

Maintaining **medicine quality** while aiming for **Universal Health Coverage: *a political economy perspective***

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Background

global attention to medicine quality in

UHC

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UHC



“ There is no universal health coverage, no health security **without access to quality medicines.** ”

Dr. Tedros Adhanom Ghebreyesus
Director-General
WHO

*As quoted in the **Oxford Statement: A Call for Global Access to Quality-Assured Medical Products***

#MedsWeCanTrust

What falls into the category of poor-quality medicines?

Source:

1) <https://iris.who.int/bitstream/handle/10665/332635/WHO-MVP-EMP-SAV-2019.04-eng.pdf?sequence=1>

What falls into the category of **poor-quality medicines?**



SUBSTANDARD

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



FALSIFIED

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



UNREGISTERED/ UNLICENSED

Medical products that have not undergone evaluation and/or approval by the national and/or regional regulatory authorities for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

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Standard and falsified medicines (SFM) can potentially harm patients & health system globally



Sources:

- 1) WHO (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products. Report.
- 2) Ozawa et al. (2019). Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: a systematic review and meta-analysis. *PLoS One*.

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10.5% of the 48,000 analyzed medical products, collected in 88 low- and middle-income (LMICs), failed at least 1 quality test¹

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Substandard and falsified medicines (SFM) can potentially harm patients & health system globally



10.5% of the 48,000 analyzed medical products, collected in 88 low- and middle-income (LMICs), failed at least 1 quality test¹

Prevalence of substandard & falsified medicines in low- and middle-income (LMICs) was overall 13.6% (19.1% for antimalarials & 12.6% for antibiotics)²

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1) WHO (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products. Report.
2) Ozawa et al. (2019). Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: a systematic review and meta-analysis. *PLoS One*.

Why is the quality of medicine essential in achieving UHC?

- A country with an existing UHC scheme also struggles with SFM
 - Ozempic case in high-income countries (2023-2024)
 - Falsified vaccine case in Indonesia (2016)

Sources:

1 Hasnida et al. (2021). Challenges in maintaining medicine quality while aiming for universal health coverage: a qualitative analysis from Indonesia. *BMJ Global Health*
2 Valente de Almeida et al. (2024). Value for money for medicine sampling and quality testing: evidence from Indonesia. *BMJ Global Health*

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Novo's Weight-Loss Drug Demand Fuels Rise in Illegal Sales

Sanne Wass, Bloomberg News



Packets of Ozempic move along a conveyor at the Novo Nordisk A/S production facilities in Hillerød, Denmark, on Tuesday, Sept. 26, 2023. Novo's Ozempic and Wegovy injectable drugs, a class of medicines known as GLP-1s, have been causing ripple effects across the stock market, for the makers of everything from snacks to booze. . Bloomberg

(Bloomberg) -- Growing demand for Novo Nordisk A/S's weight-loss and diabetes drugs is fueling a rise in illegal sales in its home country of Denmark, where authorities are now seeking to clamp down on the illicit activity.

The Danish Medicines Agency has reported to police 26 websites which claim to sell products such as Novo's Ozempic and Wegovy as well as potency drugs. The websites aren't approved to sell medicines and there are no guarantees the products are legitimate, the agency said in a statement.

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 - Affordability: price-pressure on medicines
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 - Availability: shortage

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- Expensive costs of medicine quality testing

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Ensuring medicine quality in a nation of 17,500 islands



Sources:

- 1) Statistics Indonesia (2021). Indonesia population census results in 2020
- 2) Cek BPOM (2023).
- 3) Pharmaboardroom (2017). Healthcare and sciences review: Indonesia
- 4) WHO SEARO (2019)

Ensuring medicine quality in a nation of 17,500 islands



- Total population: 278.8 millions¹
- Registered medicines & vaccines: 24.703²
- Registered pharmaceuticals companies: 225 (88% domestic)³
- Out-of-pocket spending on medicines: 37% (private) & 63% (public sector)⁴

Sources:
1) Statistics Indonesia (2021). Indonesia population census results in 2020
2) Cek BPOM (2023).
3) Pharmaboardroom (2017). Healthcare and sciences review: Indonesia
4) WHO SEARO (2019)



Main research question:

What can we learn from a political economy approach and how does it shape the efforts in tackling substandard and falsified medicines (SFM) while aiming for UHC?

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- Conducting mixed-method research with a participatory approach of stakeholders e.g., medicine regulators, MoH, procurement agencies (2018-2023)
- Focus on the private sector e.g., retail pharmacies, drug stores, online webstores

What are the **insights** from taking a political economy perspective?

Research findings

#1: Political & economic factors can drive production & trade of SFM differently

Sources:

- 1 Pisani et al. (2019). Identifying market risk for substandard and falsified medicines: an analytic framework based on qualitative research in China, Turkey, Romania. *Wellcome Open Research*
- 2 Hasnida et al. (2021). Challenges in maintaining medicine quality while aiming for universal health coverage: a qualitative analysis from Indonesia. *BMJ Global Health*

#1. Political & economic factors can drive production & trade of SFM differently

Substandard medicines

Pressure on profit margins incentivizes cost-cutting

Limited technical capacity

Limited oversight



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Falsified medicines

Shortages, market opportunity for falsification

Falsifiers can make a (huge) profit

RISK OF punishment is low



#2: Out-of-specification antibiotics were found in regulated and unregulated channels

Source:

Hasnida et al. (2025). Assessing the quality of amoxicillin in the private market in Indonesia: a cross-sectional survey exploring product variety, market volume, and price factors. *BMJ Open* (accepted for publication)

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Oral Solid Dosage Forms			
By sampling regions			
Regions	Total samples collected (N=110)	Meet specification	Out-of-specification (OOS)
Jakarta	29	25 (86.2%)	4 (13.8%)
East Java	34	31 (91.2%)	3 (8.8%)
Bekasi	18	15 (83.3%)	3 (16.7%)
Online	15	13 (86.7%)	2 (13.3%)
East Nusa Tenggara (NTT)	14	14 (100%)	0 (0%)
By types of outlets			
Outlets	Total samples collected (N=110)	Meet specification	Out-of-specification (OOS)
Pharmacies	66	58 (87.9%)	8 (12.1%)
Drug stores*	25	23 (92%)	2 (8%)
Health providers (i.e., physicians & midwives)*	4	4 (100%)	0 (0%)
Online vendors*	15	13 (86.7%)	2 (13.3%)
Dry Syrup Dosage Forms			
By sampling regions			
Regions	Total samples collected (N=10)	Meet specification	Out-of-specification (OOS)
Jakarta	6	5 (83.3%)	1 (16.7%)
Bekasi	4	2 (50%)	2 (50%)
By types of outlets			
Outlets	Total samples collected (N=10)	Meet specification	Out-of-specification (OOS)
Pharmacies	5	2 (40%)	3 (60%)
Drug stores*	5	5 (100%)	0 (0%)

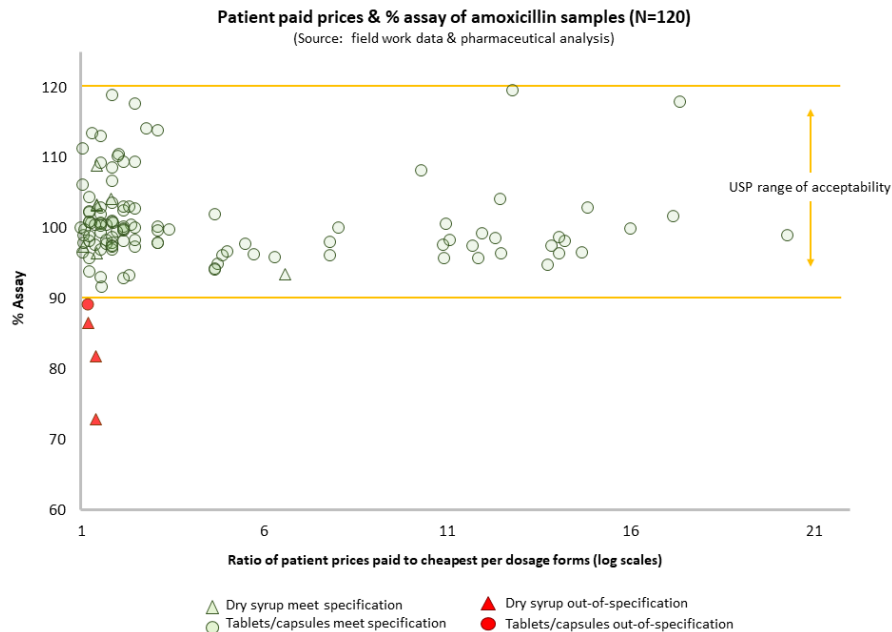
*Unlicensed outlets to sell antibiotics

there is no relation between medicine price & quality

Source:

Hasnida et al. (2025). Assessing the quality of amoxicillin in the private market in Indonesia: a cross-sectional survey exploring product variety, market volume, and price factors. *BMJ Open* (accepted for publication)

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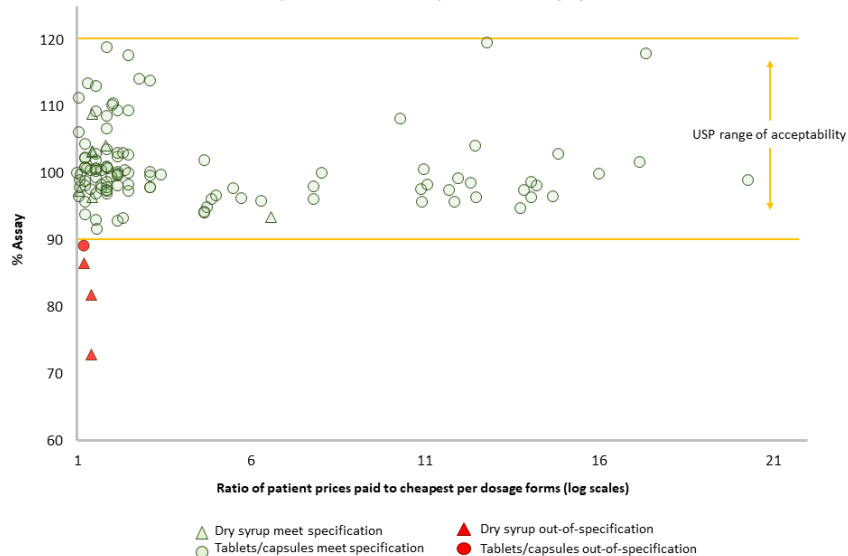
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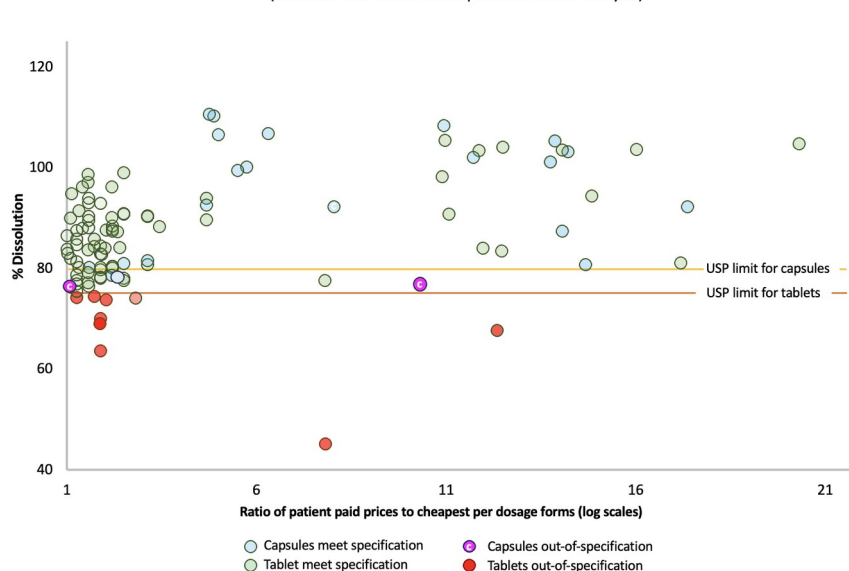
Patient paid prices & % assay of amoxicillin samples (N=120)

(Source: field work data & pharmaceutical analysis)



Patient paid prices and % dissolution of amoxicillin samples (N=110)

(Sources: field work data & pharmaceutical analysis)



Source:

Hasnida et al. (2025). Assessing the quality of amoxicillin in the private market in Indonesia: a cross-sectional survey exploring product variety, market volume, and price factors. *BMJ Open* (accepted for publication)



**How to move forward
to maintaining
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How to **move forward** to **maintaining** **medicine quality** while **aiming for UHC?**

Intersectoral collaboration

research

...including in

research collaboration greatly benefits from stakeholder engagement



Source: STARmeds documentations



research collaboration

greatly benefits from stakeholder engagement

- Case study: co-creation of a method to estimate the prevalence of substandard and falsified medicines (STARmeds project, 2020-2023)



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research collaboration greatly benefits from stakeholder engagement

- Case study: **co-creation** of a method to estimate the prevalence of substandard and falsified medicines (STARmeds project, 2020-2023)
- Examples of: **collaboration** between academic researchers & stakeholders across sectors



Source: STARmeds documentations

Source:

Hasnida et al. (2025). Making intersectoral stakeholder engagement in medicine quality research work: lessons from the STARmeds study in Indonesia. **Health Research Policy and Systems**



research collaboration

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- Case study: **co-creation** of a method to estimate the prevalence of substandard and falsified medicines (STARmeds project, 2020-2023)
- Examples of: **collaboration** between academic researchers & stakeholders across sectors
- The values of stakeholder engagement in a **collaborative intersectoral research**:
 - aligns different perspectives
 - forges a collaborative network
 - informs the research team about policy & societal relevance of subject
 - inspires the stakeholders to use routinely collected data



Source: STARmeds documentations



Four concluding remarks

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- Medicine quality is a shared responsibility among actors & institutions across sectors

Four concluding remarks

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- Political and economic factors can drive production, distribution, and consumption of substandard & falsified medicines
- Quality is intertwined with other areas in pharmaceutical policies e.g., availability, affordability, and irrational use of medicines
- Medicine quality is a shared responsibility among actors & institutions across sectors – *how can we foster and sustain intersectoral collaboration in the policy environment?*

Terima Kasih

PhD Supervisors:

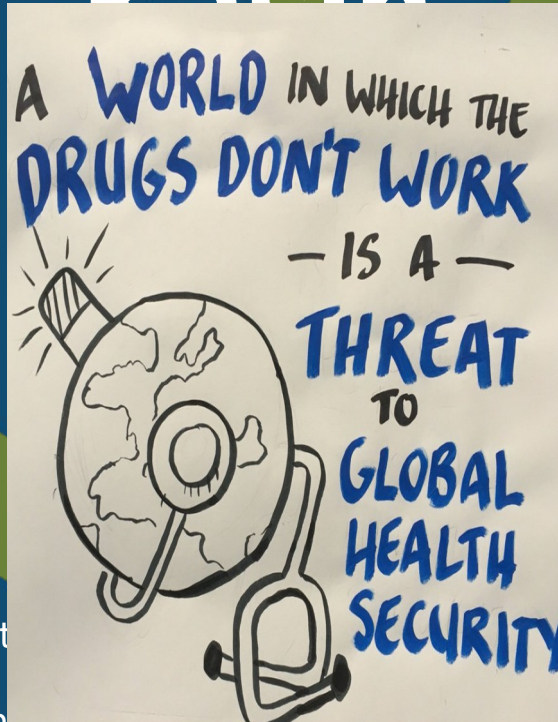
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Twitter: Prof. Dame Sally Davies



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