Session #4 Technology and Collaboration for Global Health

Part 1: Technology

Session #4 Technology and Collaboration for Global Health
WHO's support for traceability of medical products

Anita Sands
Incidents and Substandard/Falsified Medical Products Team
Regulation and Prequalification Department

Use cases for traceability

1. Prevent, detect, respond to substandard/falsified medical products
2. Corrective action through market recalls
3. Maintaining supply chain integrity
4. Pharmacovigilance
5. Reimbursement

WHO Member State mechanism on substandard/falsified medical products

Working group on traceability as prioritized activity J

Annual technical briefings on traceability

- Nepal, Botswana, Nigeria
- Using global and national standards to enable traceability

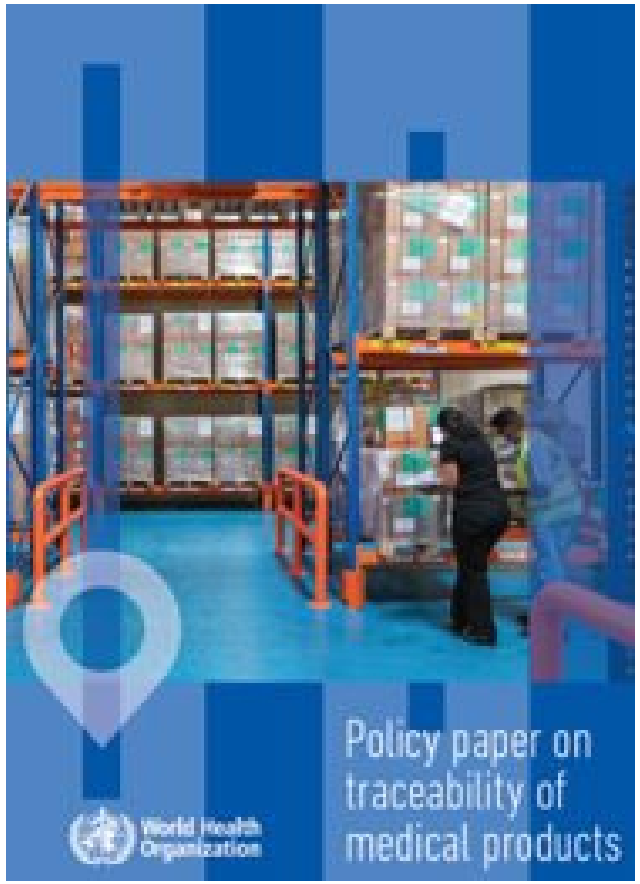
WHO | Substandard and falsified medical products

Supporting implementation of traceability

Challenges

- Technology at key points in the supply chain (ports of entry, distribution centres, remote pharmacies)
- Technical knowledge
- Funding

[Policy paper on traceability of medical products]
[Health topic on SF medical products]



Recommendations from 19th ICDRA

Recommendations to Member States

- Promote use of harmonized and interoperable global standards for medical product traceability
- Update regulatory frameworks to enable and enforce traceability of medical products

Recommendations to WHO

- Update and expand WHO guidance on harmonized product identification, labelling and data exchange standards
- Facilitate traceability gap analysis and promote best practices through knowledge exchange

Takeaway messages

- Ensure traceability is enshrined in regulatory frameworks
- Use internationally recognized standards for data capture and exchange
- Ensure readiness and plan for capacity building
- Consider phased implementation

Session #4 Technology and Collaboration for Global Health
TRVST by UNICEF

Max Kabalisa
Manager, Digitalization and Traceability
Supply Chain Strengthening Centre (SCSC)
Supply Division, UNICEF

The Verification and Traceability Initiative's (VTI) goal is to support countries in their verification and traceability journey

VTI Steering Team

Gavi The Vaccine Alliance

unicef

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL NAFDAC

RWANDA FDA Rwanda Food and Drugs Authority

European Commission

USAID FROM THE AMERICAN PEOPLE

BILL & MELINDA GATES foundation

THE GLOBAL FUND

THE WORLD BANK

UNICEF is the legal entity behind TRVST

Rationale for the VTI

Detect and reduce falsification

Enhance **supply chain visibility and efficiencies**

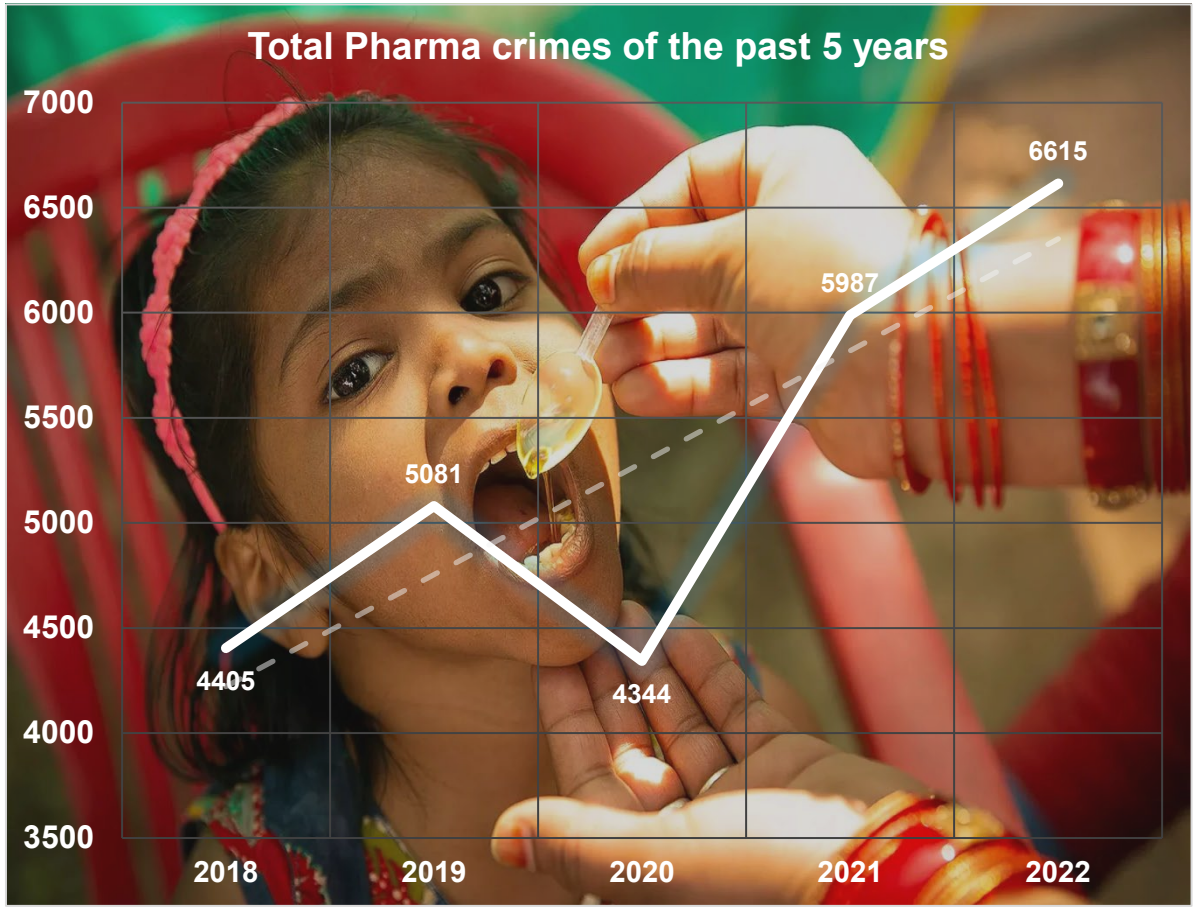
Deliver **digital equity** in LMICs

Promote and **use standards** for product identification, capture and share.

TRVST Logo © UNICEF for the TRVST All rights reserved 2024.

The Verification and Traceability Initiative was created to address the impact of falsified and diverted products

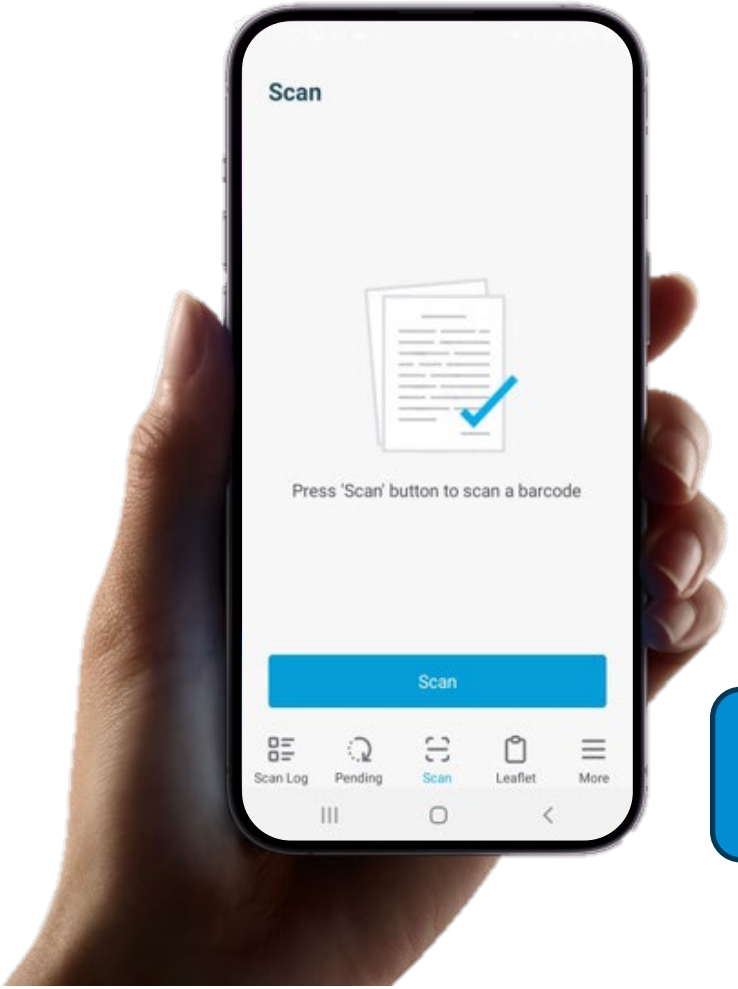
$30.5 Bn	Falsified vaccines and medicines cost LMICs $30.5 billion per year.
10.5%	Falsified products accounted for 10.5% of medicines sampled in the supply chain in these countries.
169,000	Estimated 72K –169K deaths caused by substandard and falsified antibiotics in children under 5 suffering from pneumonia*
116,000	Estimated 31K – 116K deaths caused by substandard and falsified antimalarials in sub-Saharan Africa*



Sources:
The WHO Member State Mechanism on Substandard and Falsified Medical Products Update 2022
* Public health and socioeconomic impact study 2017 https://apps.who.int/iris/handle/10665/331690
* University of Edinburgh

RVST Logo © UNICEF for the TRVST All rights reserved 2024.

WHAT IS TRVST (pronounced as “trust”)



Traceability and Verification System

Detect and reduce falsified medicines in LMICs

Increase supply chain visibility and traceability

Provide electronic leaflets

Promote the use of GS1 standards

Designed and deployed in partnership with countries, manufacturers and donor organisations

A platform to increase knowledge and experience of traceability, bringing digital equity to LMICs

Session #4 Technology and Collaboration for Global Health Addressing Shortages of medicines, vaccine and health products

Lisa Hedman hedmanl@who.int
Karen Kreidi kreidic@who.int
Tim Kempster kempstert@who.int
Peter Thanisch peter.thanisch@tuni.fi
Eystein Thanisch epthanisch@gmail.com

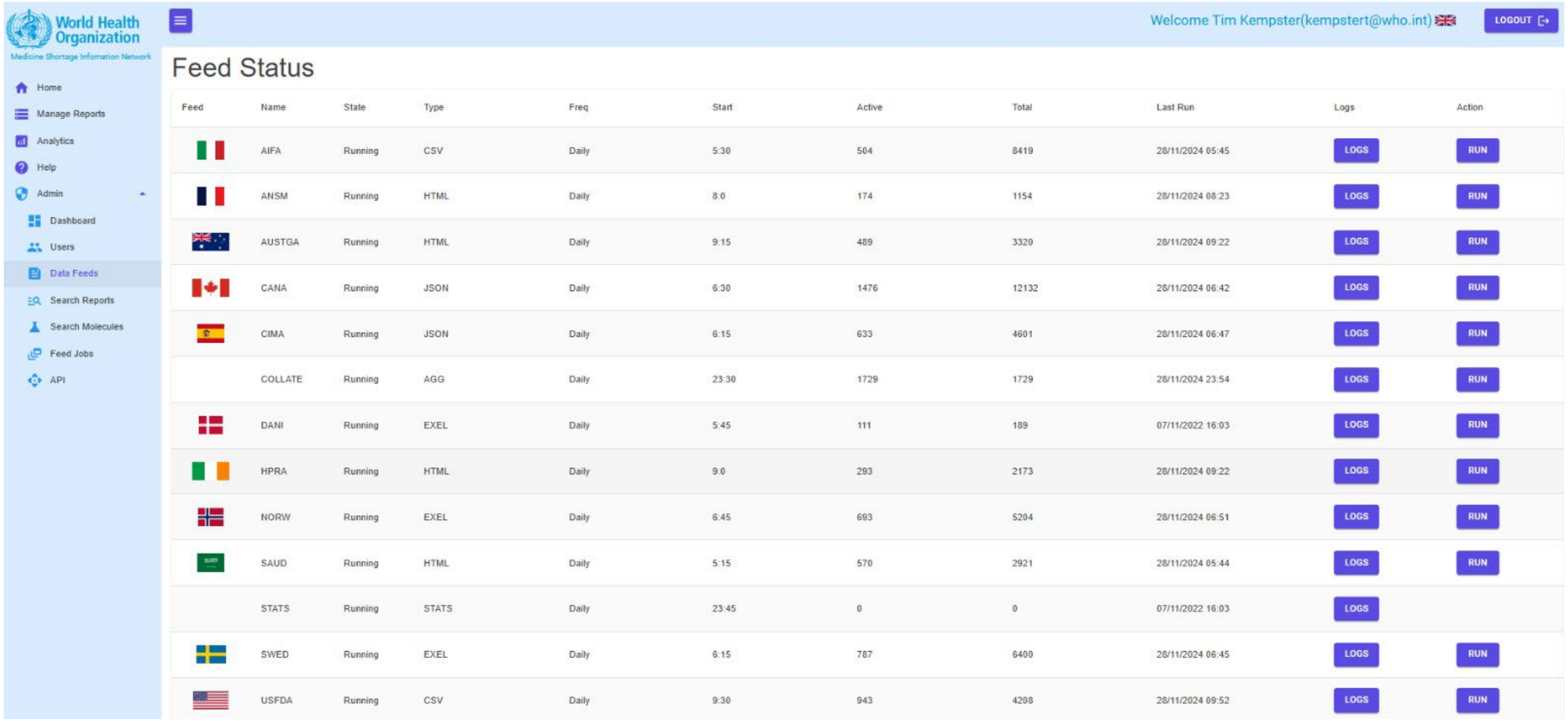
42,606 reports since Sept 2021

Since September 2021 the number of essential medicines shortage reports affecting two or more countries has increased 78%

Category	2021	2024	increase in # of reports collected and analyzed:
Total reports	3438 (report)	7026 (report)	
Total molecules (in the reports)	1204 (molecules)	1817 (molecules)	
Molecules on the Essential Medicines Lists (EML)	254 (molecules)	365 (molecules)	44%
Molecule reported shortages in 2+ countries	338 (molecules)	664 (molecules)	96%
Multi-country (Essential Medicines)	113 (molecules)	201 (molecules)	78%

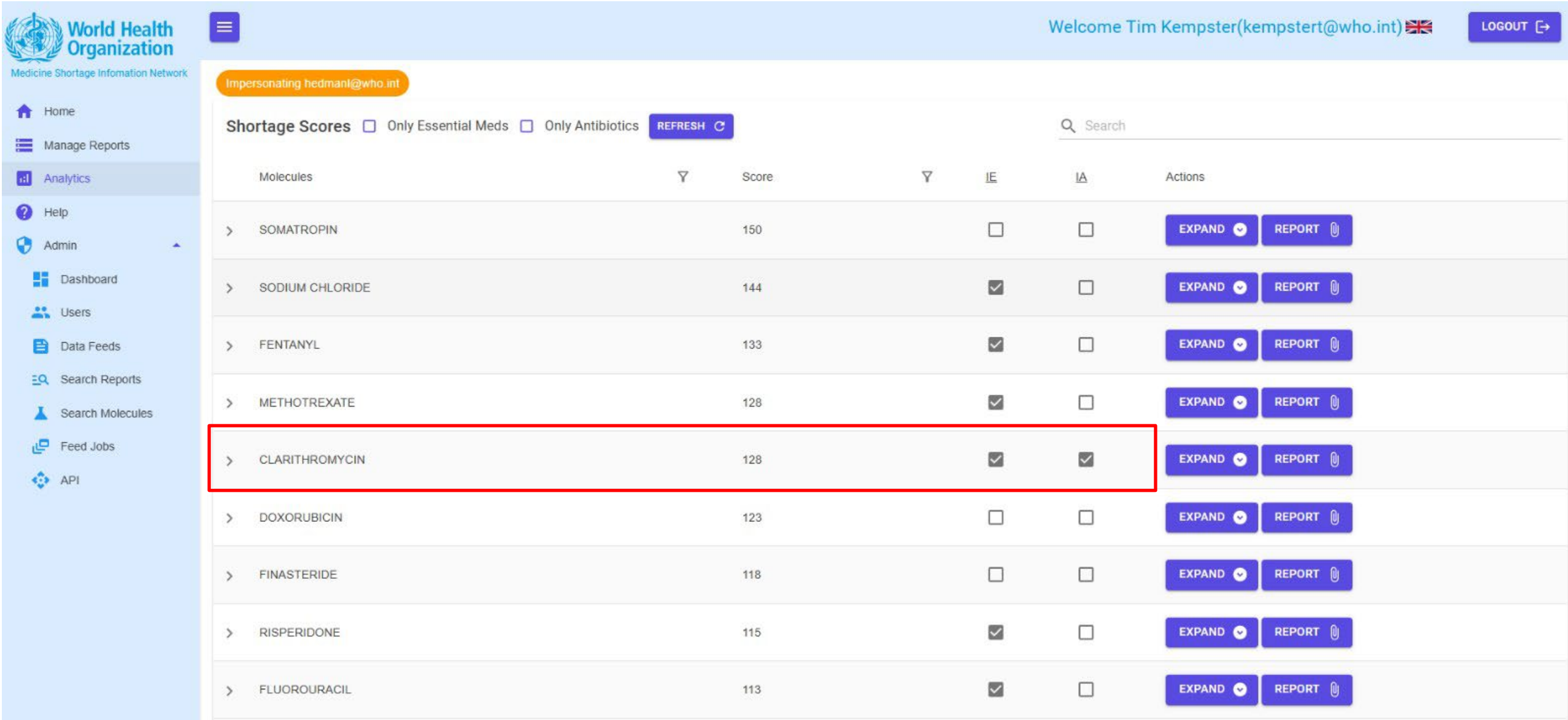
Shortages are dynamic, occuringat any time for a number of reasons.

Pulling publicly available country shortage data



Feed	Name	State	Type	Freq	Start	Active	Total	Last Run	Logs	Action
	AIFA	Running	CSV	Daily	5:30	504	8419	28/11/2024 05:45	LOGS	RUN
	ANSM	Running	HTML	Daily	8:0	174	1154	28/11/2024 08:23	LOGS	RUN
	AUSTGA	Running	HTML	Daily	9:15	489	3320	28/11/2024 09:22	LOGS	RUN
	CANA	Running	JSON	Daily	6:30	1476	12132	28/11/2024 06:42	LOGS	RUN
	CIMA	Running	JSON	Daily	6:15	633	4601	28/11/2024 06:47	LOGS	RUN
	COLLATE	Running	AGG	Daily	23:30	1729	1729	28/11/2024 23:54	LOGS	RUN
	DANI	Running	EXEL	Daily	5:45	111	189	07/11/2022 16:03	LOGS	RUN
	HPRA	Running	HTML	Daily	9:0	293	2173	28/11/2024 09:22	LOGS	RUN
	NORW	Running	EXEL	Daily	6:45	693	5204	28/11/2024 06:51	LOGS	RUN
	SAUD	Running	HTML	Daily	5:15	570	2921	28/11/2024 05:44	LOGS	RUN
	STATS	Running	STATS	Daily	23:45	0	0	07/11/2022 16:03	LOGS	
	SWED	Running	EXEL	Daily	6:15	787	6400	28/11/2024 06:45	LOGS	RUN
	USFDA	Running	CSV	Daily	9:30	943	4208	28/11/2024 09:52	LOGS	RUN

Scoring of shortages based on severity



Case Study: Clarithromycin

World Health Organization
Medicine Shortage Infomation Network

Welcome Tim Kempster(kempstert@who.int) LOGOUT

- Home
- Manage Reports
- Analytics
- Help
- Admin
  - Dashboard
  - Users
  - Data Feeds
  - Search Reports
  - Search Molecules
  - Feed Jobs
  - API

CLARITHROMYCIN SHORTAGE SCORE: 128

BACK TO ANALYSIS | FILE REPORT

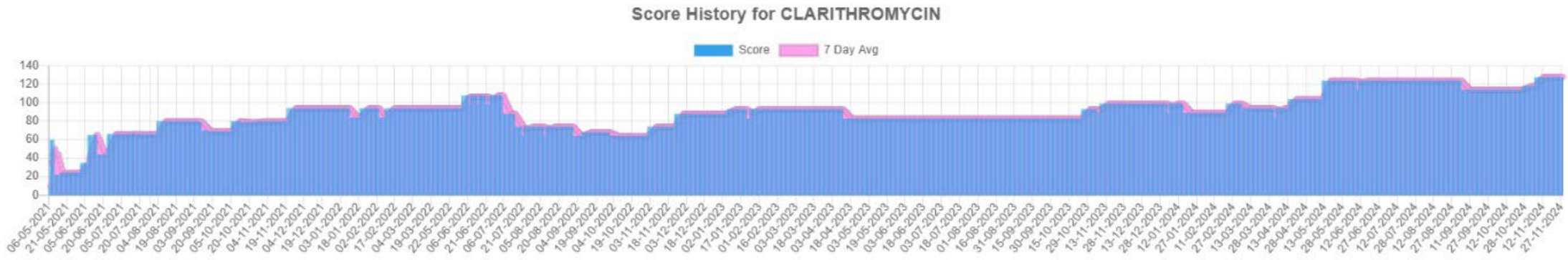
Qualification

For at least 3/8 of the countries reporting, this shortage has already started (i.e., it is not just a possible future shortage).
For at least 6/8 of the countries reporting, this shortage is occurring at the national level.
For at least 1/8 of the countries reporting, no therapeutic alternatives for this medicine are available.
For at least 3/8 of the countries reporting, the root cause is upstream in the pharmaceutical supply chain
The medicine shortage might just consist of reduced availability.

Score Reason

+10 [for total number of reports (max 10)]
+80 [+10 for each 8 distinct feed]
+30 [+10 for each 3 distinct regions greater than 1]
+8 [+4 for each 2 times that RootCause = SuddenIncreaseInDemand found in any feed (max 15)]

☑ Antibiotic ☑ Essential Medicine



Current Active Shortage Reports for CLARITHROMYCIN Used To Construct Score

A more detailed view of the shortage reported: Case Study Clarithromycin

unicef | UNFPA | World Health Organization

Organization
Medicine Shortage Information Network

Welcome Tim Kempster(kempstert@who.int) LOGOUT

- Home
- Manage Reports
- Analytics
- Help
- Admin
  - Dashboard
  - Users
  - Data Feeds
  - Search Reports
  - Search Molecules
  - Feed Jobs
  - API

Current Active Shortage Reports for CLARITHROMYCIN Used To Construct Score

CLARITHROMYCIN | 500.0 Miligram | SolutionForInjection | Essential | ✓

Start Date: 2023-10-03 • **End Date**: 2025-03-30 • **Duration**: _180to365Days • **Description**: CLARITROMICINA ALTAN 500 mg LIOFILIZADO PARA SOLUCION PARA PERFUSION EFG

PRESENTATION | TYPE/CAUSE | REGIONS AFFECTED | ACTIONS TAKEN | DATA ORIGIN | CODES/CATEGORIES | HISTORY

Description: CLARITROMICINA ALTAN 500 mg LIOFILIZADO PARA SOLUCION PARA PERFUSION EFG
Manufacturer:: Altan Pharmaceuticals Sa
Ref: 664607(71852)

CLARITHROMYCIN | 250.0 Miligram | Tablet | Essential | ✓

Start Date: 2023-04-12 • **End Date**: 2024-11-15 • **Duration**: _180to365Days • **Description**: Clarithromycin 250mg Film-Coated Tablets

CLARITHROMYCIN | 500.0 Miligram | Tablet | Essential | ✓

Start Date: 2024-07-03 • **End Date**: 2024-12-03 • **Duration**: _90to180Days • **Description**: CLARITROMICINA SANDOZ 500 mg COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG

CLARITHROMYCIN | 500.0 Miligram | Tablet | Essential | ✓ | Alt Avail

Start Date: 2024-02-27 • **End Date**: 2025-02-02 • **Duration**: _180to365Days • **Description**: Clarithromycin Accord 500 mg tablett, filmdrasjert, 14 stk blisterpakning

CLARITHROMYCIN | 500.0 Miligram | SolutionForInfusion | Essential | ✓ | Alt Avail

Start Date: 2023-01-16 • **End Date**: 2025-07-18 • **Duration**: _180to365Days • **Description**: CLARITROMICINA ALTAN

Session #4 Technology and Collaboration for Global Health
WHO's support for traceability of medical products

Part 2: Collaboration and Partnership

INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

unicef | UNFPA | World Health Organization

Panel 2: Collaborations, quality assurance and supply chain, assessments, outcomes of national procurement systems.

Understanding the gaps and shortages of essential medicines.

David Jauch
VP Government Affairs
Fresenius Kabi

On partnerships

In today's complex world there is not a 'one size fits all' solution and the understanding the perspectives of all people is essential to develop effective solutions for healthcare access.

For partnerships and collaborations to be successful they require commitment and the identification of practical targets that are fit for purpose over time.

Importantly, successful partnerships require trust and open and regular dialogue – communications that share perspectives, learnings, challenges and approaches to solutions

Procurement

Some issues include:

- In most countries around the world, there has been a consolidation of how products are purchased.
- In some cases, this consolidated procurement has been pursued with one objective, which is to lower prices with limited consideration for security of supply.
- Current overemphasis on pricing strategies has left aside pro-competition policies.

Proposed way forward

These may include:

- Exploration of complementary policies to encourage manufacturing and the diversification of supply chain
- It would make sense to consider ways to de-consolidate and to diversify supply chain to avert risk of manufacturing supply chain consolidation
- Procurement incentives are necessary to support continued investment in manufacturing.
- Consolidated diversified criteria and supply with long term agreements
- **Market predictability and viability** are essential to secure supply of medicines.

INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Thank you

info@igbamedicines.org

www.igbamedicines.org