

# Access to New Antibacterials to Address Global Public Health Needs

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**Our  
Vision**

**All infections are treatable**  
for everyone, everywhere

**Our  
Mission**

We work with partners  
to **accelerate the development**  
**and access to treatments** for  
drug-resistant infections

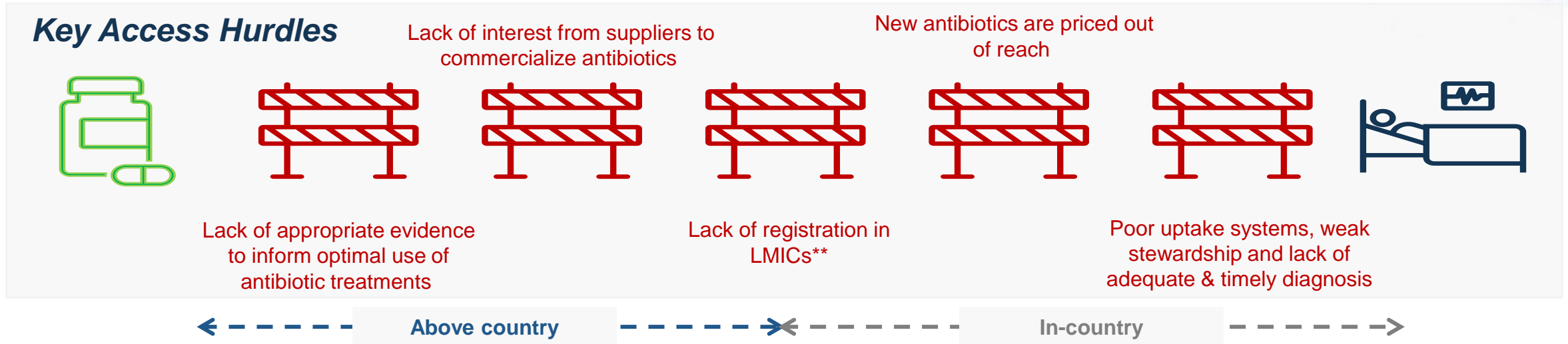
# Targeting WHO priority pathogens

DISEASE AREA	DISEASES/ INFECTIONS	WHO PRIORITY PATHOGENS	POTENTIAL TREATMENTS
SEPSIS	Hospital and community-acquired serious bacterial infections in: Adults Children Neonates	CRE	cefepime-taniborbactam / cefiderocol
		ESBL-PE	fosfomycin-amikacin / flomoxef-amikacin / fosfomycin-flomoxef
		CRPA	cefepime-taniborbactam / cefiderocol
		CRAB	New chemical entity
SEXUALLY TRANSMITTED INFECTIONS	Gonorrhoea	Neisseria gonorrhoeae	zolidodacin
			New chemical entity

At GARDP, we **prioritize public health needs** and target priority pathogens.

CRE: carbapenem-resistant *Enterobacteriaceae*; ESBL: extended spectrum beta-lactamases – producing Enterobacteriales; CRPA: carbapenem-resistant *Pseudomonas aeruginosa*; CRAB: carbapenem-resistant *Acinetobacter baumannii*.

# Challenges prevent sustainable access to life saving antibiotics



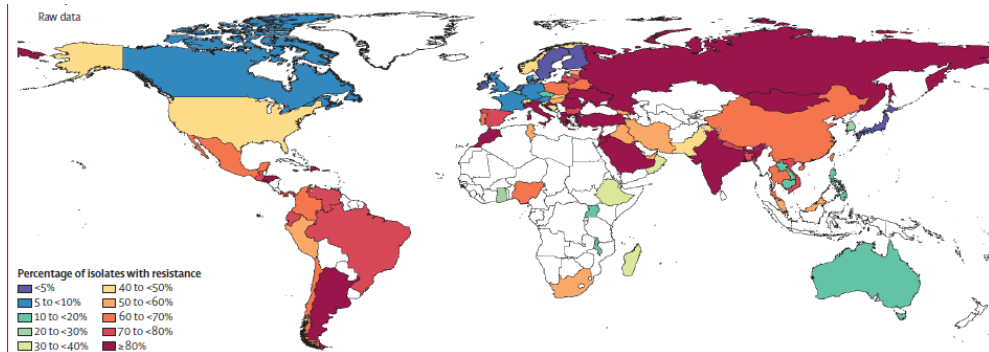
\*Using estimates from 2019 GRAM study (published in Lancet), we have calculated the access levels for Carbapenem resistant bacterial infections in India

# “... Where is the disease? The disease is where the drugs are not.”

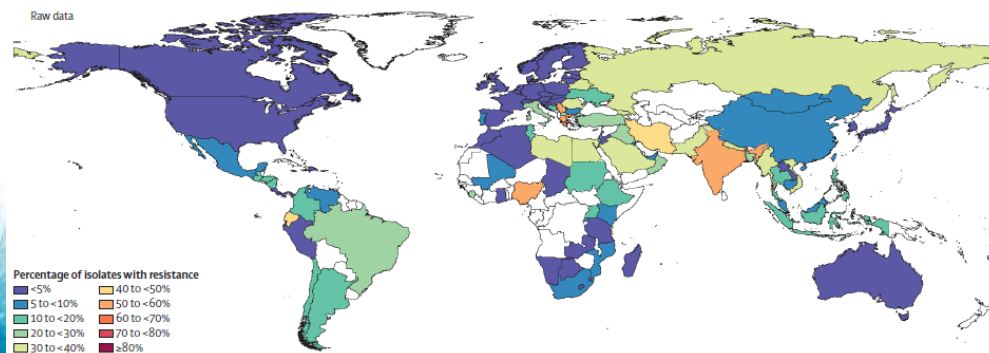
Peter Mugenyi, Ugandan HIV/AIDS researcher 13th Int. AIDS Conference Durban, 2000

## 1. Growing antibiotic resistance

Carbapenem-resistant *Acinetobacter baumannii*

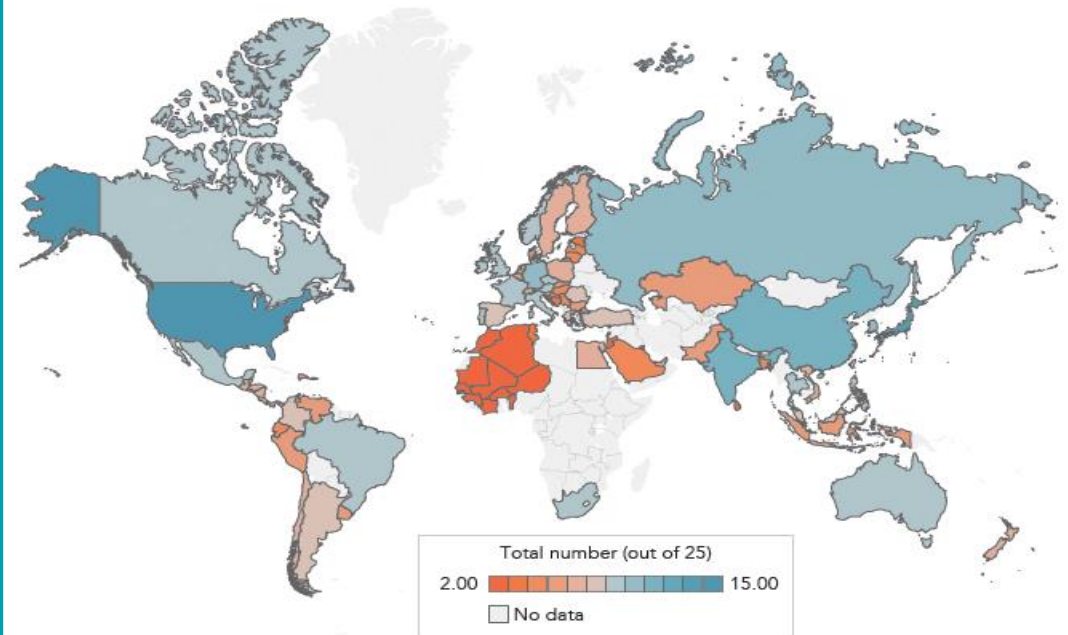


Carbapenem-resistant *Klebsiella pneumoniae*

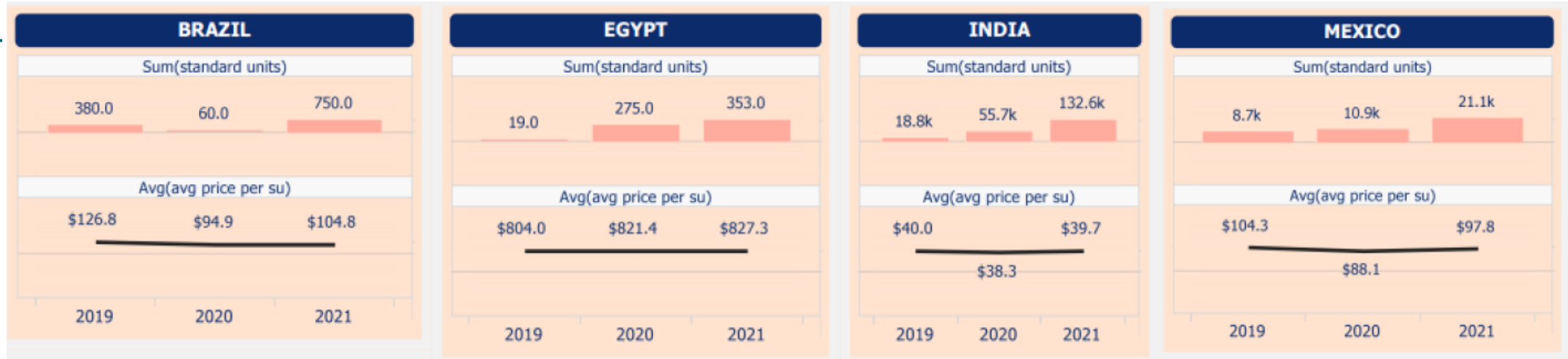


## 2. Not widely registered

Number of antibiotics registered 1999-2014



# High and variable prices for on-patent Reserve antibiotics (price in USD per vial)



## Ceftazadime-avibactam

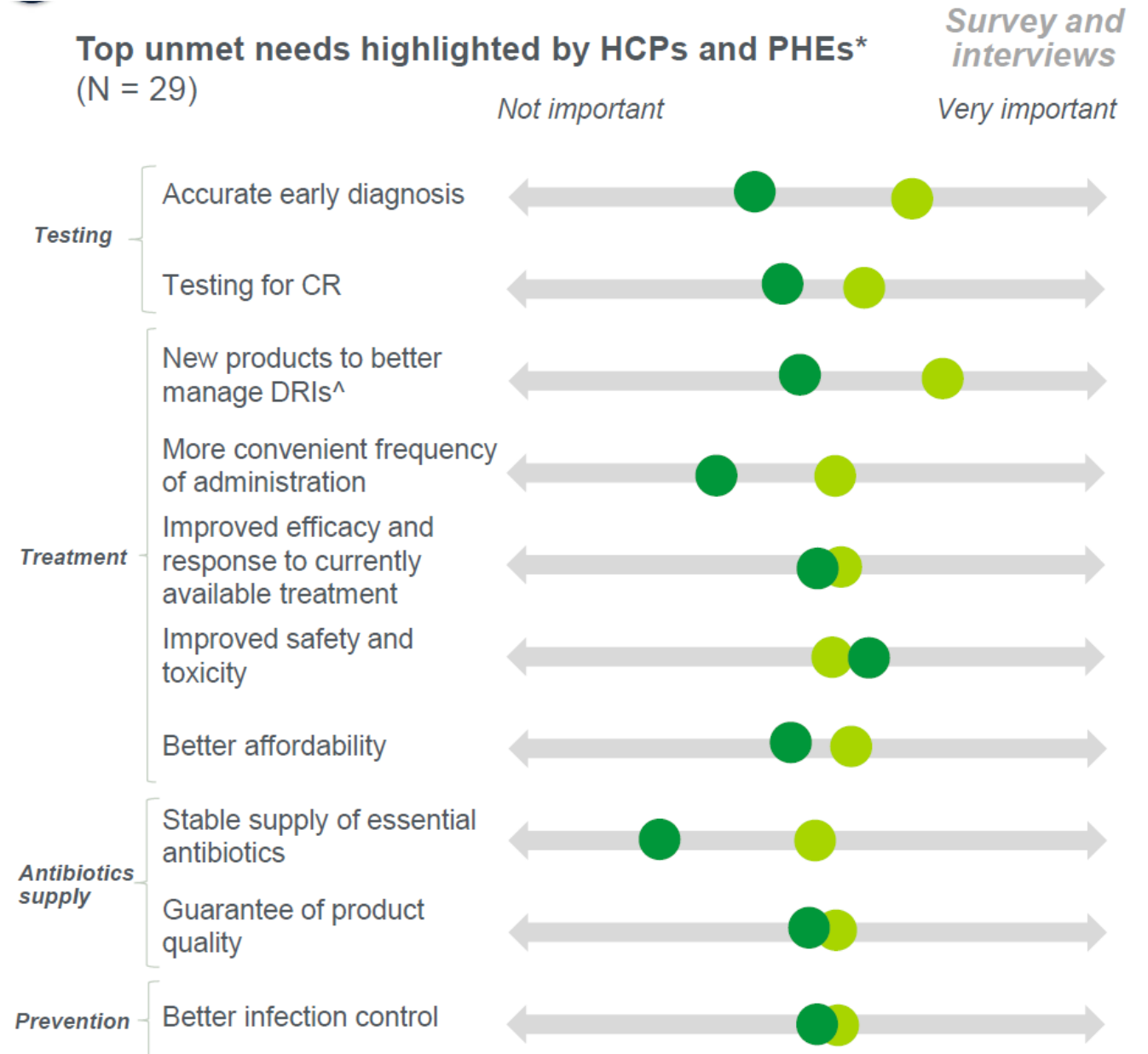
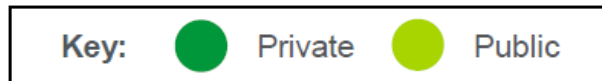


## Ceftolozane-tazobactam

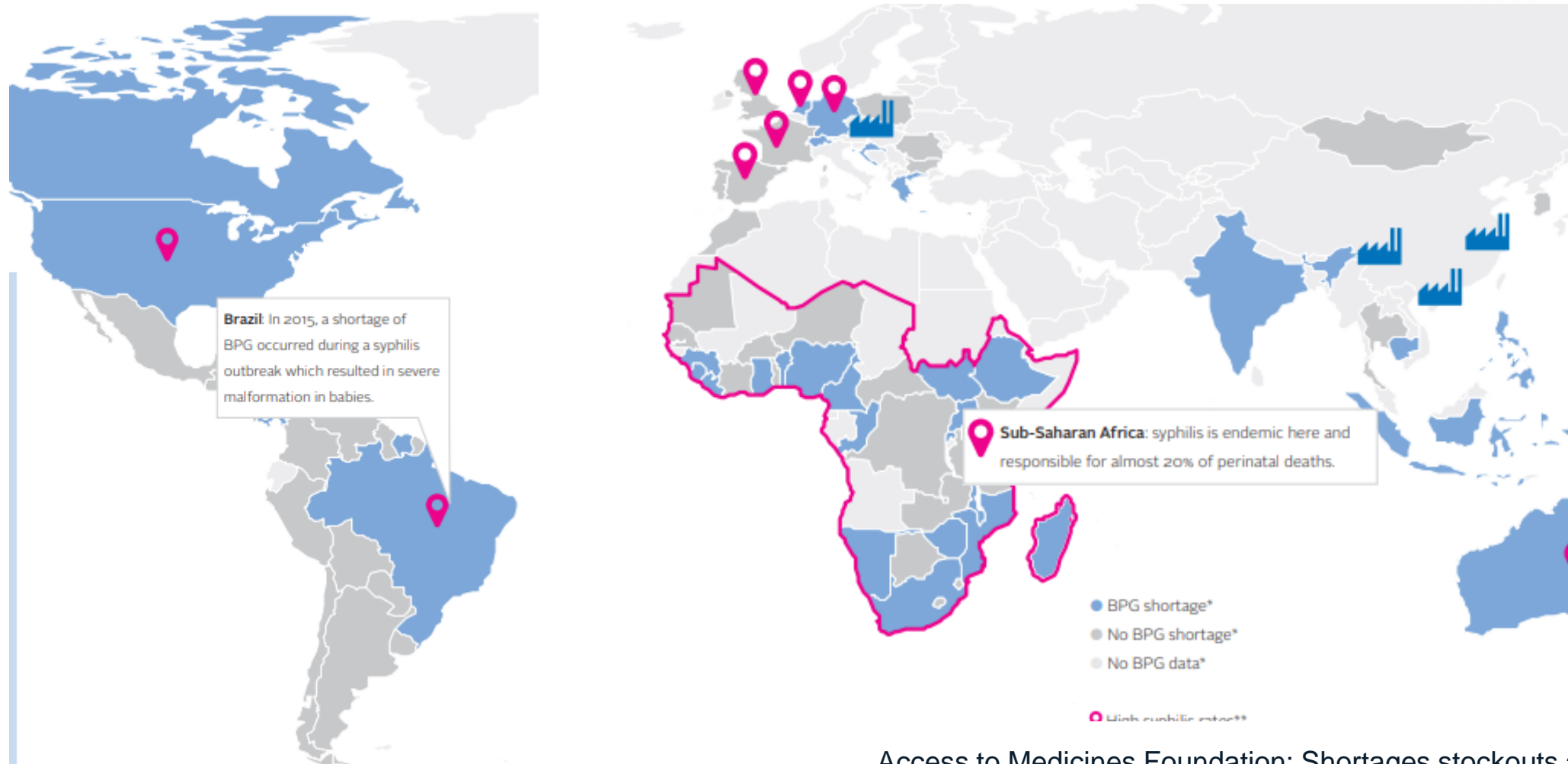


# Top unmet AMR needs in South Africa

\*The survey responses are drawn from qualitative interviews that were conducted in South Africa in 2022 with 16 physicians and public health experts, as well as quantitative research with 20 physicians who deal with AMR.

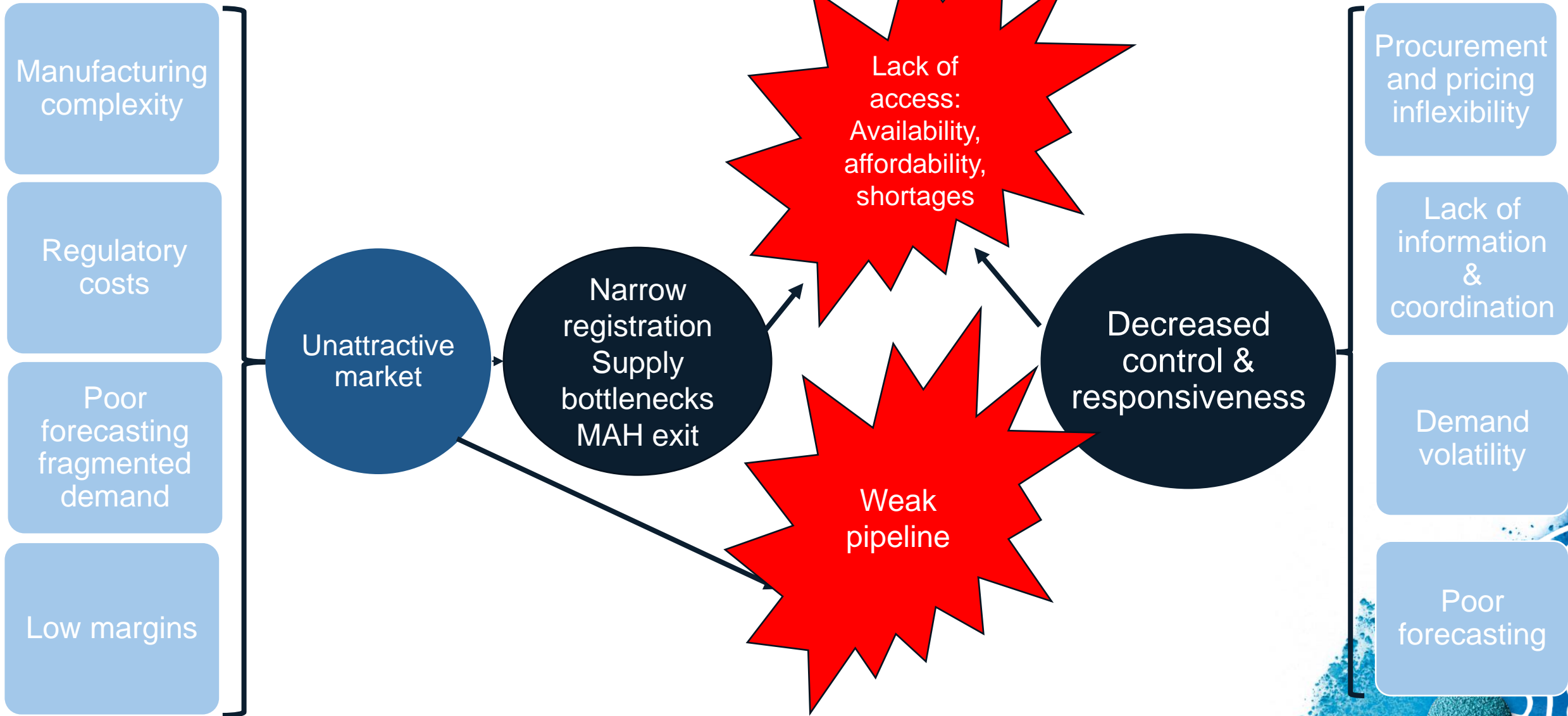


# Not just new drugs: Drug shortages also have global impact on antibiotic access

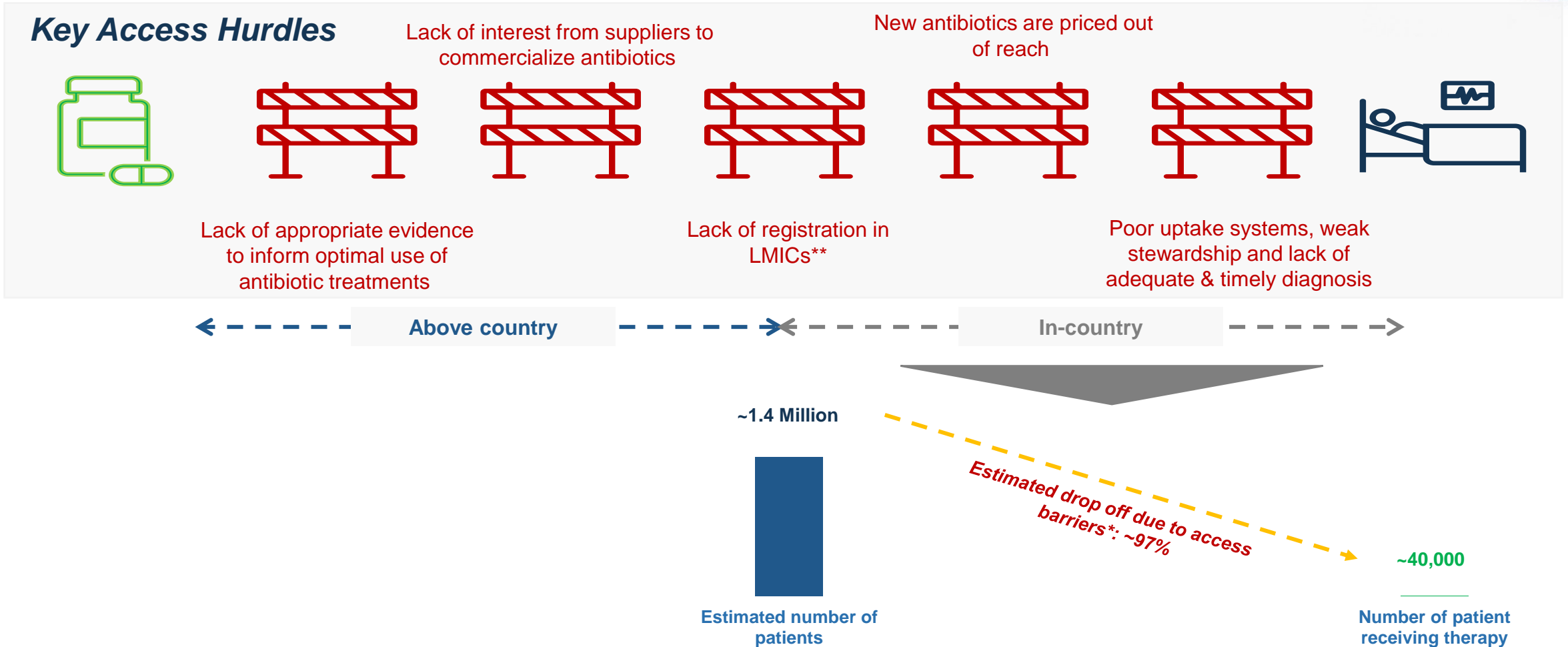




# A multi-faceted problem



# Challenges prevent sustainable access to life saving antibiotics



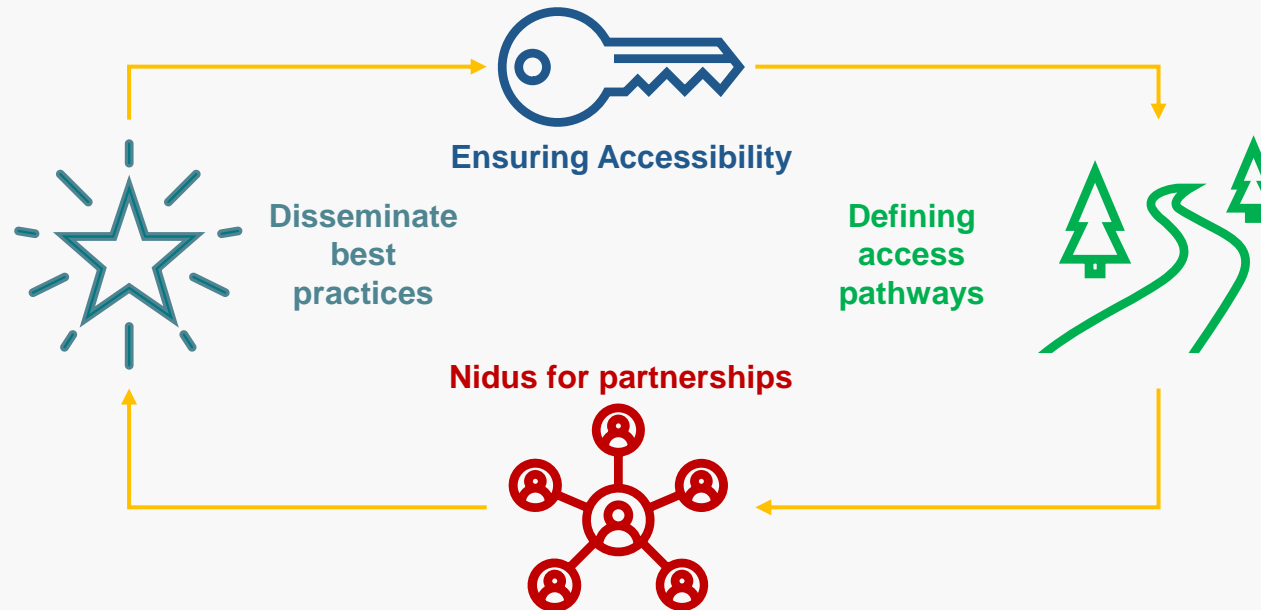
\*Using estimates from 2019 GRAM study (published in Lancet), we have calculated the access levels for Carbapenem resistant bacterial infections in India

# Can we work to accelerate access to antibiotics for appropriate use around the world?

## Our vision for Access

To ensure that GARDP's portfolio of products are **available, affordable, and appropriately used** across populations that need them

To serve as **incubator and catalyst** by developing and disseminating best practices on antibiotic access



To develop and demonstrate diverse access models, using portfolio products as **"pathfinders"**

To serve as a **nidus for the global AMR access ecosystem**, enabling partnerships to drive drug optimization, pooled procurement and scale stewardship etc.



# Case Study 1

## Cefiderocol:

A pathfinder project to ensure  
sustainable, stewardship driven  
access



# Through the Cefiderocol access project, GARDP and its partners are looking to address these hurdles

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

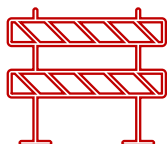


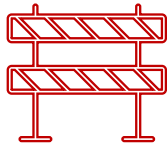


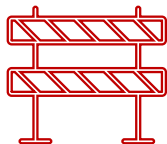





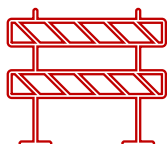





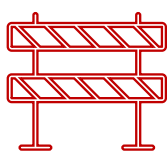






## Guidelines

Evidence-based guidance to steward appropriate use

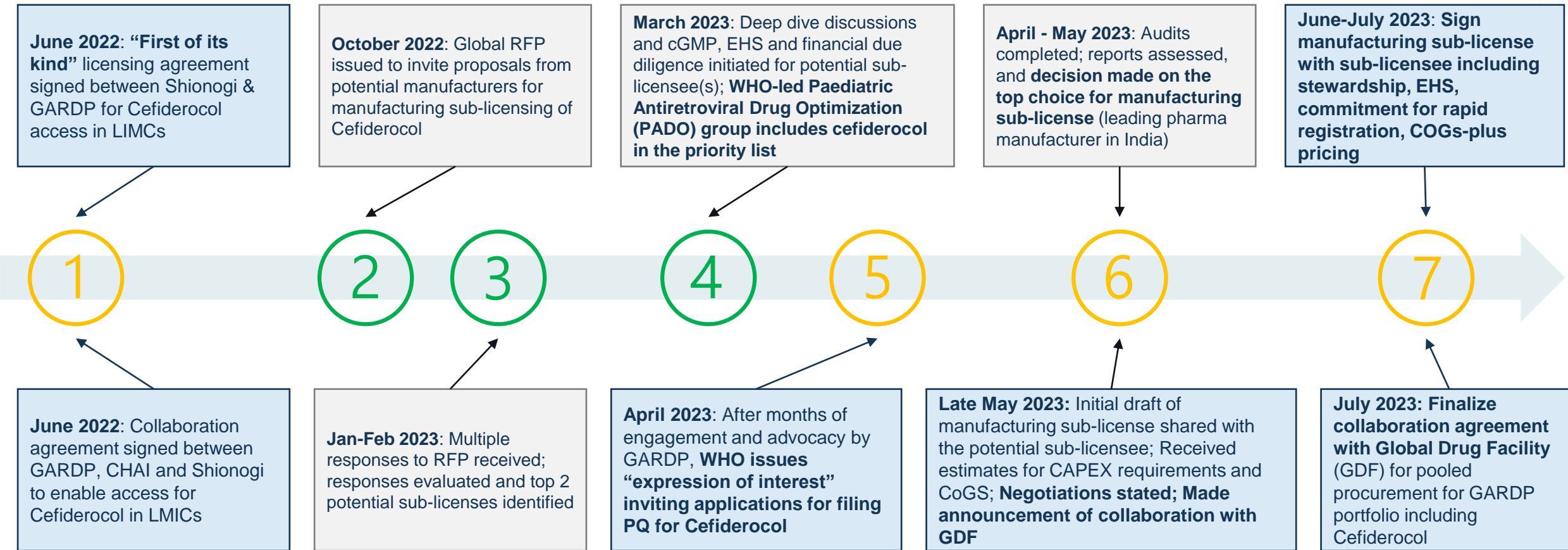
\*In addition to the licensing agreement signed between Shionogi & GARDP, we also signed a 3-way collaboration agreement with Clinton Health Access Initiative (CHAI) to drive the execution against the above-mentioned objectives

# Partnering to Build an Ecosystem for Antibiotic Access

Key Barriers	Solutions	Partners (Indicative, not exhaustive)
 <p>Lack of interest from suppliers to commercialize antibiotics</p>	<p>Support for product <b>demand forecasting</b> and market intelligence, improved economic models to incentivize supplier market entry, maintenance and financial market entry incentives</p>	 
 <p>Lack of registration in LMICs</p>	<p>Support suppliers to use regional <b>regulatory</b> harmonization schemes, and WHO Prequalification (PQ), including through technical support for dossier preparation as well as support <b>special importation waivers</b> where relevant</p>	 
 <p>Lack of appropriate evidence to inform optimal use of antibiotic treatments</p>	<p>Support <b>evidence generation</b>, including providing technical and implementation support for real-world and cost-effectiveness to inform guidelines and optimal use</p>	    
 <p>New antibiotics are priced out of reach</p>	<p>Increase appropriate demand through <b>pooled procurement</b>. Identify and <b>create efficiencies in manufacturing to optimize CoGS</b> (e.g., through standardizing product packaging, optimizing process chemistry and <b>manufacturing in LMICs</b>)</p>	    
 <p>Poor uptake systems, weak stewardship and lack of adequate &amp; timely diagnosis</p>	<p>Work with local partners to develop <b>access implementation networks</b> for rapid introduction of antibiotics in the hospital and community setting. To support a responsible and robust access strategy, a network of early adopters can help build evidence of effectiveness in implementation and stewardship models</p>	   

# Since the launch of the project, we have achieved key important milestones and are on track to deliver on our objectives

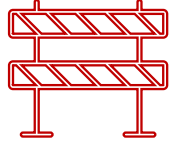
## Key milestones in our journey so-far and in the immediate future



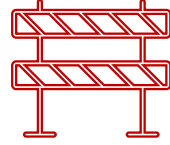
*Note: We have developed detailed activity-based project plans with SMART milestones that articulate our expected progress for the next few years including completion of tech transfer to manufacturing sub- licensee, identification and on-boarding of commercial sub- licensees in different markets/regions, regulatory registrations in key markets leading to actual launch of the product in prioritized markets in 2026; These plans can be shared upon request*

**#** One of a kind “pathfinder” events paving the way for other antibiotics globally

**Barriers addressed**



New antibiotics are priced out of reach



Lack of interest from suppliers to commercialize antibiotics

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

**April - May 2023:** Audits completed; reports assessed, and **decision made on the top choice for manufacturing sub-license** (leading pharma manufacturer in India)

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

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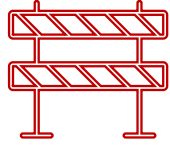
**June 2022:** Collaboration agreement signed between GARDP, CHAI and Shionogi to enable access for Cefiderocol in LMICs

**Late May 2023:** Initial draft of manufacturing sub-license shared with the potential sub-licensee; Received estimates for CAPEX requirements and CoGS; **Negotiations stated; Made announcement of collaboration with GDF**

**July 2023:** **Finalize collaboration agreement with Global Drug Facility (GDF)** for pooled procurement for GARDP portfolio including Cefiderocol



**Barrier addressed**



Lack of registration in LMICs

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

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

1

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

**April 2023:** After months of engagement and advocacy by GARDP, **WHO issues “expression of interest” inviting applications for filing PQ for Cefiderocol**

# 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

- Guidance development
- Identification of local evidence needs
- Align EML and regulatory prioritization to guidelines

## GUIDELINES

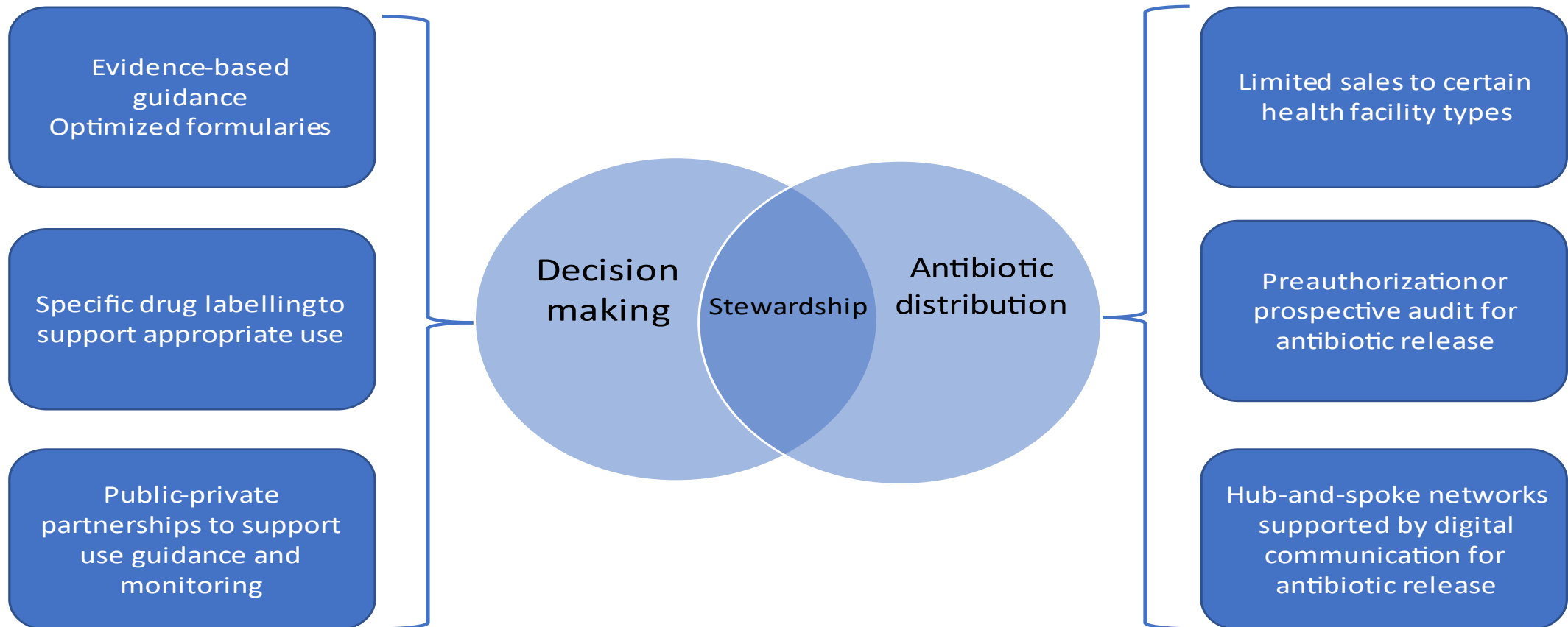
## IMPLEMENTATION

- Strengthen local antibiograms
- Diagnostic network map and strengthening
- Training, site monitoring and mentorship
- Incentives

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

## POST-APPROVAL RESEARCH

# Demonstrate Uptake Models: An Introduction Pathway for New Antibiotics





# Case Study 2

**SECURE: Improving visibility,  
predictability and risk in the  
antibiotic market while  
supporting appropriate use**



## ► **SECURE** | An initiative to assist countries to treat drug-resistant bacterial infections



### “The antibiotic facility”

SECURE’s mission is to expand access to essential antibiotics to treat drug-resistant bacterial infections.

SECURE is a collaborative initiative from GARDP & WHO

SECURE will work with **countries to understand their needs for**

- **Sustainable, equitable and appropriate access to:**
  - **quality-assured antibiotic portfolio driven by public health and clinical needs**
- To a portfolio of
  - **new antibiotics especially reserve** to address drug-resistant infections
  - **existing antibiotics** that are not widely available or that suffer from frequent supply chain interruptions and/or shortages

*\* New = SRA approved but not available in country potentially or available with access issues.*

## ► SECURE Antibiotic Portfolio

SECURE's portfolio includes antibiotics where there is an “access” issue AND where countries are unable to solve that access problem on their own,

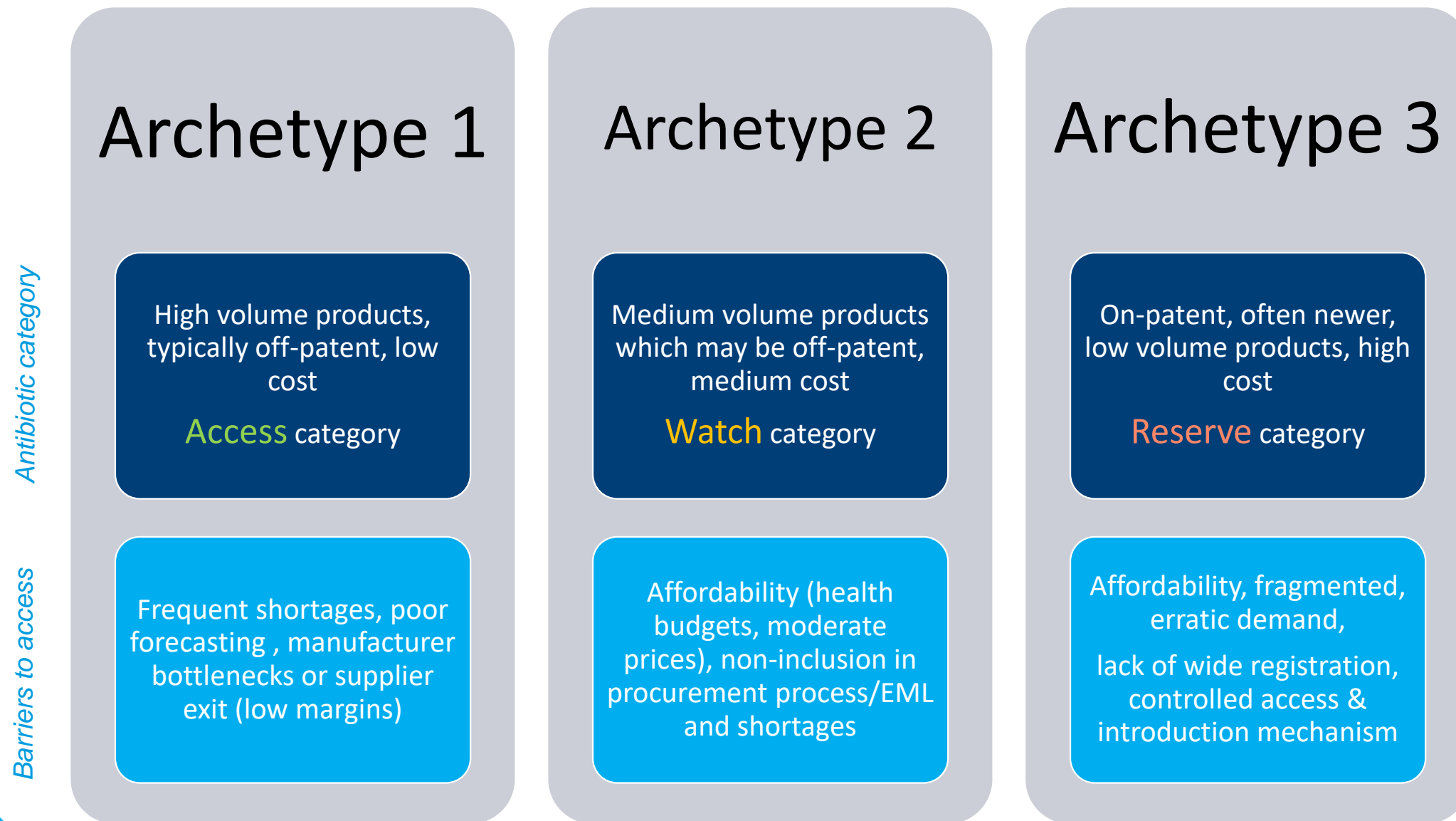
PLUS the antibiotic must be critical to address a public health need based on emergence of resistance (AMR) and priority pathogen treatment.



secure  
Antibiotic characteristics

- EML
- Registered or not registered

# 1. Challenges with Access expressed in Antibiotic Archetypes



## Existing antibiotics prone to shortages

## New (Reserve) antibiotics

### Coordinated pooled procurement & forecasting

#### Access interventions

- Regional stockpile of critical Antibiotics with shortage risk
- Strengthen regulatory requirements for supplier mitigation plans

- Product Introduction strategy to accelerate entry
- Facilitate registration, product indications & quality assurance
- Supplier guarantees, subsidy or bridge financing to improve affordability

#### Stewardship interventions

- Optimized EML
- Monitoring - surveillance of resistance & consumption (via WHO/partners)
- Prescriber-level training & stewardship (via WHO/partners)

- New guidelines and inclusion on national EML
- Evidence generation, monitoring - surveillance of resistance & consumption (via WHO/partners)
- Prescriber-level training & stewardship (via WHO/partners)



## ▶ 2. Procurement and financial levers

### Economic and financial toolbox



Toolbox

**A** Purchasing options

Pooled procurement

Stockpile (Global/Reg.)

National procurement

**B** Supplier-facing models

Volume-delinked

Volume guarantee

Revenue guarantee

Advance purchasing agreement

Volume-based

Unit costing

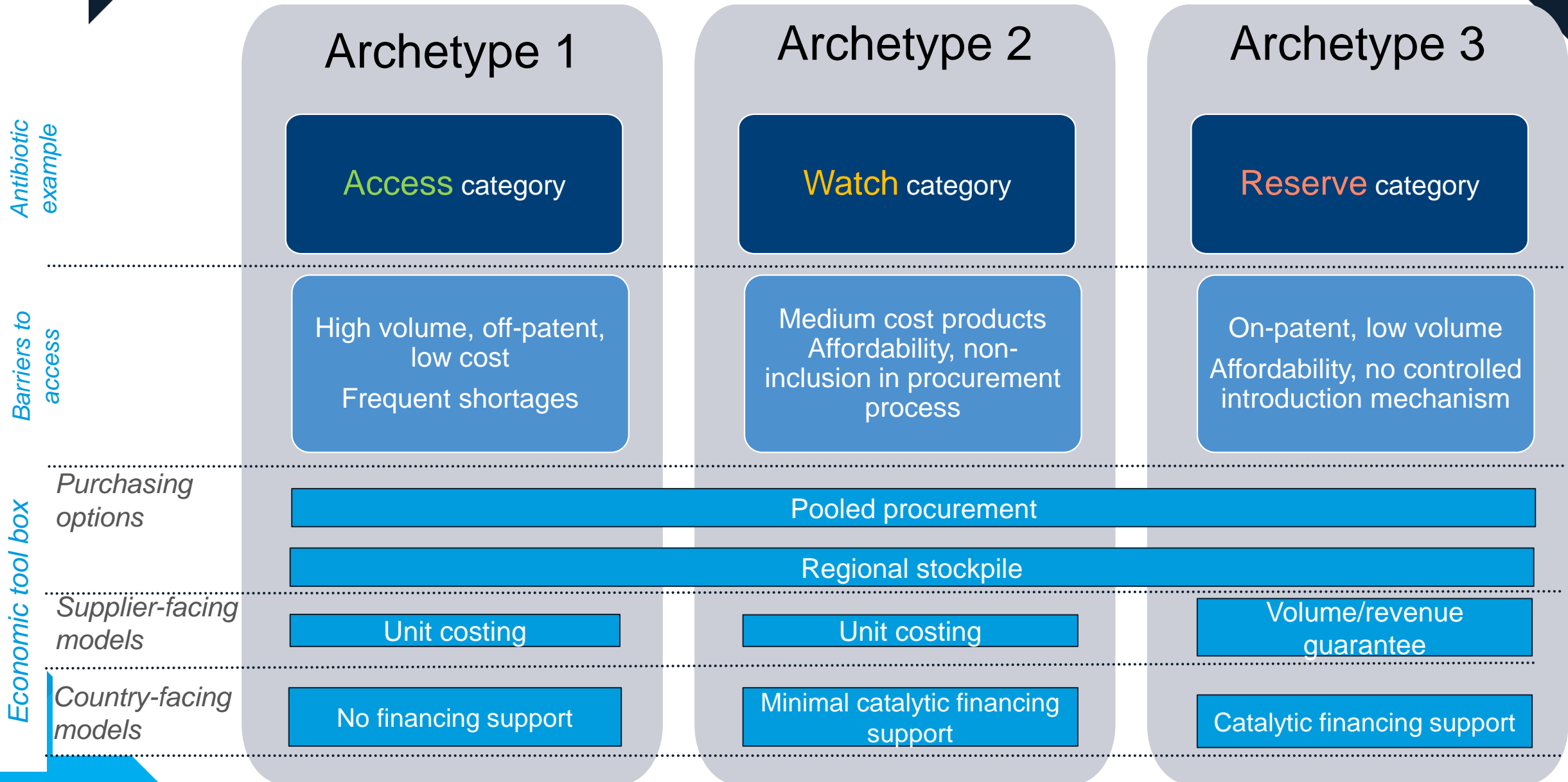
**C** Country-facing models

Catalytic subsidy scheme1

No financing support

1. Scheme based on countries economic level

# 3. Testing against scenarios | toolbox applied to antibiotic archetypes



# Strengthen Supply-Demand Match: Example of Market Intelligence Dashboard

## GARDP Analysis on Reserve Antibiotics

Please Select the required Metrics & Filters

Sales in USD  
 Volume in Units

**32.08K**  
Sales

Molecule: Multiple selecti...  
 IV or NON-IV: IV  
 Country name: BRAZIL

Please use the slider bar to drill down to the required date range

2022      2022

2018      2019      2020      2021      2022

# MAH

8

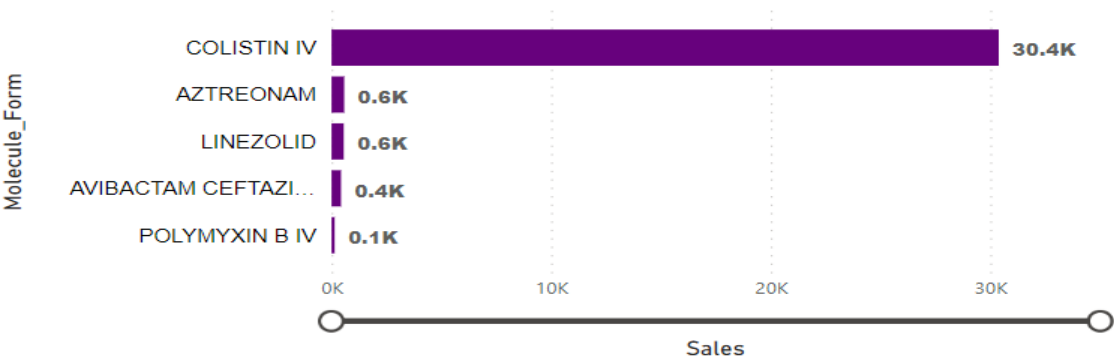
# Products

9

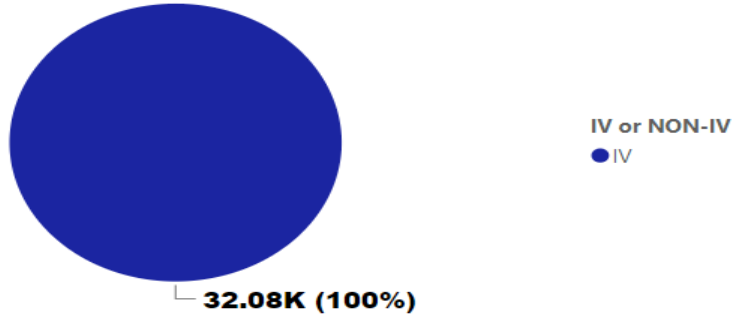
# Molecules

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Sales by Molecule



Sales by product form

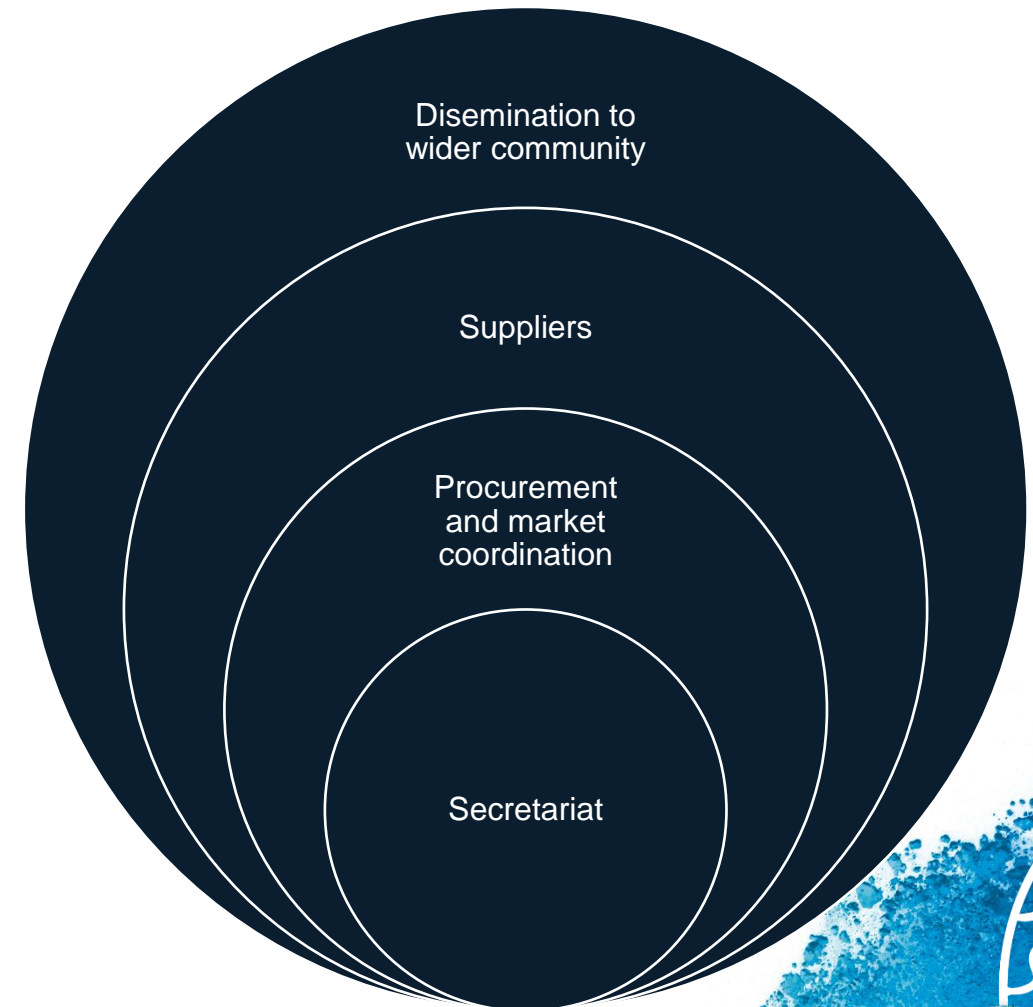


# Strengthen Supply-Demand Match: Example of RESERVE+ Antibiotic Market Working Group

Goal: To share intelligence about and intervene in the market to ensure consistent access to RESERVE antibiotics or other products during market transition or threat

## Objectives

- Coordinate efforts to ensure timely and consistent access to RESERVE antibiotics
- Align supply availability with demand
- Collect, analyze and share market intelligence
- Improving efficiencies of market
  - Pool demand/forecasts
  - Support order alignment
  - Understand procurement pathways and market segmentation in major markets
- Develop procurement and supply chain tools
- Convenes key stakeholders including governments, suppliers, major procurers or early adopters
- Serve as a platform to share key threats (e.g. product shortages, demand/supply mismatch) and build responses





**Access  
challenges...absolutely**

**Testing creative solutions  
Building an ecosystem  
Documenting and scaling  
success**





**Thank you**

