

The devastating scale and human impact of fake medicines

Oksana Pyzik

Associate professor (teaching), practice & policy at UCL School of Pharmacy; and Academic / youth group chair, Fight the Fakes Alliance



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The Devastating Scale & Human Impact of Falsified Medical Products

Oksana Pyzik MPharm FHEA

Associate Professor Pharmacy Practice & Policy UCL School of Pharmacy



Fight the Fakes Academic Chair UCL Fight The Fakes Lead <u>o.pyzik@ucl.ac.uk</u> @OksanaPyzikUCL



What is a falsified medicine?

World Health Organization Definitions of Substandard and Falsified (SF) Medical Products Seventieth World Health Assembly update, 29 May 2017

Substandard

Also called "out of specification", these are authorised medical products that fail to meet either their quality standards or specifications, or both.

Unregistered/Unlicensed

Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified

Medical products that deliberately/ fraudulently misrepresent their identity, composition or source.



Growing Global Threat 1 in 10

FIGH

of all falsified medicines detected in the supply chain are related to life-saving treatments. **150 countries** affected.

52.8% 5200-432 billion

or falsified

Estimated size of the global falsified medicine market



medicines in LMICs are substandard

OECD & EUIPO. (2020). Trade in counterfeit pharmaceutical products. OECD Publishing. https://doi.org/10.1787/a7c7e054-en

Deaths Attributed to SFs

Up to **267k**

Annual deaths from malaria in Sub-Saharan Africa



200 Children died from SF cough syrup manufactured in Indonesia, 70 in The Gambia, 65 in Uzbekistan.

About **170K**

Annual deaths of children from falsified pneumonia medicine in Sub-Saharan Africa



1240 Of Antibiotics in LMICs were found to be SFs contributing to antimicrobial resistance (AMR).

Ozawa, S., Evans, D.R., Bessias, S., Haynie, D.G., Yemeke, T.T., Laing, S.K., & Herrington, J.E. (2018). "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, 1(4), e181662.https://doi.org/10.1001/jamanetworkopen.2018.1662



Harmful Impacts on Everyone





SFMP Distribution: LMIC VS HIC



LMIC

-Higher prevalence, average SFMP **10.5% up to 33%** in some regions e.g., Sub-Saharan Africa).

-More likely to infiltrate legal supply chains in regions with fragmented/ weak regulation.

-Commonly found in open markets, street vendors, unlicensed pharmacies.

HIC

- -Lower prevalence in HIC legal supply chain.
- Often enter via **illegal online pharmacies, dark web & social media** marketplaces

-High-demand medications e.g.,GLP-1 agonists, hormonal therapies, biologics and cancer medications.



Examples – "The more one looks, the more one finds"

- WHO issued global alert for falsified Ozempic in the legal supply chain identified in the US, UK & Brazil in 2024.
- MHRA seized **869** fake Ozempic pens since 2023.
- Many patients unaware of Rx requirements or how to verify online pharmacies.
- Public perception skewed by celebrity endorsements – seen as "lifestyle" product vs. regulated medication.
- Healthcare providers also show low awareness of verification methods.



Other examples include cancer medications, antihypertensives, OTCs & antibiotics – essentially *ALL medicine classes have been reported.*

Online Pharmacy (DSP) Trends in the UK



Source: <u>NHS Business Services Authority freedom of</u> <u>information request response (FOI-01635, FOI-31001, and FOI-22304)</u> •

- The number of items dispensed by DSPs in England **quadrupled** with **a 301% increase** between 2016- 2021.
- 6% of all Rx items are dispensed by DSPs in England.
- # of Brick & mortar pharmacies declining - net loss of 1,223 bw 2019 – 2024 in England.
- In the US, 7,000 pharmacies have closed since 2019.



Which one is fake?



Image courtesy of NovoNordisk

HCP Training needs - Online Risks SFMPs

- 44% of UK adults aged 18–30 years old have bought medicines online.
- Pharmaceutical crime incidents are up 38% from 2020 (PSI).
- 58% of Pharmacists lack confidence in advising patients about illegal online pharmacies.







Nearly 95% of websites offering prescription-only drugs online operate illegally. 96% of illegal online pharmacies reviewed by NABP did not require a valid prescription for the sale of prescription-only medicine.



24% of Americans who have used an online pharmacy have been exposed to harmful, counterfeit, or substandard medication, according to <u>ASOP</u>.

SFMP Solutions

- Increased Education & Training (all across supply chain HCP + law enforcement, border control etc).
- Increased public awareness through campaigns such as Fight the Fakes
- Harmonised Legislation (MEDICRIME)
- Social Media / Tech companies held accountable. Google demoting tactics.
- Track & trace FMD approach.
- Application of GS1 standards globally





Fight the Fakes Alliance

Fight the Fakes Alliance is an inclusive **multi-stakeholder non-profit ssociation** including partners from across the medicines **supply chain**, that raise awareness about the dangers and the impact of fake and substandard medicines.



UCL

Fight the Fakes Alliance Mission *stronger together*:

- *Raise awareness* about the dangers of SF medicines to the public.
- Give a voice to victims who have been personally impacted.
- **Build a global movement** of organizations and individuals against fake medicines multi-stakeholder alliance.
- Advance regulatory policies against SF medical products.



More Reasons to Get Involved



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The first line of defense starts with you

Every healthcare and supply chain professional can be part of the solution

SF knows no boundaries

No disease or therapeutics areas are immune from SFs. They also spread widely across frontiers



Take a stand and prioritise quality and safety of lives, in line with your professional identity



Your support can catalyze others to follow the lead and creat co-financed impact opportunities

Thank You! JOIN US NOW!

FIGHT THE



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@FightTheFakes



www.fightthefakes.org



Secretariat@FightTheFakes.org