

# MedSIN

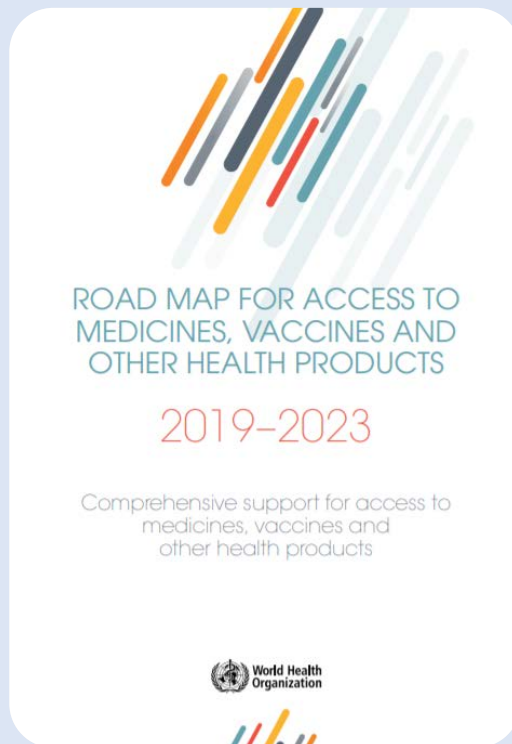
Medicine Shortage  
Intelligence Network



# World Health Assembly and Global Program of Work

## Shortages are a constant concern, especially in emergencies

- 69<sup>th</sup> World Health Assembly Resolution 69.25  
“Addressing the Problem of Shortages and Stock  
outs of Medicines and Vaccines” including specific  
call outs to the WHO Secretariat and to Member  
States.
- Calls out to WHO and Member States to improve  
supply chain data availability and **reporting  
mechanisms** to improve visibility and solutions.
- <https://www.who.int/publications/i/item/9789241517034>
- [https://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R25-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R25-en.pdf)



There is no “one size fits all:  
*An example of a current shortage*

Off-patent (generic) antibiotics were in critical shortage in 2022.

Demand peak was anticipated with increased post-mask cold and flu season, but the severity with more “naïve” patients was not.

The shortage is anticipated to persist in 2023-2024 countries that report. But what about countries that do not have visibility?



Visibility of shortages at manufacturing levels is limited. Most information comes from 35+ regulators in HICS. Short term advice may be included, e.g., substitutions.



Information from LMICs currently depends more on supply chain data. Currently, there is little visibility.



Initiatives of regulators from HICs will not capture LMIC issues e.g., regionally segmented, generic markets with high dependency on wholesale markets.



Data from LMICs sensitive, and there are barriers to sharing e.g., hoarding, price gauging, and increased SF medicines when shortage information is abused.

# What information is collected and how is it useful

Cisplatin example: increased demand caused a shortage and regulator authorizes temporary alternate source

<https://www.fda.gov/media/169001/download>

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**IMPORTANT PRESCRIBING INFORMATION**

May 24, 2023

**Subject: Temporary Importation of Cisplatin Injection with non-U.S. Labeling to Address Drug Shortage**

Dear Healthcare Professional,

Due to the critical shortage of Cisplatin Injection in the United States (U.S.), Qilu Pharmaceutical Co. Ltd (Qilu), in conjunction with Apotex Corp., is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug. Qilu has initiated temporary importation of Cisplatin Injection (50 mg/50 mL) with vial and carton labels in Chinese into the U.S. market. The Cisplatin Injection from Qilu is marketed and manufactured in China and is not FDA-approved.

Only Qilu or its distributor, Apotex Corp., is authorized by the FDA to import or distribute Qilu's Cisplatin Injection in the United States.

Effective immediately and during this temporary period, Apotex Corp. will distribute the following presentation of Cisplatin Injection to address the critical shortage:

Product Name	Quantity	Description	U.S. NDC Number	Lot Number	Expiration Date
Cisplatin Injection (50 mg/50 mL)	1 vial per carton	Colorless to yellowish clear liquid. Each 1 mL contains 1 mg of Cisplatin and 9 mg of Sodium Chloride in water for injection.	60505-8277-0 <b>The linear barcode on the imported product label may not register accurately on the U.S. scanning systems. See Appendix 1 for scannable linear barcode.</b>	3E001C88	05/02/2025
				3E002C88	05/02/2025
				3E003C88	05/02/2025
				3E004C88	05/03/2025

It is important to note the following:

- The carton labeling and container label did not include the warning statements, "Stop! Verify Drug Name and Dose!" or "Cisplatin doses greater than 100 mg/m<sup>2</sup> once every 3 to 4 weeks are rarely used". Thus, a sticker containing this warning statement, the name of the product, strength, concentration, U.S. NDC number and linear barcode has been applied to the vial and the carton.
- The container label did not have the translated name of the product "Cisplatin". Thus,

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a sticker containing the information noted in the bullet above has been applied to the vial.

- Drug- drug interaction with bisulfite, metabisulfite, sodium bicarbonate and fluorouracil.
- The product is colorless to yellowish clear liquid.
- The vial and carton labels will display the text used and approved for marketing the products in China containing Chinese only text. Example images of this labeling are provided in [Appendix 2](#).
- There are differences in the format and content of the labeling between the FDA-approved product and Qilu's Cisplatin Injection. Please see the product comparison table in [Appendix 3](#) and corresponding English translations.

Cisplatin injection is available only by prescription in the U.S. The imported lots did not have the statement "Rx only" on their labeling. Thus, a sticker containing the information noted in the bullet above has been applied to the vial and the carton.

**The linear barcode on the imported product label may not register accurately on the U.S. scanning systems.** Institutions should manually input the imported product information, including the NDC, into their systems and confirm that the linear barcode, if scanned, provides correct information. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

In addition, the carton of the imported product does not include a product identifier as required under the Drug Supply Chain Security Act (DSCSA). Specifically, each package of product does not include the NDC, unique serial number, lot number, and expiration date in both human-readable form and a two-dimensional data matrix barcode.

Please refer to the package insert for the FDA-approved Cisplatin Injection drug product for full prescribing information.

**Finally, please ensure that your staff and others in your institution who may be involved in the administration of Cisplatin Injection receive a copy of this letter and review the information.**

**If you have any questions** about the information contained in this letter, any quality related problems, or questions on the use of Qilu's Cisplatin Injection, please contact Apotex Corp. Customer Service at 1-800-706-5575.

**For ordering information, please contact your primary wholesaler or distributor to place an order with Apotex Corp. at 1-800-706-5575.**

Healthcare providers should report adverse events associated with the use of Qilu's Cisplatin Injection to Apotex Corp. at 1-800-706-5575.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

“Dear Provider” letters, dates, root causes help determine appropriate solutions

# WHO Medicine Shortage Intelligence Network (MedSIN)

What does it do and where is it going?

Extracts existing public (but hard to find) reports made from manufacturers to regulator to “push” information

Consolidates and “cleans” data into useful info: date, duration, root cause, tags essential medicines

Gives a “score” to highlight more severe shortage to users (seen in demo)

Give automated qualitative information based on 150 definitions currently in use by HICs

Since September 2021 the number of molecules reported in shortage in two or more countries has increased 101%

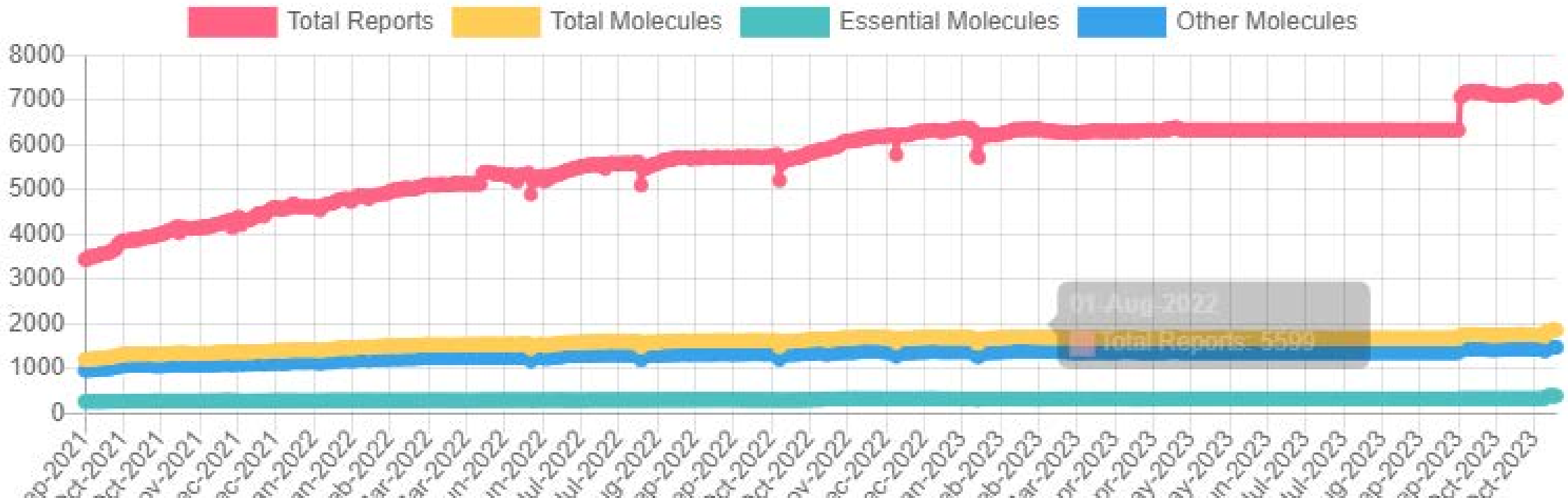
Category	2021	2023	Significant increase in # of reports collected and analyzed:	
<b>Total reports</b>	3438 (report)	7196 (report)		
<b>Total molecules (in the reports)</b>	1204 (molecules)	1865 (molecules)		
<b>Molecules on the Essential Medicines Lists (EML)</b>	254 (molecules)	382 (molecules)	50%	
<b>Molecule reported shortages in 2+ countries</b>	338 (molecules)	681 (molecules)	101%	
<b>Multi-country (Essential Medicines)</b>	113 (molecules)	217 (molecules)	92%	

More than 20% of the molecules reported are on the WHO Essential Medicines List

Over 30% of total reports are multi-country shortages and 10% of reports are EML AND multi-country

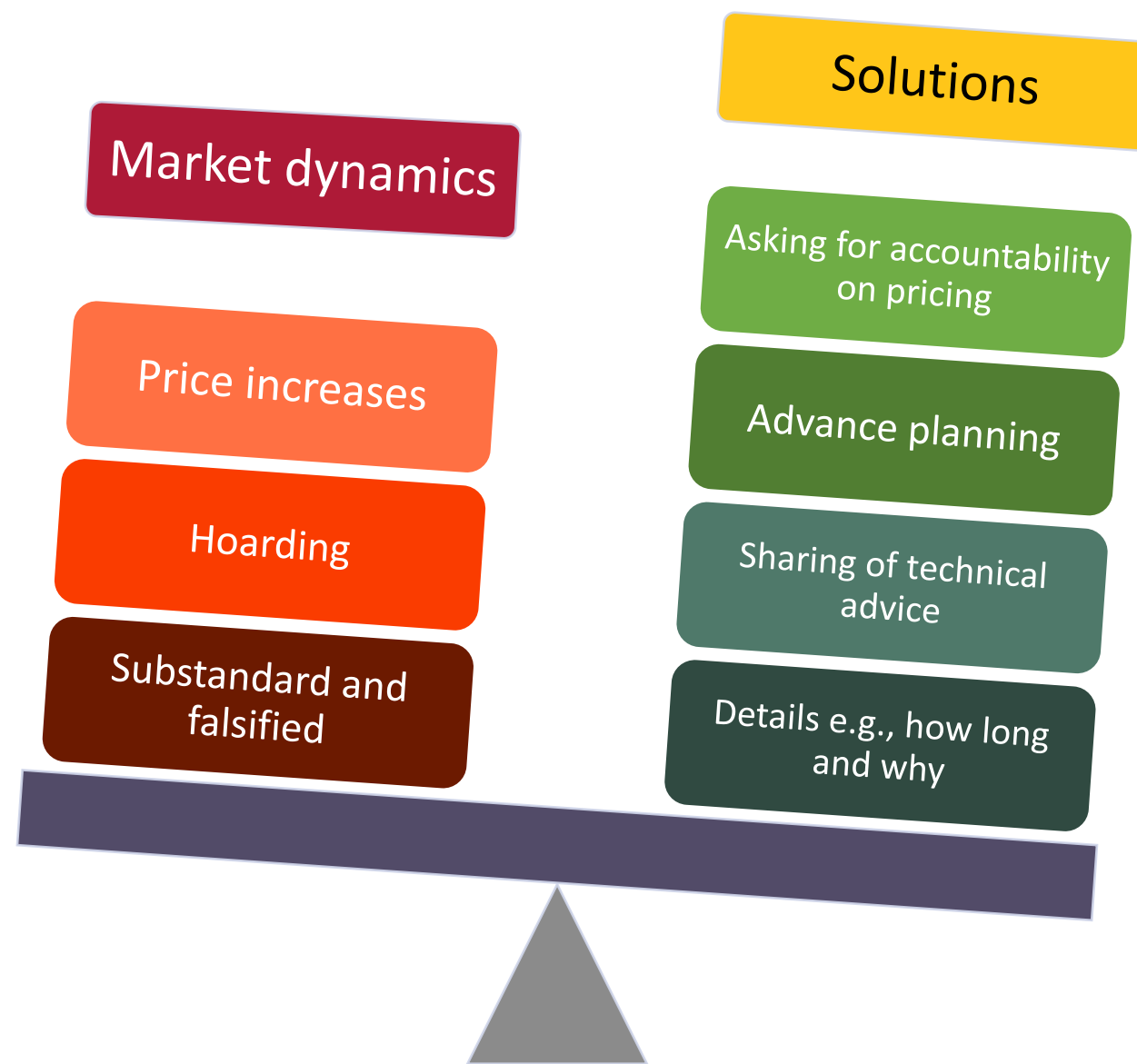
## Example of information from MedSIN

- Collected and collated over 7,000 shortage reports from 11 countries since early 2021.
- 1,800+ different molecules logged with 380+ WHO essential medicines.
- The system currently harvests information in the public domain. Data agreements will be needed in the next phase.



## Engaging LMIC procurement and regulators

- There are challenges with reporting shortages, but benefits outweigh.
- Knowledge drives the most appropriate solution e.g., short term rationing, substitutions.
- Many shortages are shorter term and are solved within the country, but visibility of shortages at manufacturing level is limited.



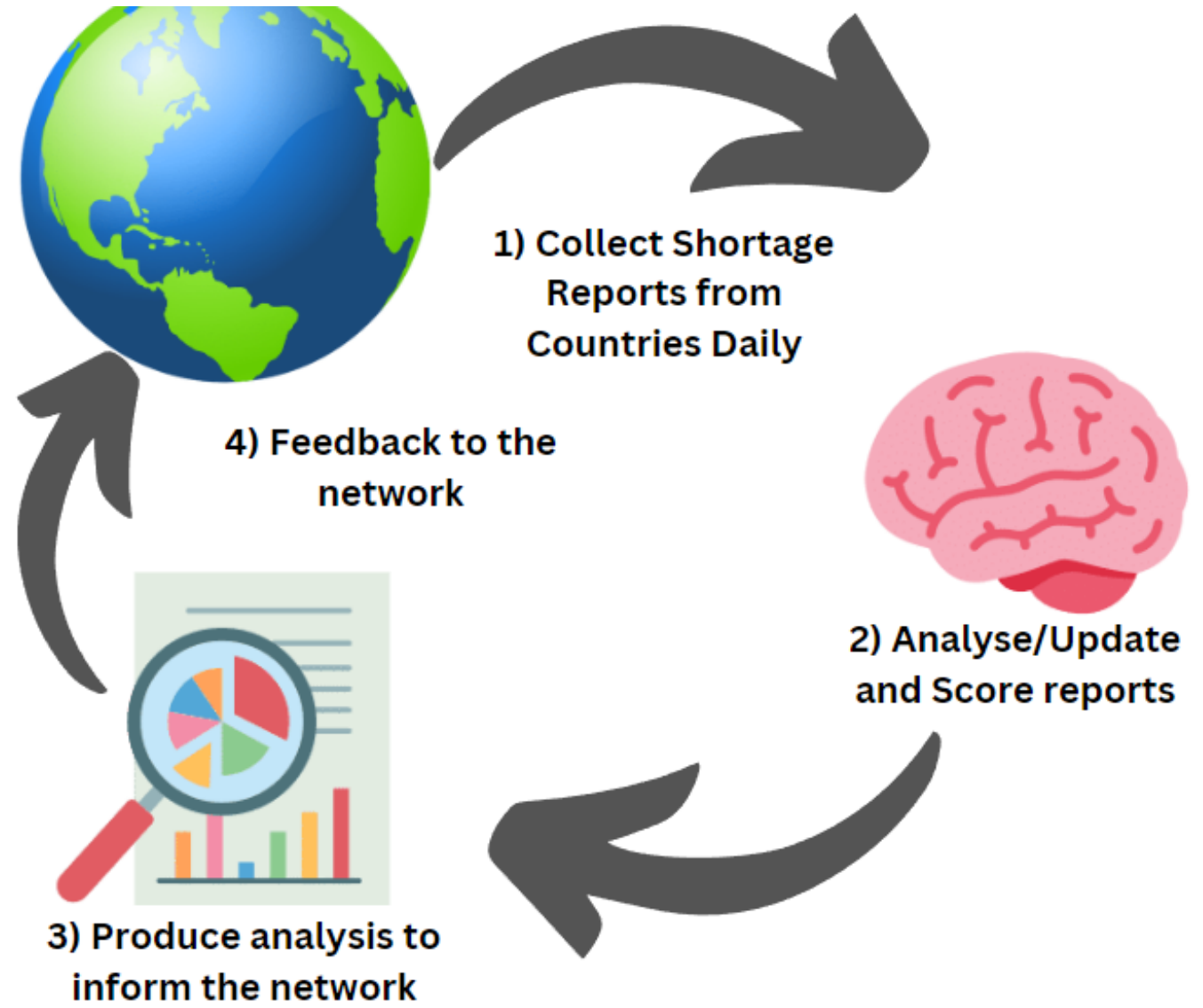


## Virtuous Circle of Collaboration

Creating greater visibility and transparency through collaboration with partners on existing shortages data

Easy and simple engagement process

**Closed platform** where sharing of information is used to promote solutions – whether it is country-level data or on molecules



# Deep Dive 1: Amoxicillin



Evolution of Shortage of Amoxicillin over time

**amoxicillin** 100.0 MgPerMI Oral Suspension Essential ✓ 🇸🇪

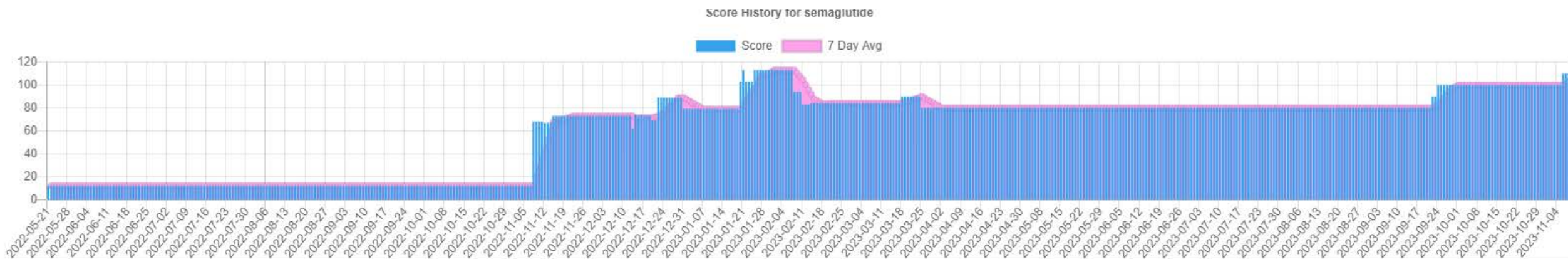
Start Date: 2023-09-01 • End Date: 2024-02-19 • Duration: \_90to180Days • Description: Amoxicillin Sandoz - Pulver till oral suspension ^

Presentation Type/Cause Regions Affected Actions Taken Data Origin Codes/Categories History

Description: Amoxicillin Sandoz - Pulver till oral suspension  
Packaging: BottleQuantity: 0  
Manufacturer: Företaget har inte godkänt att Läkemedelsverket publicerar orsaken till restdituationen.  
Ref: Amoxicillin Sandoz - Pulver till oral suspension

Example of one Shortage Report. Currently 65 different shortage reports exist for Amoxicillin creating a high score

# Deep Dive 2: Semaglutide (Ozempic/Wegovy)



Clear trend of increasing problem. Likely due to pivot from diabetes to weight control use case.

**semaglutide** 1.34 Milligram Solution Anticipated 🇨🇦

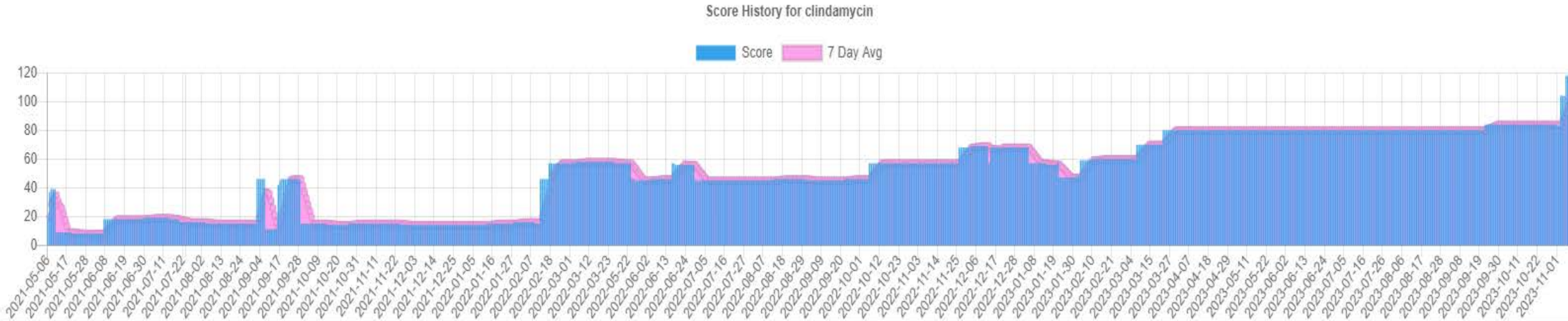
**Start Date:** 2023-11-15 • **End Date:** 2024-03-31 • **Duration:** \_90to180Days • **Description:** ozempic 1.34mg solution ▲

[Presentation](#) [Type/Cause](#) [Regions Affected](#) [Actions Taken](#) [Data Origin](#) [Codes/Categories](#)

Description: solution  
Manufacturer: NOVO NORDISK CANADA INC  
Ref: 208495

Example of an anticipated shortage report.

# Deep Dive 3: Clindamycin a critical antibiotic/antimicrobial injectable



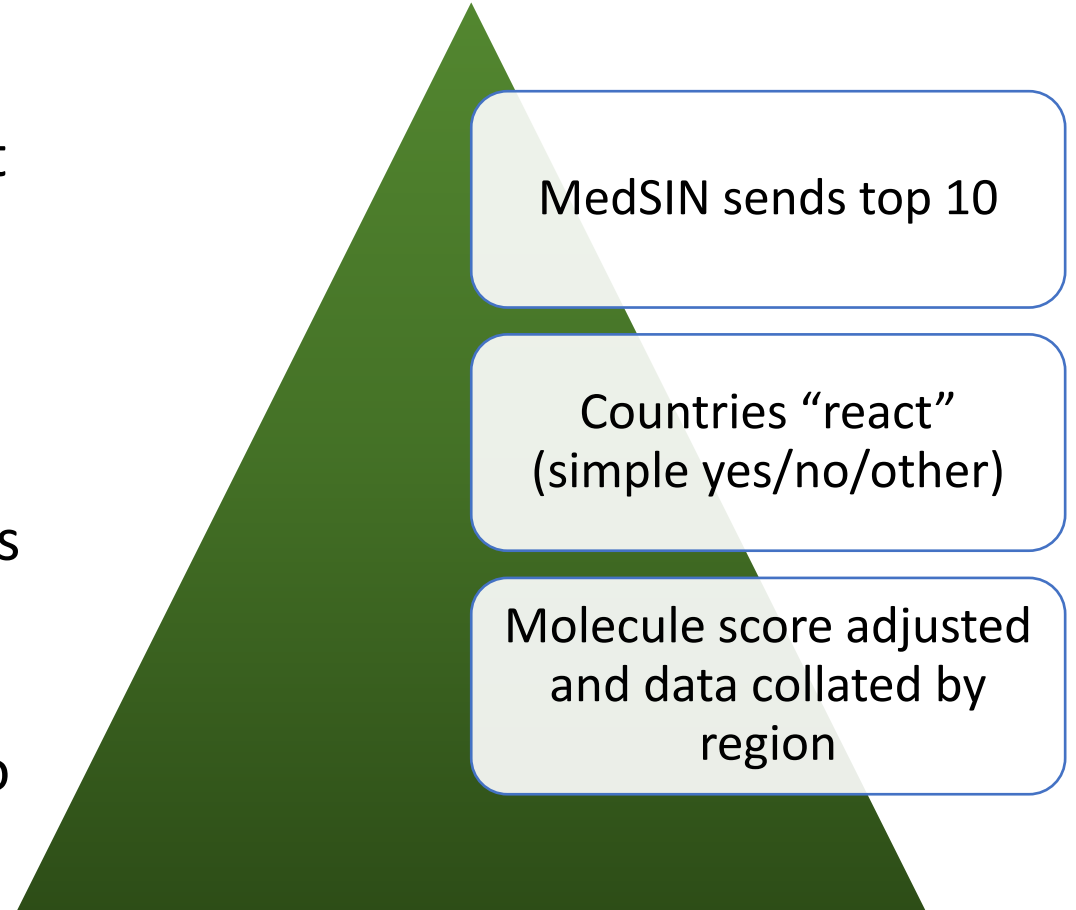
Digging a bit deeper we see that there are a number of factors shown in the panel on the right

- Restock dates vary but e.g. Pfizer 2023Q4.
- Alternatives exist e.g. cephalexin, doxycycline, or trimethoprim / sulfamethoxazole can be considered for soft tissue infections.

Manufacturer	Reason for Shortage	Notes
Almaject	Discontinued	Clindamycin injection discontinued in 2023.
Baxter	Third Party Issue	Baxter is experiencing a shortage of clindamycin injection due to a third party supplier issue.
Pfizer	Manufacturing Delays	Pfizer is facing manufacturing delays, resulting in a shortage of clindamycin injection.
Sagent	Manufacturing Delays	Sagent is experiencing manufacturing delays, leading to a shortage of clindamycin injection.
Sandoz	Not Provided	Sandoz has not provided a specific reason for the shortage of clindamycin injection.

# Stakeholder engagement and feedback from Global Health Supply Chain Summit

- Users requested opportunities to explore the inclusion of supply chain data to predict shortages, especially countries that are dependent on wholesale markets.
- Wholesale distributors are not traditionally required to report but expressed willingness to participate.
- A call out to WHO and other UN agencies to require reporting from contracted suppliers was also discussed.



# Thank you!

Special Initiatives, Access to Medicines and Health Products

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