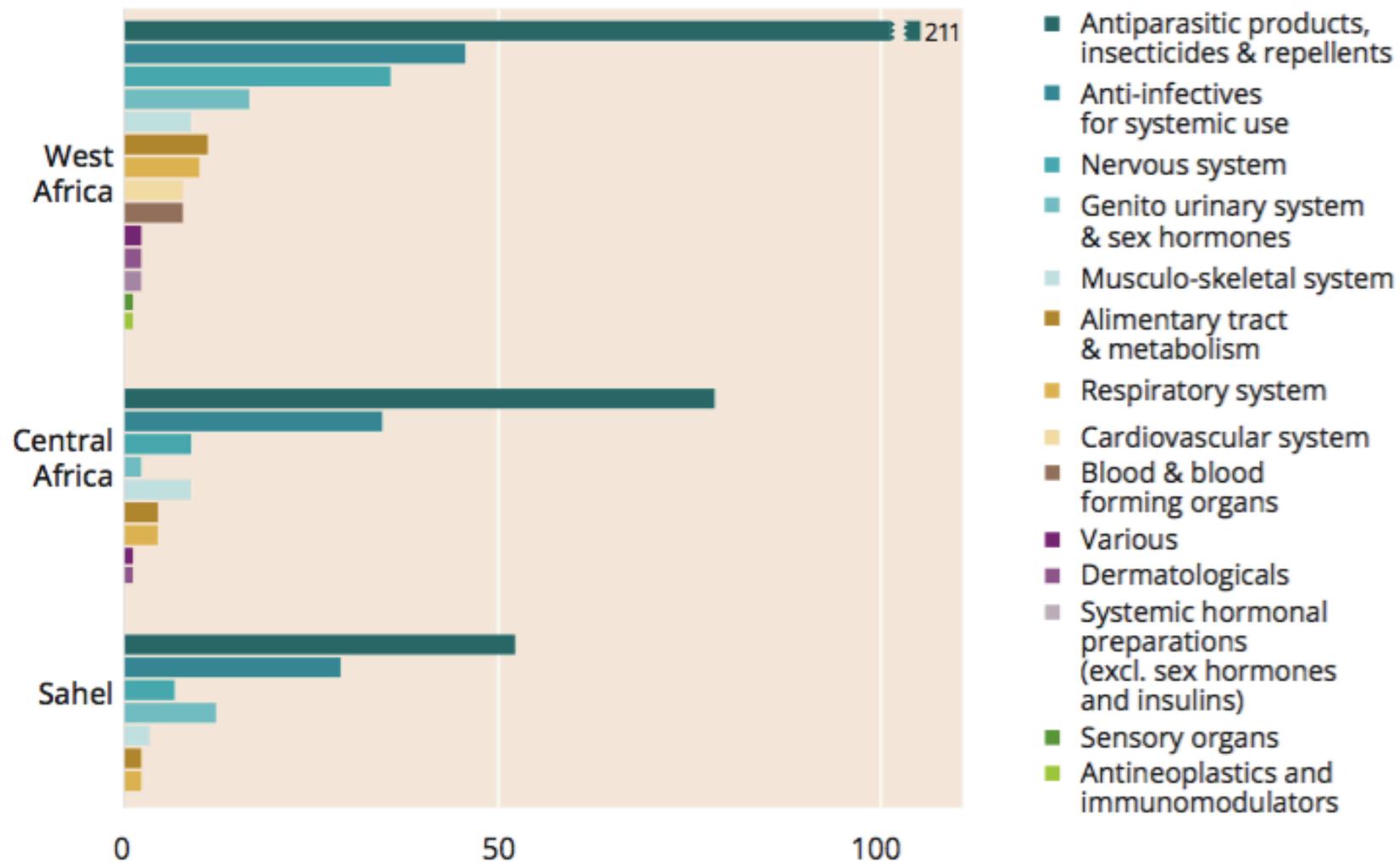
Step 2 :
Localisation of
substandard and
falsified medicines
in the world

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.

Source: Elaborated by UNODC from Sachiko Ozawa et al., "Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: a systematic review and meta-analysis", JAMA Network Open, 2018.

Source : UNODC / TOCTA - Sahel (Transnational Organized Crime Threat Assessment), 2022, *Trafficking in Medical Products in the Sahel*, Vienna : https://www.unodc.org/documents/data-and-analysis/tocta_sahel/TOCTA_Sahel_medical_2023.pdf

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



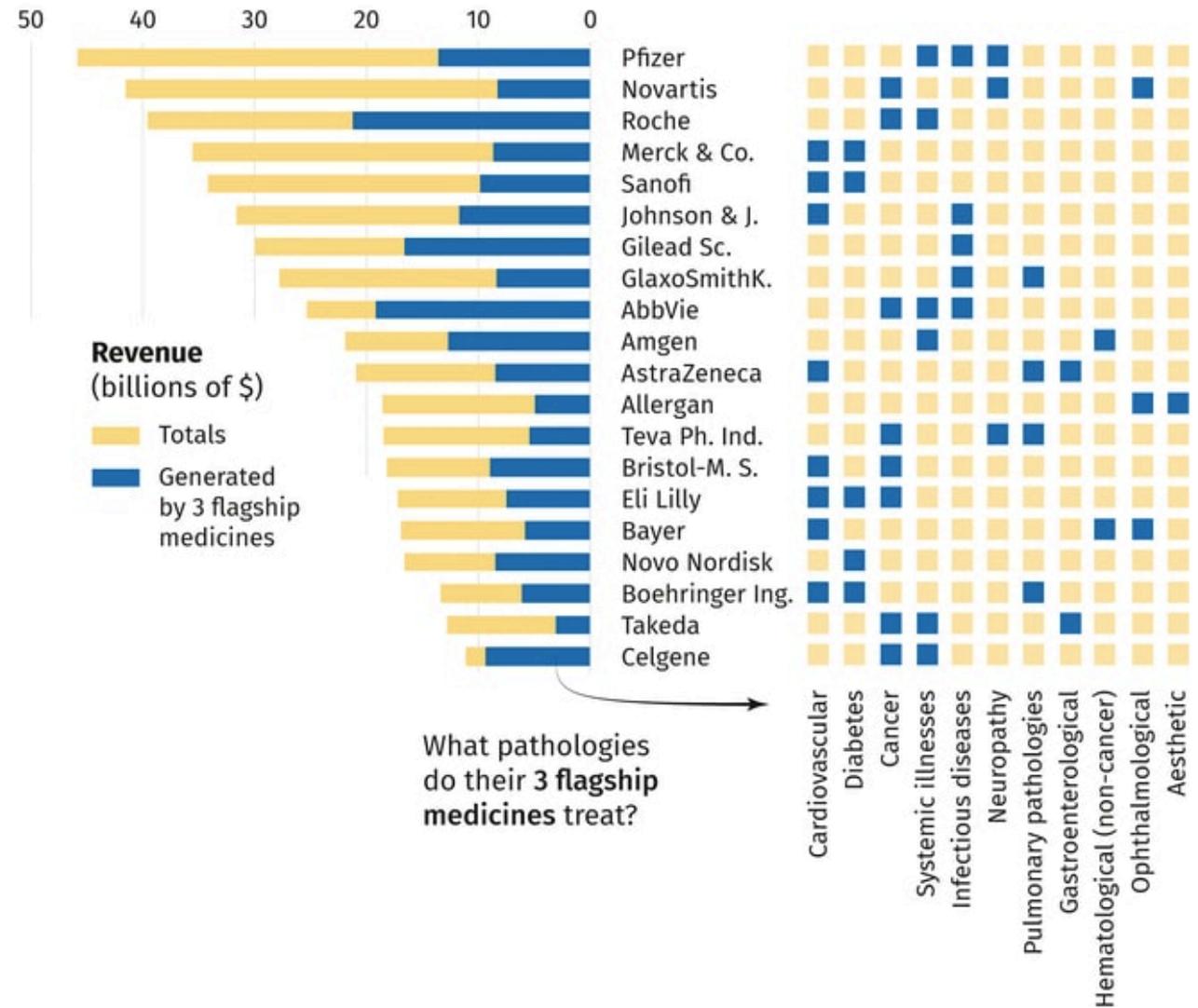
Source: WHO, Global Surveillance and Monitoring System confidential thematic report for UNODC, July 2022.

Note: The total number of medical products is 623.

Source : UNODC / TOCTA - Sahel (Transnational Organized Crime Threat Assessment), 2022, *Trafficking in Medical Products in the Sahel*, Vienna : https://www.unodc.org/documents/data-and-analysis/tocta_sahel/TOCTA_Sahel_medical_2023.pdf

The World's 20 Leading Pharmaceutical Companies, 2016

Step 3 : World Top 20 Pharmaceutical Companies' medical priorities



"Global Diseases" *World Atlas of Global Issues*, 2018, [online], accessed on 19/06/2023 :
<https://espace-mondial-atlas.sciencespo.fr/en/topic-contrasts-and-inequalities/article-1A07-EN-global-diseases.html>

Top 20 worldwide pharmaceutical companies in 2023

(<https://www.pharmexec.com/view/2023-pharm-exec-top-50-companies>)

		2022 Rx Sales*	2022 R&D Spend*	2022 Top-Selling Drugs*	
1	Pfizer NEW YORK, NEW YORK (PFIZER.COM)	\$91.303	\$12.381	Comirnaty 37.806 Paxlovid 18.933 Pvovnar 13 6.337	
2	AbbVie NORTH CHICAGO, ILLINOIS (ABBVIE.COM)	\$56.179	\$6.435	Humira 21.237 Skyrizi 5.165 Imbruvica 3.526	
3	Johnson & Johnson NEW BRUNSWICK, NEW JERSEY (JNJ.COM)	\$50.179	\$14.140	Stelara 9.723 Darzalex 6.977 Invega Sustenna 2.982	
4	Novartis BASEL, SWITZERLAND (NOVARTIS.COM)	\$50.079	\$9.088	Cosentyx 4.788 Entresto 4.644 Promacta 2.088	
5	Merck & Co. KENILWORTH, NEW JERSEY (MERCCK.COM)	\$49.627	\$11.842	Keytruda 20.937 Gardasil 6.897 Lagevrio 5.684	
6	Roche BASEL, SWITZERLAND (ROCHE.COM)	\$47.909	\$14.781	Ocrevus 6.349 Perjeta 4.299 Tecentriq 3.909	
7	Bristol Myers Squibb NEW YORK, NEW YORK (BMS.COM)	\$45.417	\$10.016	Eliquis 11.789 Revlimid 9.978 Opdivo 8.249	
8	AstraZeneca LONDON, ENGLAND (ASTRAZENECA.COM)	\$42.998	\$9.500	Tagrisso 5.444 Farxiga 4.247 Soliris 3.762	
9	Sanofi PARIS, FRANCE (SANOFI.COM)	\$40.353	\$7.156	Dupixent 8.850 Fluzone 3.177 Pentacel 2.438	
10	GSK BRENTFORD, ENGLAND (GSK.COM)	\$38.254	\$6.337	Shingrix 3.703 Xevudy 2.890 Triumeq 2.252	

		2022 Rx Sales*	2022 R&D Spend*	2022 Top-Selling Drugs*	
11	Takeda OSAKA, JAPAN (TAKEDA.COM)	\$29.690	\$4.697	Entyvio 5.283 Vyvanse 3.010 Gammagard Liquid 2.841	
12	Gilead Sciences FOSTER CITY, CALIFORNIA (GILEAD.COM)	\$26.615	\$4.968	Biktarvy 10.390 Veklury 3.905 Genvoya 2.404	
13	Eli Lilly INDIANAPOLIS, INDIANA (LILLY.COM)	\$25.463	\$7.191	Trulicity 7.440 Verzenio 2.484 Taltz 2.482	
14	Novo Nordisk BAGSVAERD, DENMARK (NOVONORDISK.COM)	\$25.384	\$3.450	Ozempic 8.571 NovoRapid 2.218 Victoza 1.768	
15	Amgen THOUSAND OAKS, CALIFORNIA (AMGEN.COM)	\$22.536	\$4.341	Enbrel 4.117 Prolia 3.628 Otezla 2.288	
16	Boehringer Ingelheim INGELHEIM, GERMANY (BOEHRINGER-INGELHEIM.COM)	\$19.473	\$5.386	Jardiance 6.224 Ofev 3.444 Tradjenta 1.817	
17	Bayer LEVERKUSEN, GERMANY (BAYER.COM)	\$18.898	\$7.013	Xarelto 4.243 Eylea 3.429 Mirena 1.363	
18	Moderna CAMBRIDGE, MASSACHUSETTS (MODERNATX.COM)	\$18.435	\$2.993	Spikevax 18.435	
19	Viatrix CANONSBURG, PENNSYLVANIA (VIATRIS.COM)	\$15.999	\$698	Lipitor 1.635 Fluticasone Propionate, Salmeterol Xinafoate 1.134 Norvasc 775	
20	CSL MELBOURNE, AUSTRALIA (CSL.COM.AU)	\$13.123	\$1.347	Privigen 2.928 Hizentra 1.735 Human albumin (CSL) 1.131	

Source: EvaluatePharma® May 2023, Evaluate Ltd, www.evaluate.com

*USD in billions, lower numbers in millions

Source: EvaluatePharma® May 2023, Evaluate Ltd, www.evaluate.com

*USD in billions

How the listings were compiled: 2022 Rx Sales and R&D Spend analyses were provided by life sciences market intelligence firm Evaluate Ltd via its EvaluatePharma® service, www.evaluate.com. Pharm Exec would like to thank EvaluatePharma for assisting in the development of this year's Pharma 50 listing.

non-prescription pharmaceuticals. Figures in green are Evaluate Consensus Estimates and are included where actual reported sales data was not available at the time of generation. Evaluate's Sales and R&D Spend figures represent the fiscal year that ended in 2022. For most American and European companies, that means the year ending Dec. 31, 2022. For many Japanese companies, the fiscal year ending March 31, 2023, was used. Historic averages were used in the conversion of companies' native currency to USD.

PLEASE NOTE: 2022 figures represent prescription pharmaceutical sales from the named company only and exclude revenues from royalties, co-promotions, etc., as well as sales from

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 Illicite 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 :

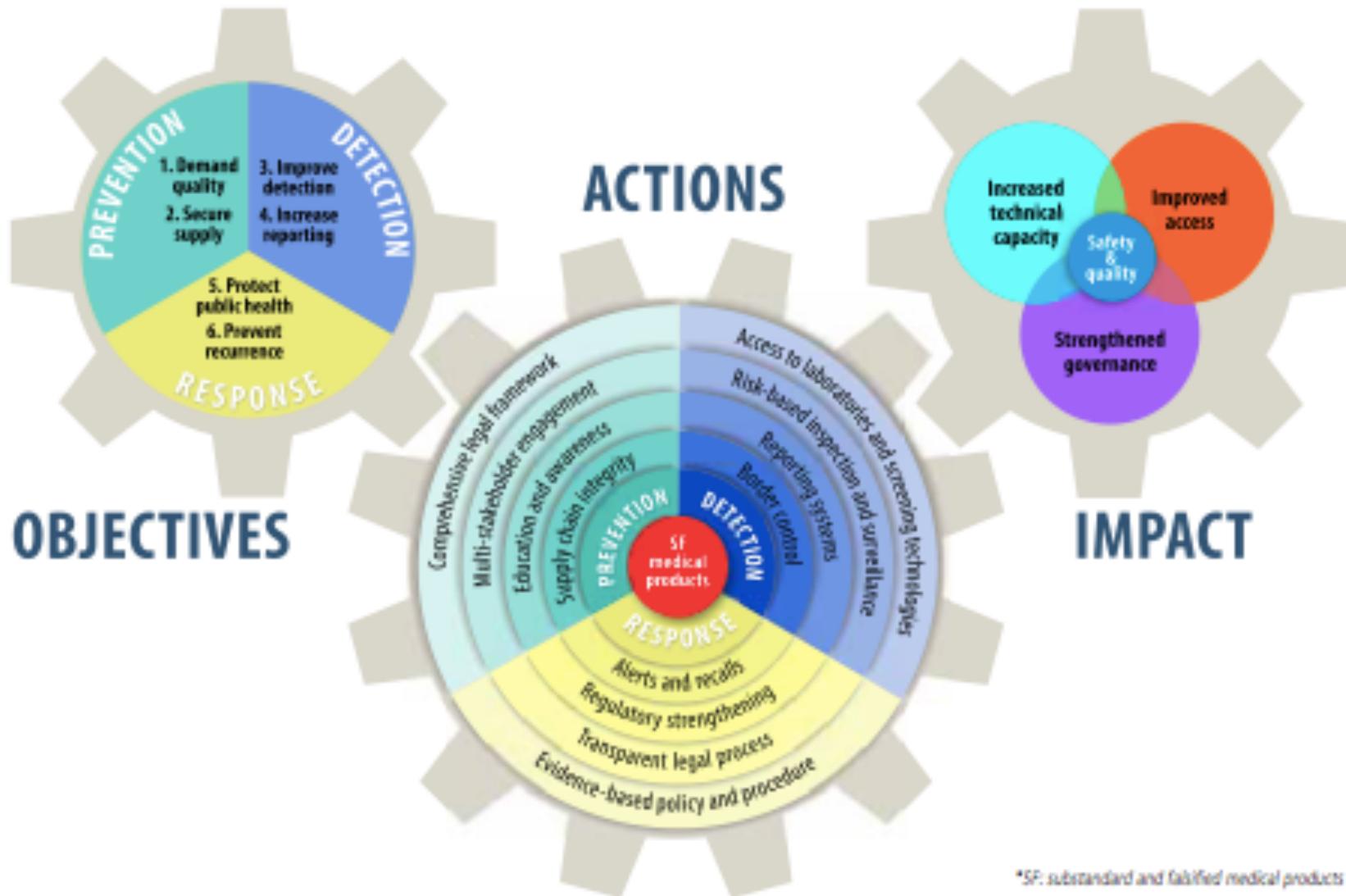
hospitals, doctors, researchers

Civil society :

NGOs & patients' associations

Diverging IO's responses : WHO Global Surveillance and Monitoring System

FIG. 21: PUTTING PREVENTION, DETECTION AND RESPONSE INTO MOTION



Source : WHO, 2017, *WHO Global Surveillance and Monitoring System for substandard and falsified medical products*. Geneva, World Health Organization.

Diverging IO's responses : Interpol



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.



Diverging IO's responses : Interpol

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 1st operation involving their common member countries. The operation will target counterfeit and illicit vaccines, medicines and medical devices and their use across Africa.

Diverging IO's responses : European institutions

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**

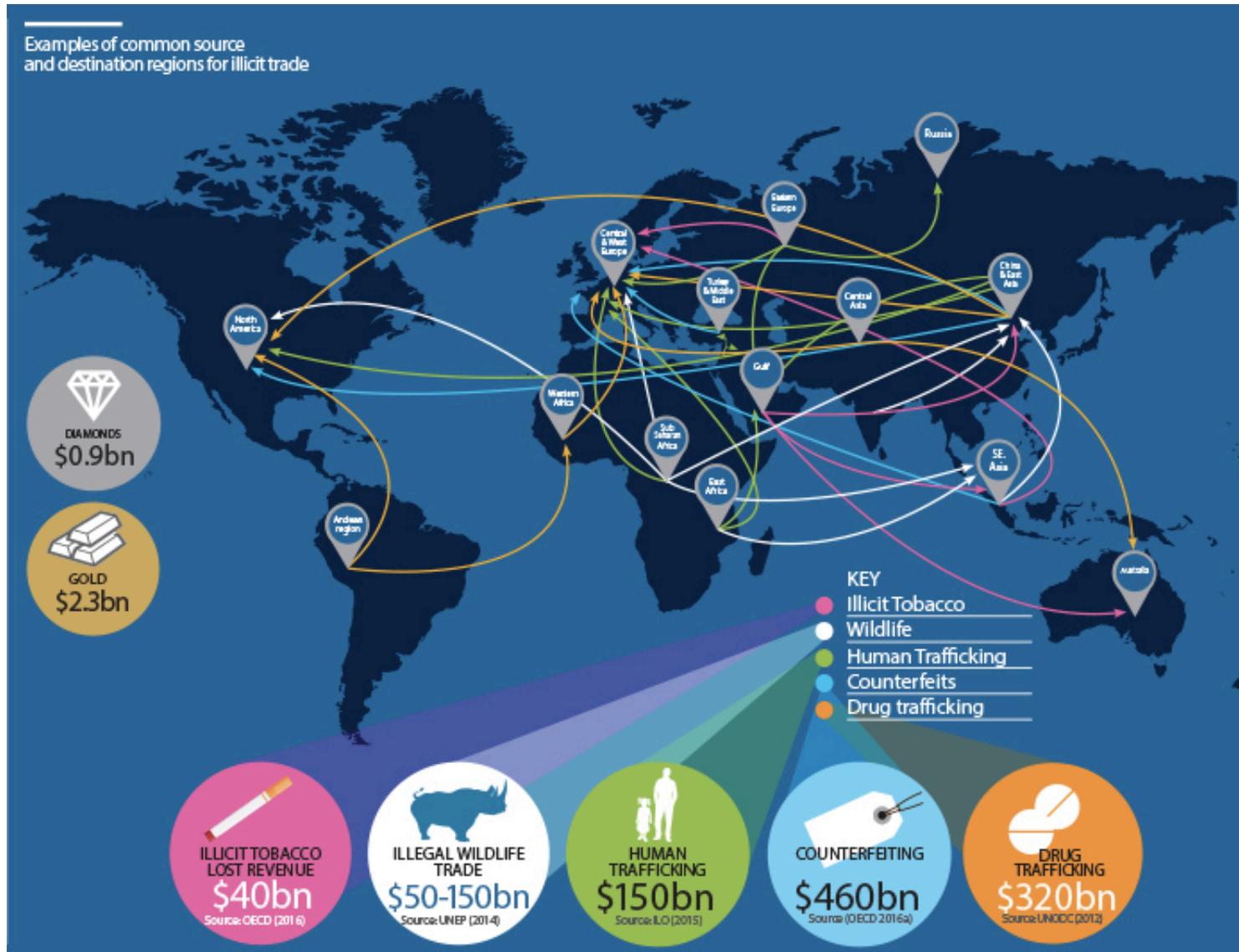
aims to prevent counterfeit medicines entering the legal supply chain

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)

Mapping illicit trade



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) ?

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Thanks for your attention !