

Improving sustainable access to antibiotics through market intelligence and coordination

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All infections are treatable
for everyone, everywhere

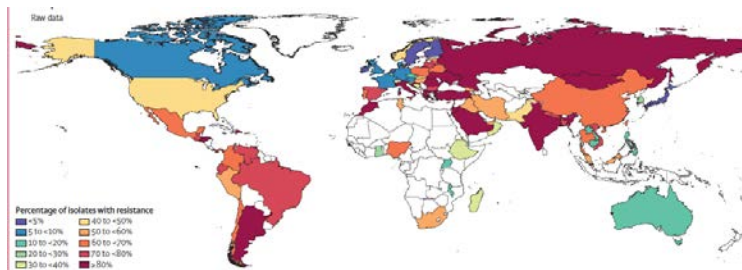
We work with partners
to **accelerate the development**
and access to treatments for
drug-resistant infections

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

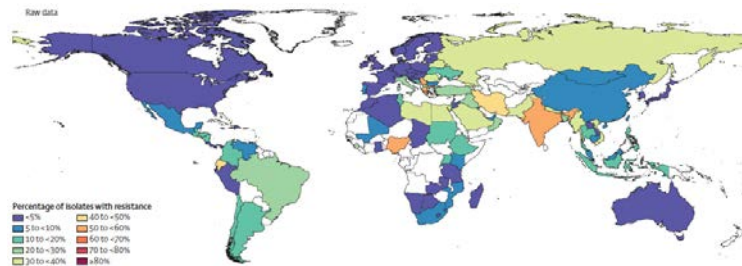
Peter Mugenyi, Ugandan HIV/AIDS researcher 13th Int. AIDS Conference Durban, 2000

1. Growing antibiotic resistance

Carbapenem-resistant *Acinetobacter baumannii*

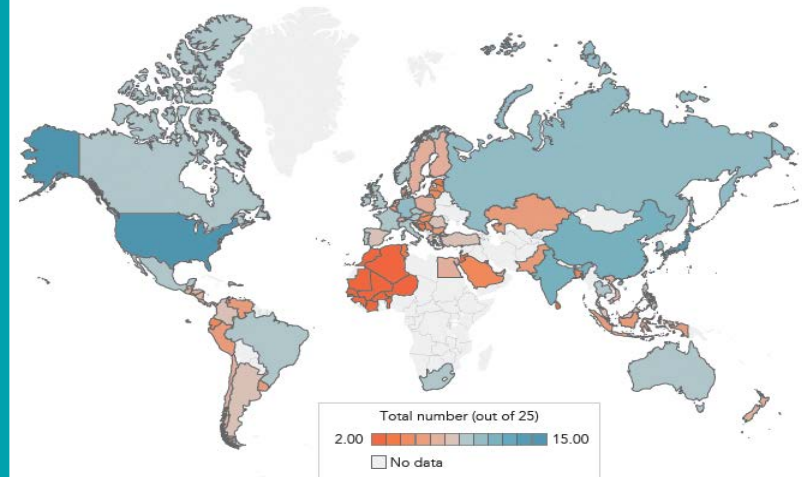


Carbapenem-resistant *Klebsiella pneumoniae*



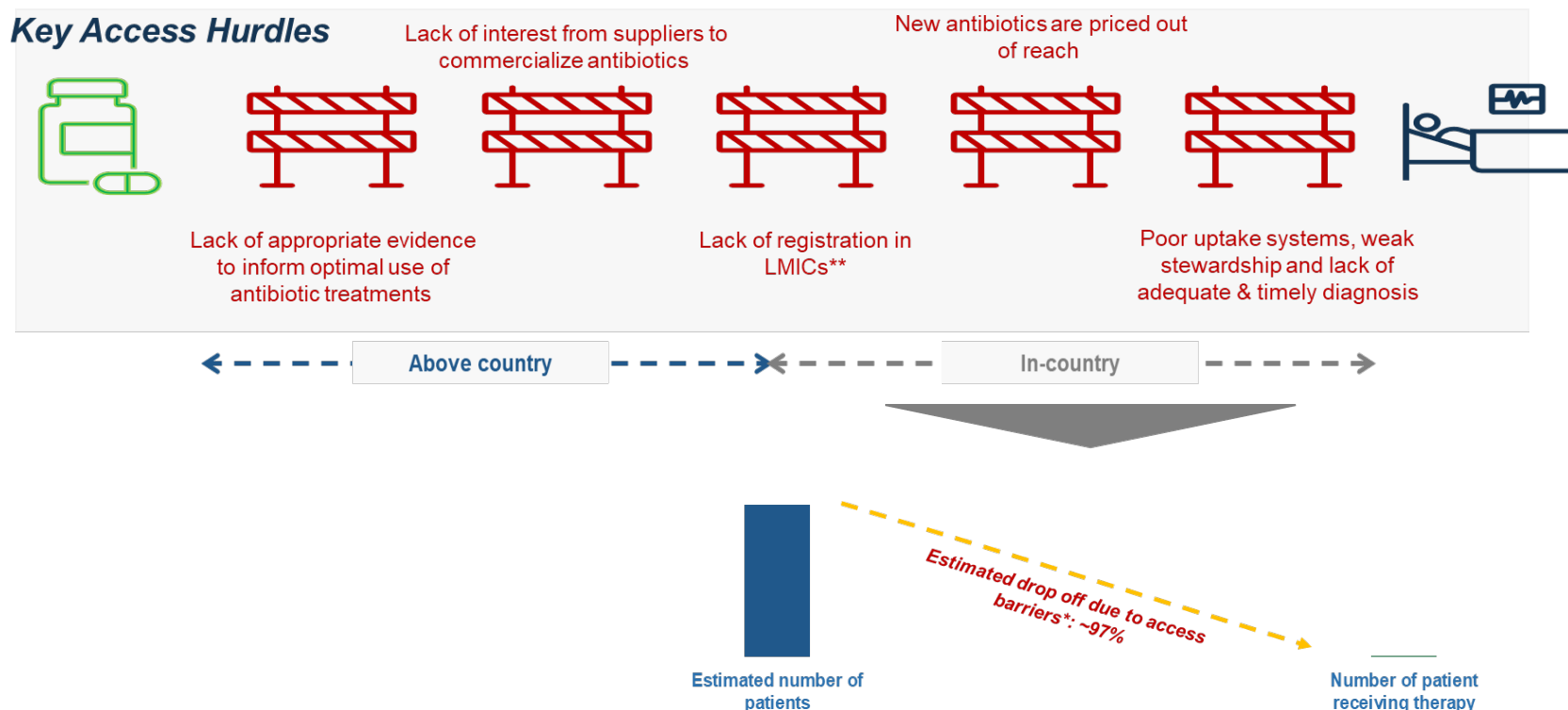
2. Not widely registered

Number of antibiotics registered 1999-2014



AMR collaborators, Lancet 2021; Kallberg et al, PLoS One 2018

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

The Cefiderocol Access Project: A Pathfinder for Equitable and Appropriate Antibiotic Access

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

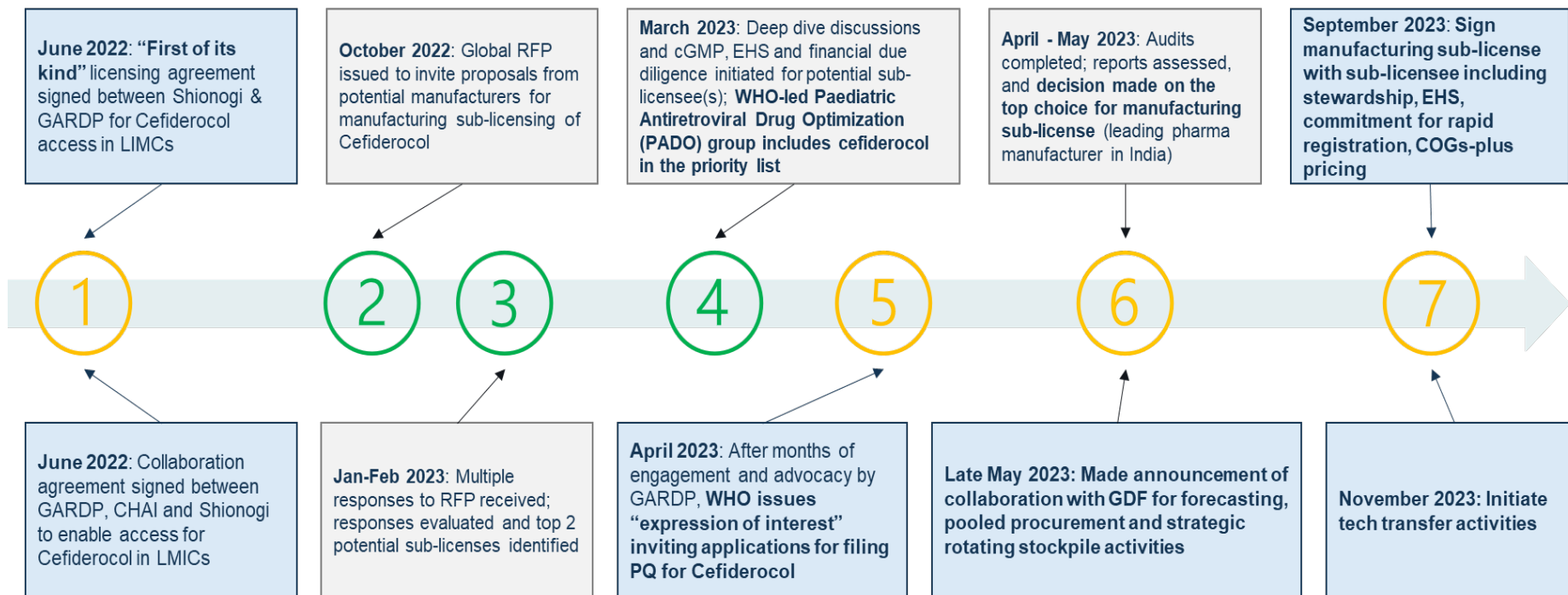


Guidelines
Evidence-based guidance to steward appropriate use

*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

The GARDP cefiderocol access project: Market shaping milestones

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

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



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**

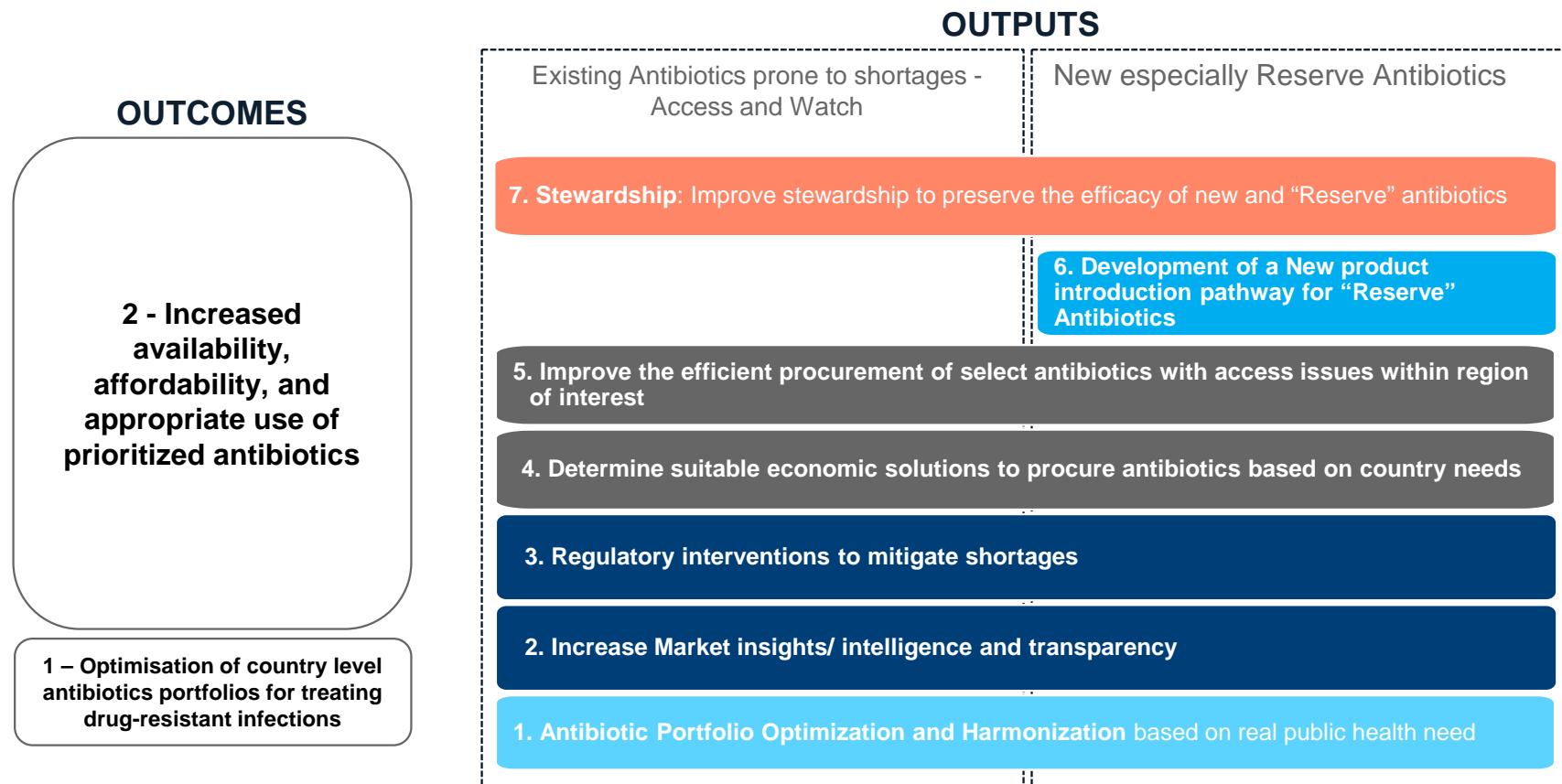
To a portfolio of

- **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

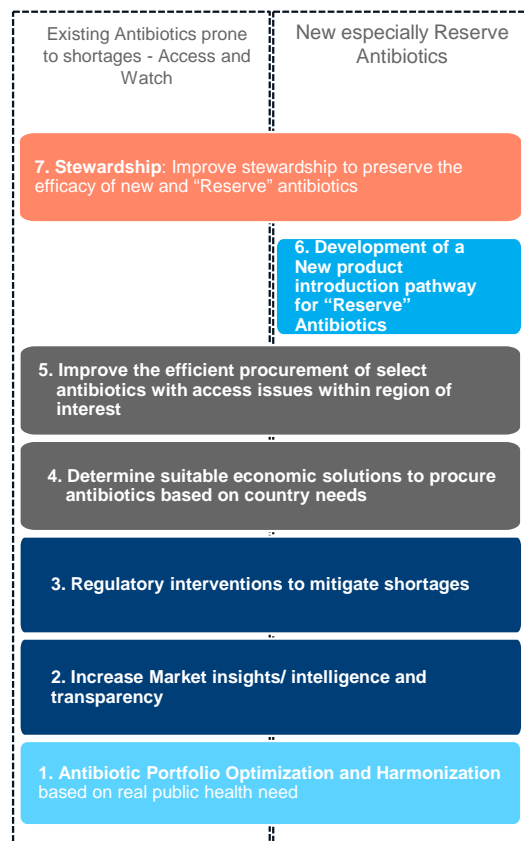
** New = SRA approved but not available in country potentially or available with access issues.*

How will SECURE achieve this in a way that adds value

“Building block” Interventions to address goal



Key achievements to date per output



1. Antibiotic portfolio Optimisation:

- GARDP research on portfolio to treat CRE and ESBL infections (Gram Negative with greatest impact on AMR Mortality)

2. Market insights/ intelligence:

- Forecasting model RFP issued September and about to be awarded
- GARDP – IQVIA analysis on Reserve antibiotics dashboard
- Reserve + Market Working Group to be established in Q1 2024

3. Regulatory Interventions to mitigate shortages:

- Review of regulatory authorities role to address antibiotics shortages in LMICS - RFP issued September and about to be awarded

2. Example of Market Intelligence Dashboard

GARDP Analysis on Reserve Antibiotics

Please Select the required Metrics & Filters

☐ Sales in USD
 ☒ Volume in Units

32.08K

Molecule
 Multiple selecti...

IV or NON-IV
 IV

Country name
 BRAZIL

Sales

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

2022

2022

2018

2019

2020

2021

2022

MAH

8

Products

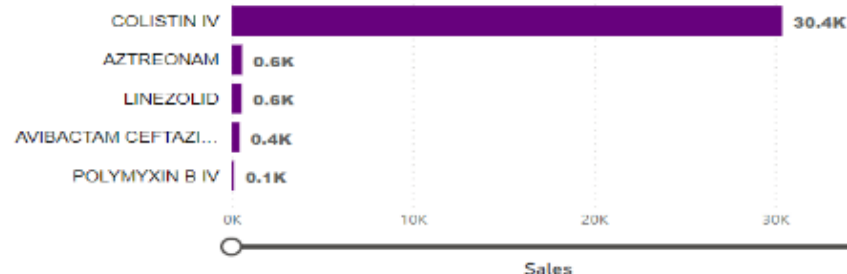
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Molecules

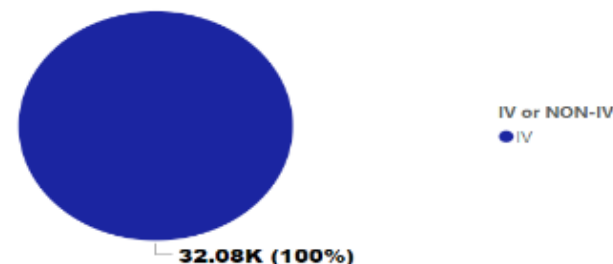
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Sales by Molecule

Molecule_Form



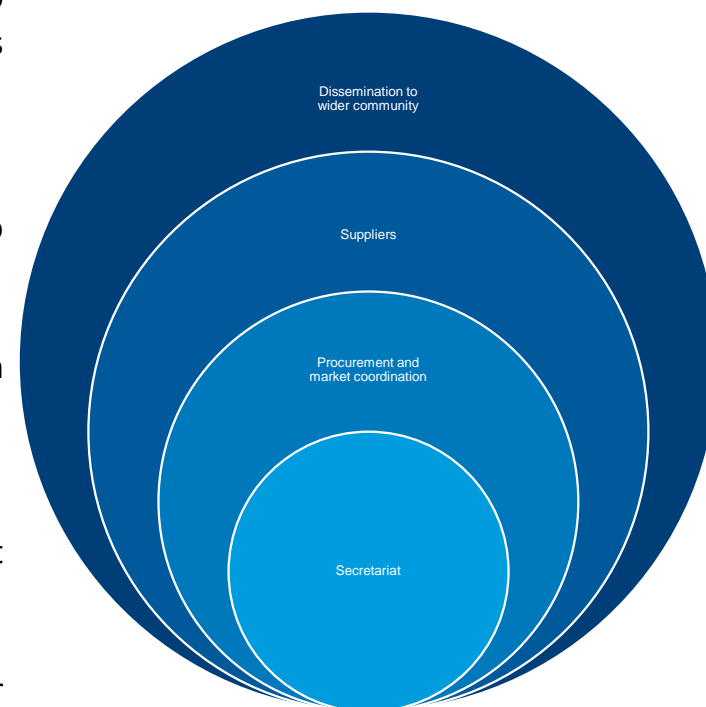
Sales by product form



2. Increase Market insights/ intelligence and transparency: Reserve+ 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
 - Collect, analyze and share market intelligence
 - Understand procurement pathways and market segmentation in major markets
 - Align supply availability with demand - Pool demand/forecasts
 - Develop procurement and supply chain tools
 - Serve as a platform to share key threats (e.g. product shortages, demand/supply mismatch) and build responses

Convene key stakeholders including governments, suppliers, major procurers or early adopters



Thank you

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