

Access to Reserve antibiotics in low- and middle-income countries

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Challenges prevent sustainable access to life-saving antibiotics

KEY ACCESS HURDLES



Lack of appropriate evidence to inform optimal use of antibiotic treatments

Lack of interest from suppliers to commercialize antibiotics

Lack of registration in LMICs**

New antibiotics are priced out of reach

Poor uptake systems, weak stewardship and lack of adequate & timely diagnosis



~1.4 Million

Estimated number of patients

Estimated drop off due to access barriers*:

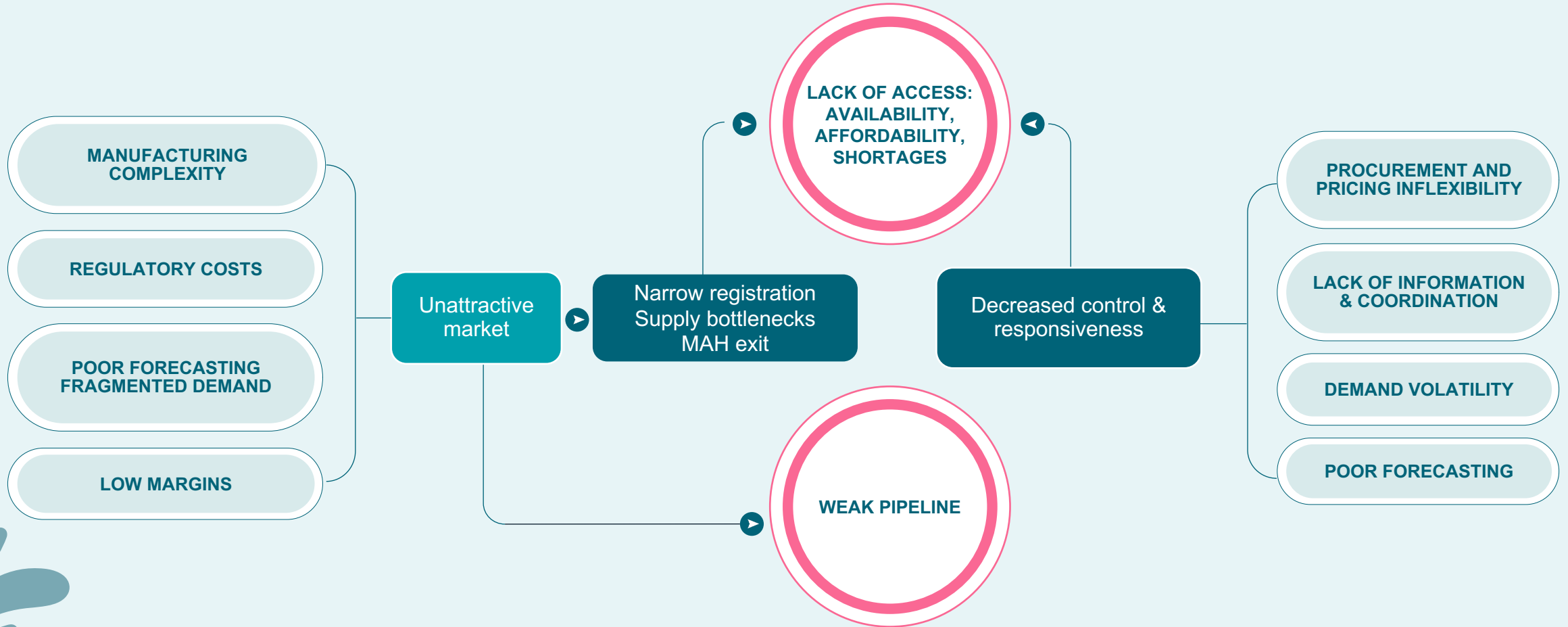
~97%

~40,000

Number of patients receiving therapy

*Using estimates from 2019 GRAM study (published in Lancet), we have calculated the access levels for Carbapenem resistant bacterial infections in South Asia

Supply and demand-side barriers: A multi-faceted problem





A new model for sustainable antibiotic access





Push
funding



Pull
incentives



Sustainable
Global
Access

An Ecosystem Approach

Driven by public health priorities

Non-profit drug development

Antibiotic optimization and robust uptake

Led by diverse and coordinated actors

Leveraging public-private partnerships

Licensing for manufacture and access

Market efficiencies and transparency

Responding to growing strength of regional systems



Non-profit
drug
development

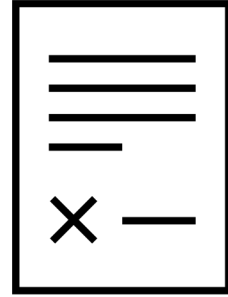
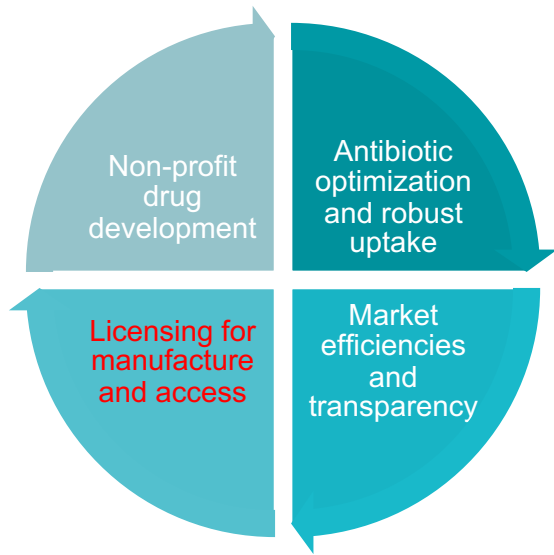
Antibiotic
optimization
and robust
uptake

Licensing for
manufacture
and access

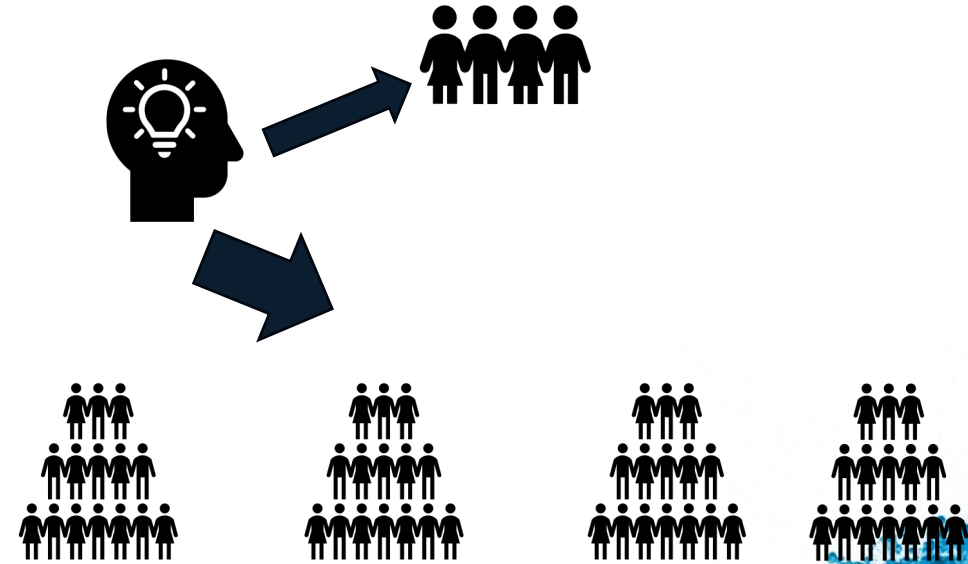
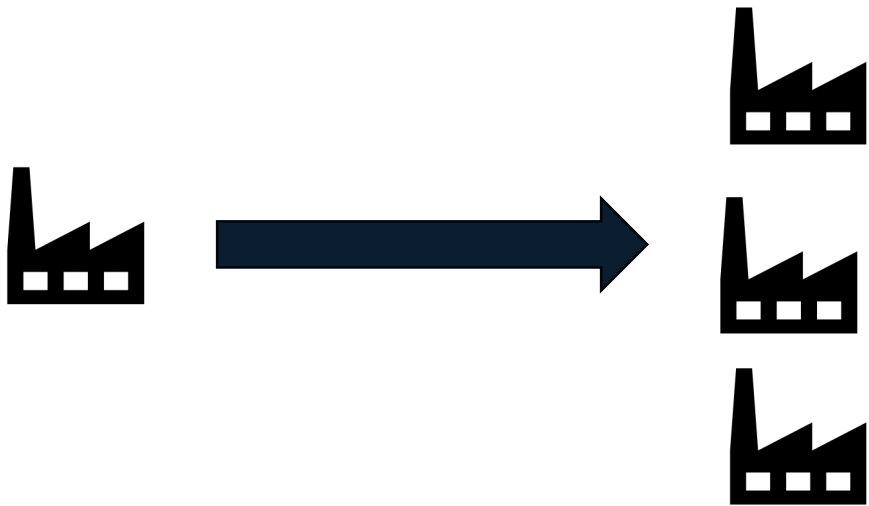
Market

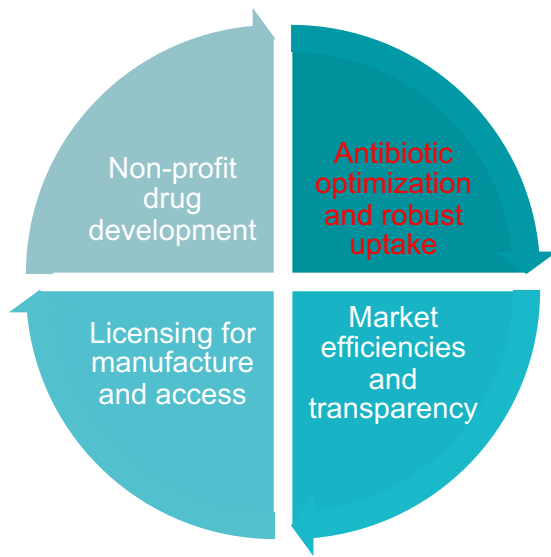
WHO publishes list of bacteria for which new antibiotics are urgently needed





- Broad geographic scope
- Quality assurance
- Rapid registration in high-burden areas
- Affordability terms
- Ability to innovate to improve manufacturing efficiency





Consolidated formularies to respond to local public health needs

- Enables forecasting and improves predictability of demand
- Improves buying power
- Focuses resourcing

Regional or supra-regional harmonization of formularies

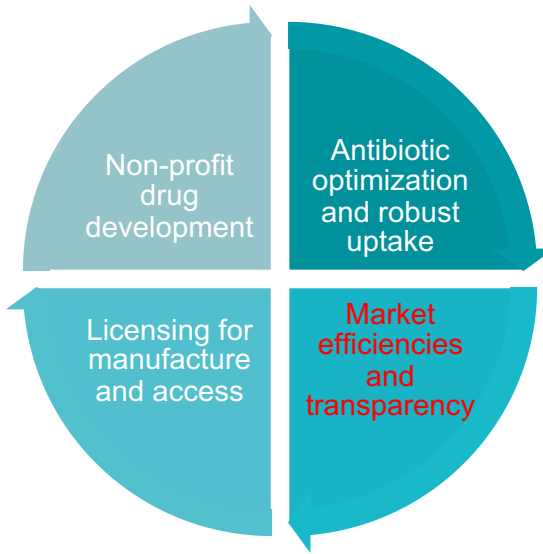
- Further strengthens buying power
- Enables pooled or coordinated procurement



PAediatric Drug Optimization (PADO) for Antibiotics

Meeting report

30 NOVEMBER, 5 AND 7 DECEMBER 2022



PAHO STRATEGIC FUND

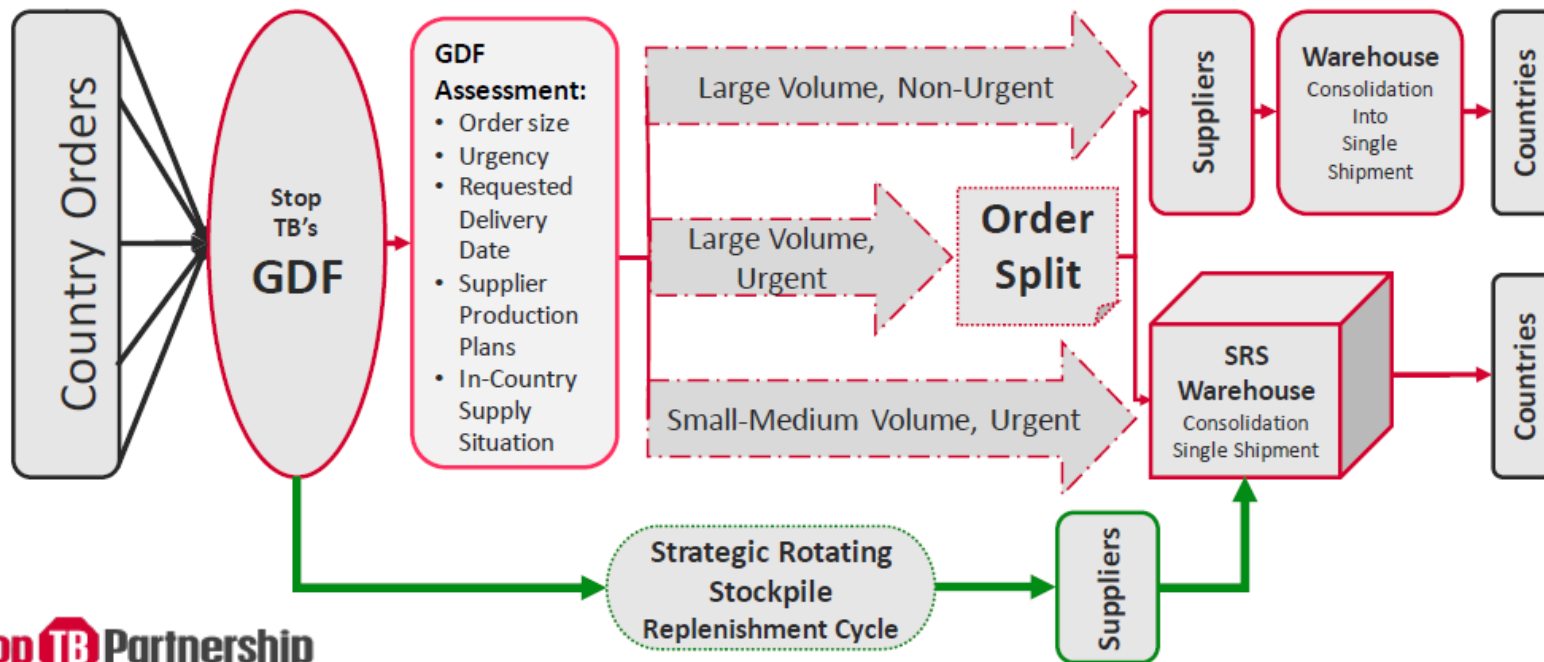
Access to quality medicines and health supplies for all in the Americas

Regional interprogrammatic missions related to HIV, hepatitis C, malaria, Chagas disease, cardiovascular diseases, and cancer to improve

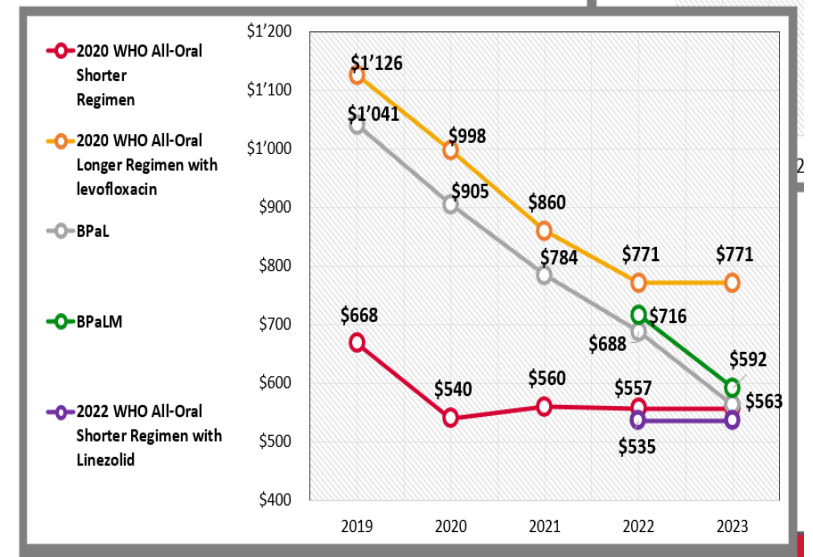
Technical cooperation missions to more than ten countries.

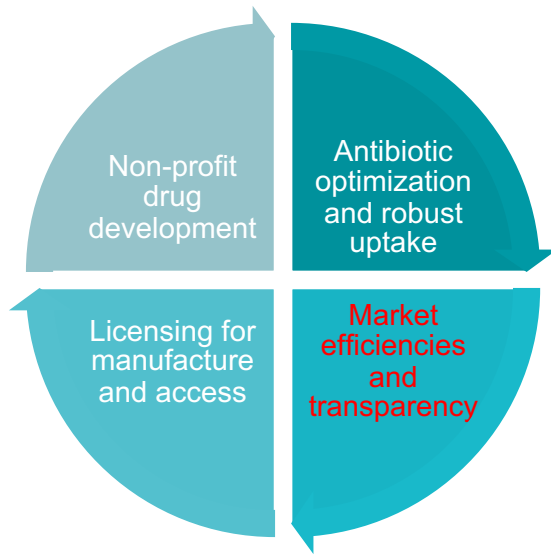
Strengthening supplier relationship management by acquiring market intelligence and improving supply chain service levels in

In-country engagement to facilitate demand planning & consolidation, support agency donations, and prevent stockouts &



Current WHO-Recommended Regimens

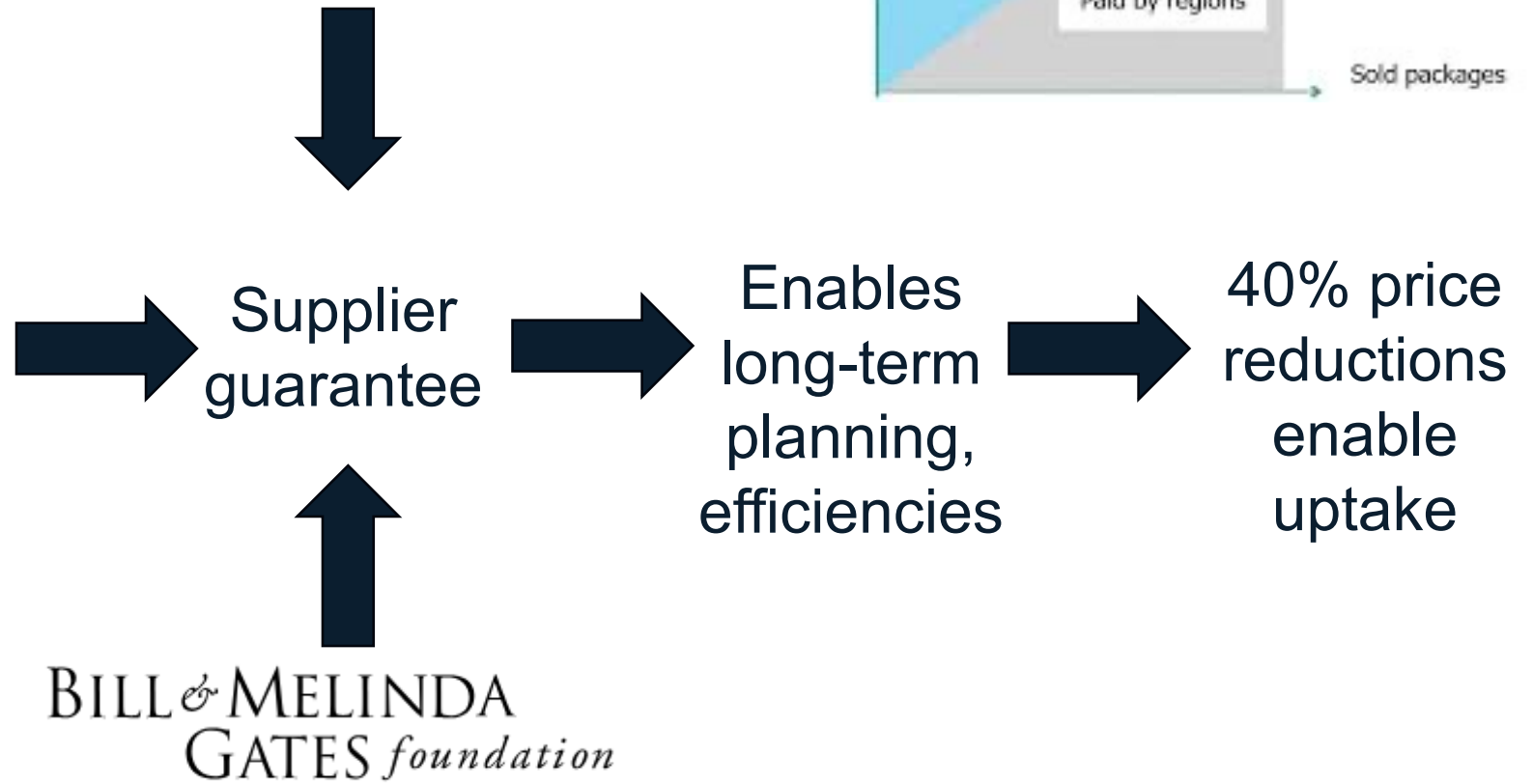


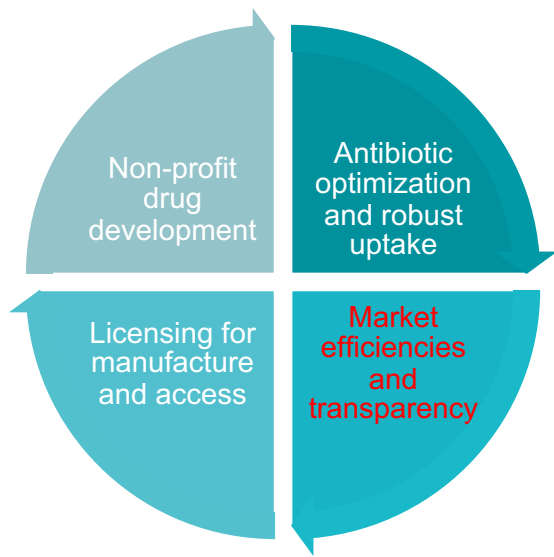


Sweden revenue guarantee



 MedAccess





CIVICA®

the nonprofit
solution for
reliable drug
supply

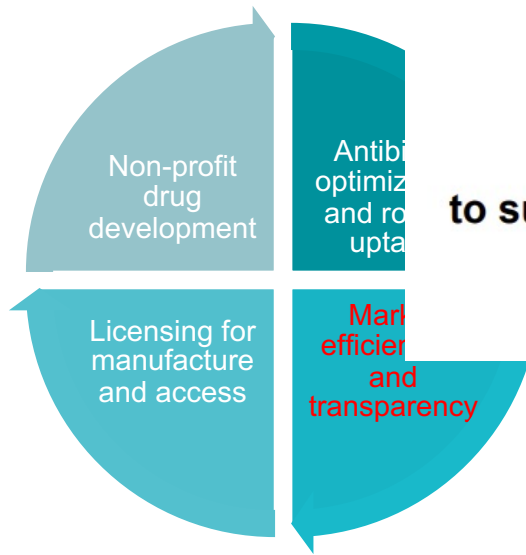
ARTICLE | POLITICS, POLICY & LAW

Cipla's withdrawal of antibiotic marketing application latest sign of AMR market failure

STEVE USDIN, WASHINGTON EDITOR

13 July 2020 9:42 PM GMT+2

**1st Invitation
to manufacturers of medicinal products
for treatment of multi-drug resistant bacterial infections,
to submit an Expression of Interest (EOI) for product evaluation to the
WHO Prequalification Unit**

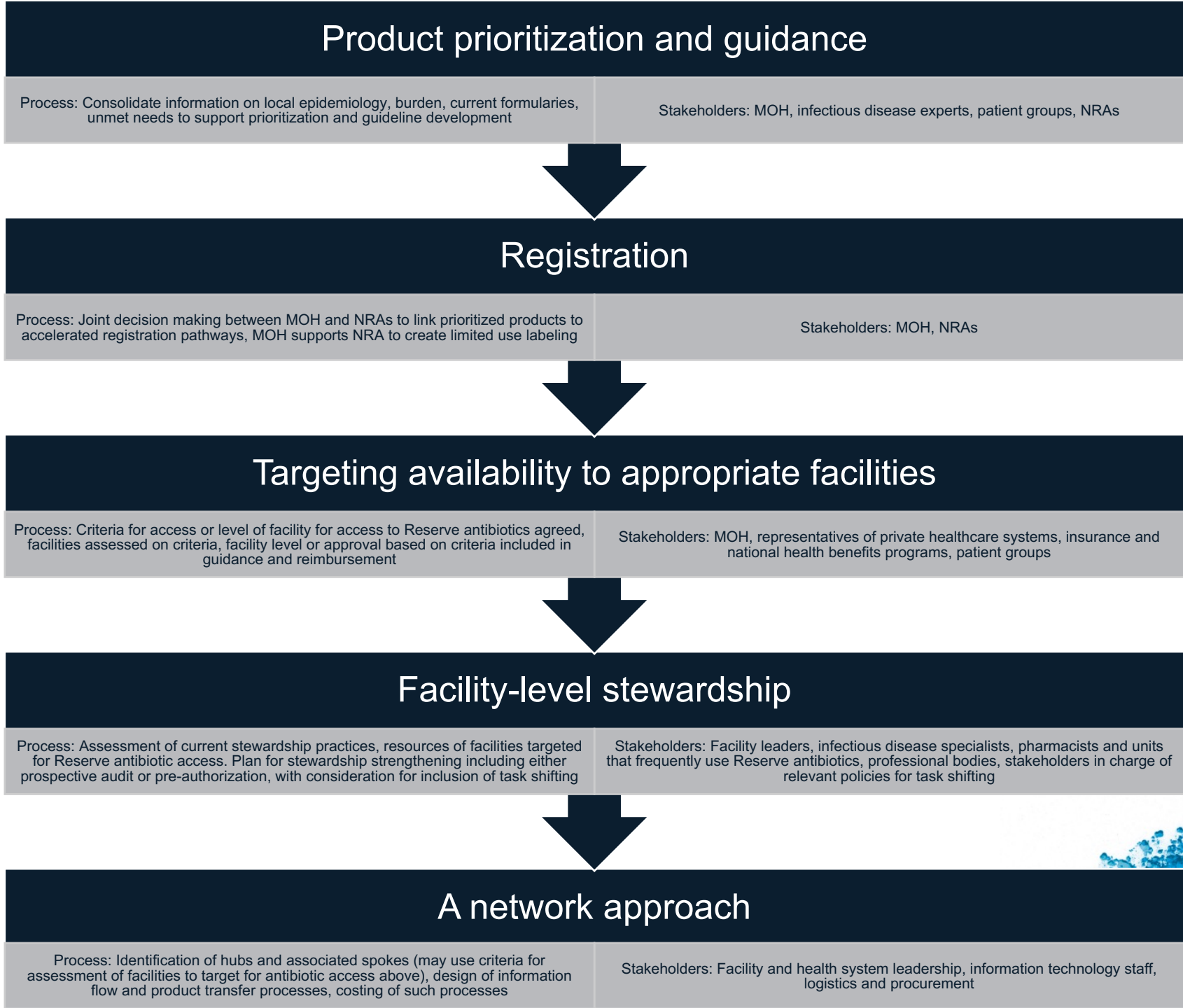
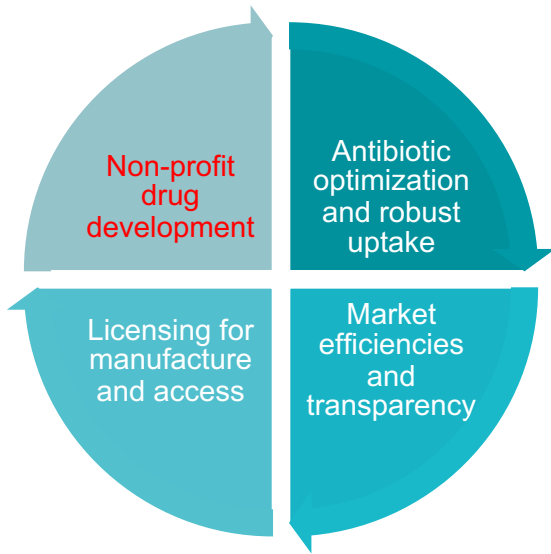


performance of regulatory seeking
designation as WHO-listed authorities

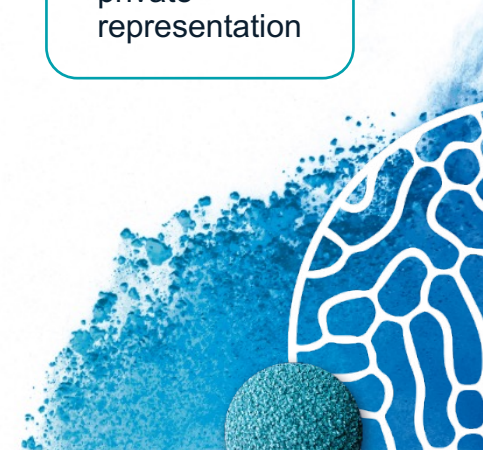
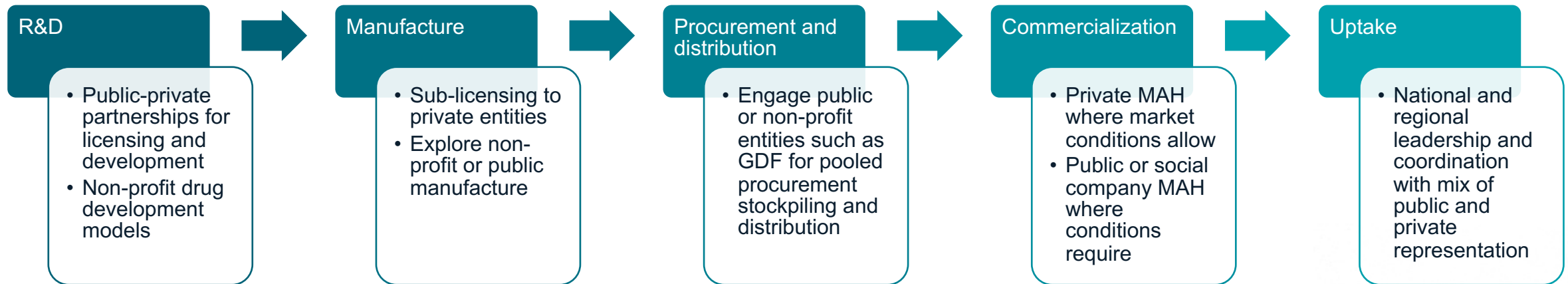
MOVING TOWARDS REGULATORY HARMONIZATION

Source: AMRH 2015





The product to patient pathway: An ecosystem approach



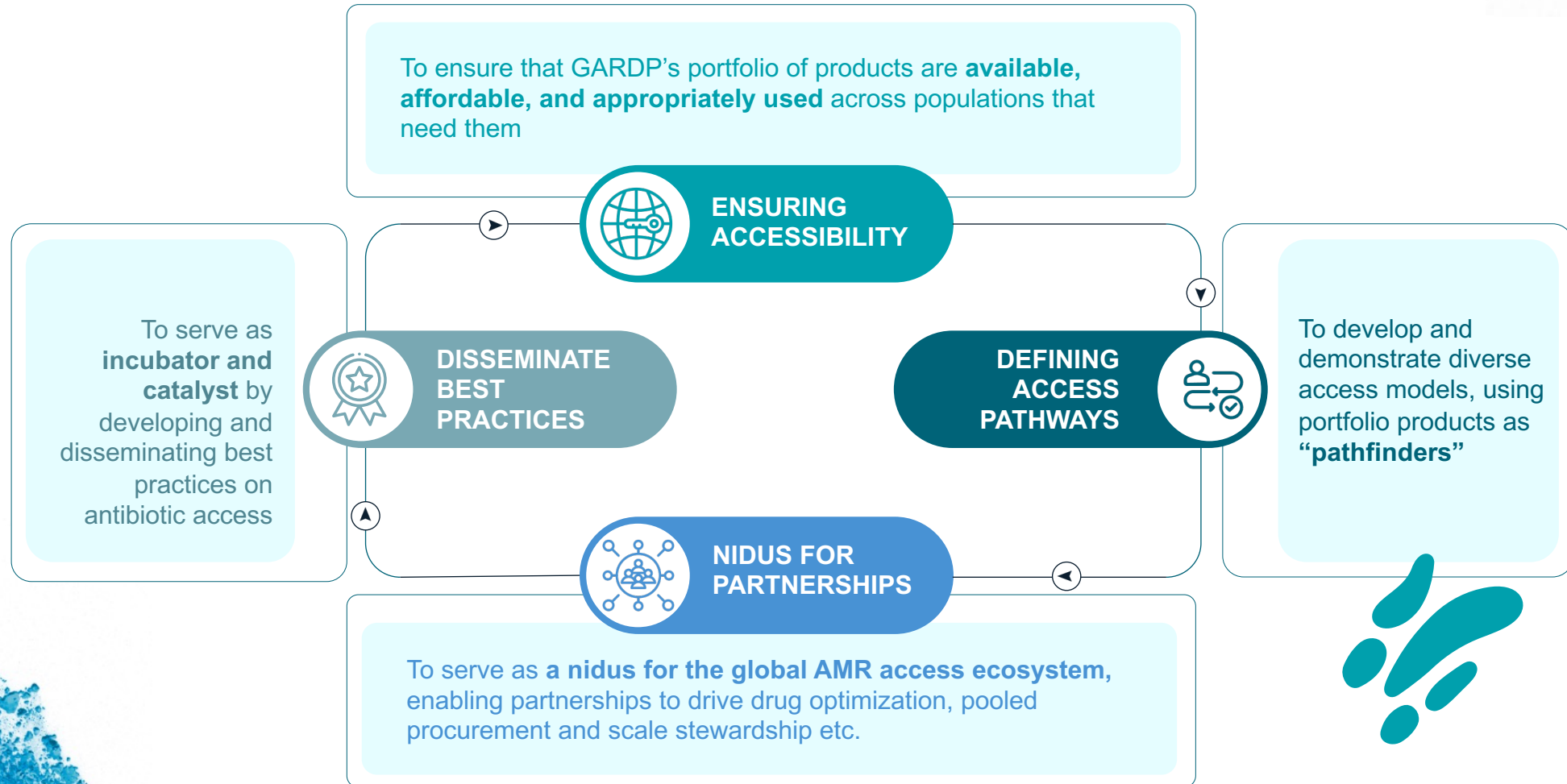


Case Study

**Cefiderocol:
A pathfinder project
addressing serious bacterial
infections**



GARDP's vision for access



A breakthrough licensing agreement and comprehensive access program

A “first-of-its kind” licensing agreement signed between Shionogi & GARDP* in June 2022 to improve access to cefiderocol in 135 countries, mostly low- and middle-income, can pave the way for sustained, stewardship driven access to this and establish a pathway for other novel antibiotics.



Manufacturing

Affordable and quality-assured products from a licensed manufacturer



Registration

Support for commercialization in high-burden countries



Implementation

Partnerships to co-develop and introduce robust implementation plans



Guidelines

Evidence-based guidance to steward appropriate use

*In addition to the licensing agreement signed between Shionogi & GARDP, we also signed a 3-way collaboration agreement with Clinton Health Access Initiative (CHAI) to drive the execution against the above-mentioned objectives

Cefiderocol as an access pathfinder

BARRIERS ADDRESSED



New antibiotics are priced out of reach

Lack of interest from suppliers to commercialize antibiotics

Lack of registration in LMICs



June 2022: “First of its kind” licensing agreement signed between Shionogi & GARDP for Cefiderocol access in LMICs



April 2023: WHO issues “expression of interest” inviting applications for filing PQ for Cefiderocol



September 2023: Sign manufacturing sub-license with sub-licensee including stewardship, EHS, commitment for rapid registration, COGs-plus pricing



June 2022: Collaboration agreement signed between GARDP, CHAI and Shionogi to enable access for Cefiderocol in LMICs

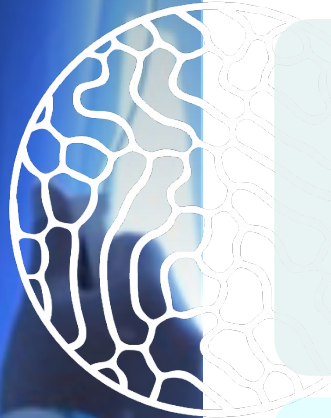


May 2023: Collaboration announced with Global Drug Facility (GDF) for pooled procurement for GARDP portfolio including Cefiderocol

November 2023: MedAccess and GARDP explore development of a supplier guarantee to support cefiderocol access in LMICs

The cefiderocol access project has provisions for appropriate use

Every step is a potential “stewardship lever”



LICENSE AND MANUFACTURE

- Adhere to marketing guidelines / no marketing
- Quality assurance
- No incentives for volume sales
- Waste management
- Report on forecasts versus volume sales



GUIDELINES

- Provide data for guidance development
- Identification of local evidence needs
- Align EML and regulatory prioritization to guidelines



IMPLEMENTATION

- Cumulative antibiograms
- Strengthen local antibiograms
- Diagnostic network map and strengthening
- Training, site monitoring and mentorship
- Incentives for appropriate use?



POST-APPROVAL RESEARCH

- Real world data on optimal use
- Operational research on stewardship models



Access challenges: Time to Act

- **Designing and testing creative solutions**
- **Building an access ecosystem**
- **Documenting and scaling success**





Thank you

