

SECURE DEVELOPMENT PHASE UPDATE

September 2023

SECURE is an innovative initiative being developed by World Health Organization (WHO) and the Global Antibiotic Research and Development Partnership (GARDP) to improve access to both existing and new antibiotics.

The antibiotic access challenge

Access to essential antibiotics is a vital component of the global response to antimicrobial resistance (AMR) and overall pandemic preparedness. However, existing antibiotics (which are often generic) are increasingly subject to supply interruptions in low-, middle- and high-income countries (LMICs) alike, or are simply not available. As a result, the best tools for combating infections fail to reach those in greatest need, and the subsequent use of alternative antibiotics contributes to the development and spread of resistance. At the same time, newer products especially Reserve ¹ antibiotics, have limited access because of low and erratic volumes and high prices. Demand is therefore limited and as a result, products are often not registered or supplied in many countries, particularly in LMICs.

SECURE will increase access to a **portfolio of quality-assured antibiotics in a sustainable, equitable and appropriate way**. It will improve appropriate access **to both existing and new antibiotics**. SECURE's antibiotic portfolio will be adapted to meet national public health and clinical needs.

How will SECURE work?

SECURE will work directly with, as well as through partnerships with organizations and countries. A key objective of SECURE is to encourage collaboration between countries and regions to create self-sustaining mechanisms to boost resilience. SECURE will also play a key role in ensuring that global, regional and country activities are coordinated and mutually reinforcing.

What will SECURE do?

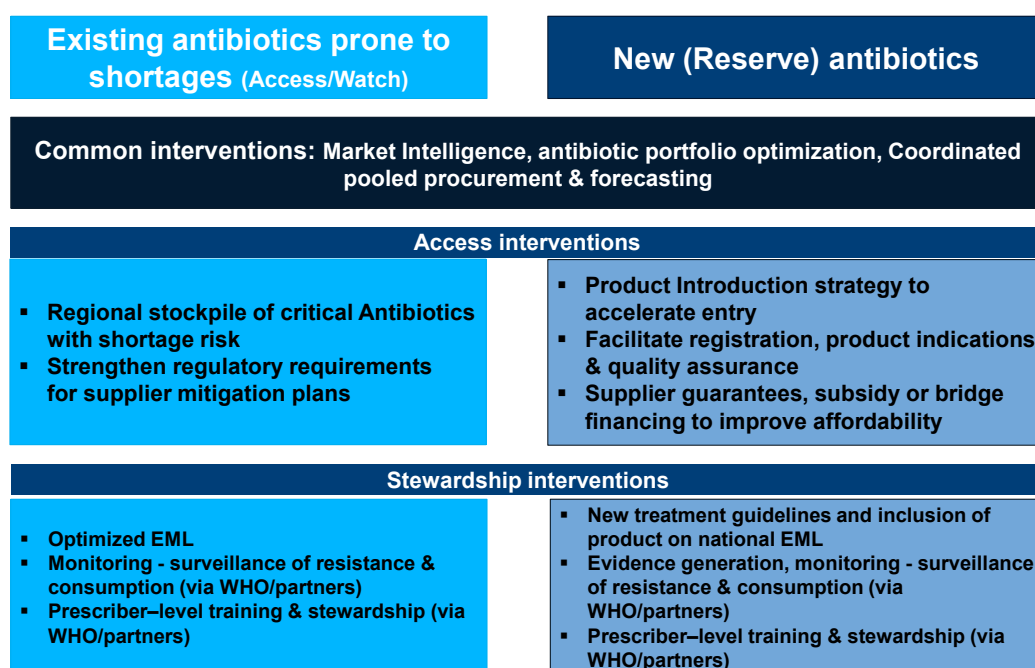
- SECURE will increase demand predictability and attractiveness for suppliers by aggregating demand across countries:
 - SECURE is creating an **antibiotic forecasting model** to support pooling, stockpiling and contracting with suppliers, using a prioritized portfolio of antibiotics
 - SECURE is embarking on work with existing procurement mechanisms to establish **pooled or coordinated procurement mechanisms**
- SECURE will implement measures to address recurrent antibiotic shortages, including identifying the need for **stockpiles** of selected antibiotics and working to establish these within existing systems.
- SECURE will establish mechanism to collect and collate **antibiotic and supplier market intelligence** to improve decision-making on procurement, warn of shortages and identify priorities for expanded manufacturing, including domestic manufacturing.

¹ Based on the World Health Organization AWaRe classification of antibiotics – Access, Watch and Reserve.
<https://www.who.int/publications/i/item/2021-aware-classification>

- SECURE has evaluated how **economic tools** can be used to incentivize suppliers to enter country markets and support country purchasing through catalytic financing methods. SECURE aims to apply and test these tools as part of an overall proof-of-concept of the SECURE model.
- Working through partners at country and regional level, SECURE will support:
 - the simplification of antibiotic portfolios through **prioritization, optimization or harmonization at a country/regional level**, which will support clinical best practice and improve the efficiency of forecasting and procurement and supply.
 - Gathering **real-world evidence on the local use of antibiotics** and monitoring both consumption and resistance, to inform updated treatment guidelines as well as forecasting and procurement, and evaluate the impact of SECURE interventions.

Recognizing that the access challenges of existing and new antibiotics are different, SECURE has defined a set of tailored interventions that target each of these product types (Figure 1):

Figure 1 – SECURE interventions tailored to existing and new antibiotics



Stewardship is at the core of SECURE - The introduction of new (often Reserve) antibiotics, needs to go hand in hand with monitoring their appropriate use, as well as governance structures and policies to protect the longevity of antibiotics. SECURE will work with countries to support optimization of their broader antibiotic portfolio and by developing product introduction pathways. This will be supported by broader operational guidance being developed by WHO on the introduction and preservation of new Reserve antibiotics. Stewardship activities could also include working with country partners to create guidelines and provide training for prescribers, if required.

SECURE will also work with relevant partners to support stewardship as part of product registration and regulatory interventions, for example through the inclusion of specific drug registration product indications; marketing and labelling requirements; data reporting requirements; and quality assurance of products.

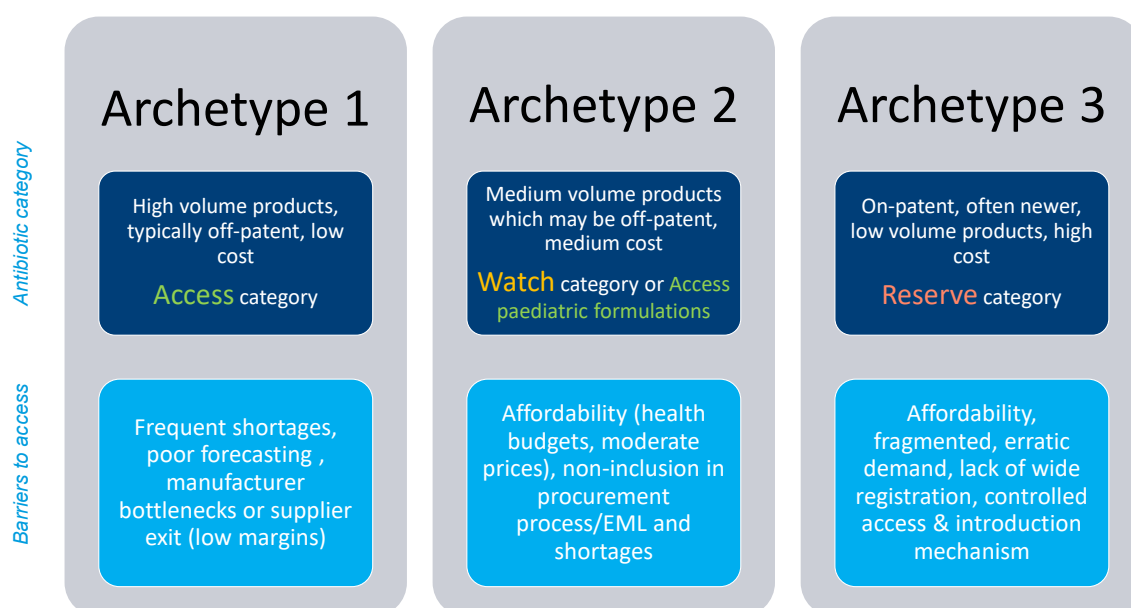
Update on SECURE Development Phase activities

The following key activities were completed from March to August 2023:

- A. **Identification of key access barriers for different antibiotics and potential interventions to address these:** Three priority antibiotic access archetypes were identified representing key challenges that SECURE needs to address:
1. **Archetype 1: high volume, off-patent antibiotics characterized by low margins under the "Access" category.** Recurrent shortages, stemming from inaccurate forecasting, manufacturing constraints, or suppliers ceasing production, were identified as the most significant barrier.
 2. **Archetype 2: antibiotics that are of medium volume, possibly off-patent, classified under the "Watch" or mid-volume "Access" category, notably those for paediatric use.** Challenges to access encompass factors such as cost considerations relative to national budgets, omission from procurement policies, and frequent product shortages.
 3. **Archetype 3: Reserve antibiotics that are on-patent, typically recently introduced, that are used at low volume and are highly priced.** Key challenges hindering access to these products involve financial constraints and inconsistent and segmented demand, leading to limited registration across essential geographical areas.

Based on these product archetypes, a set of tailored interventions has been designed to address key challenges through SECURE (Figure 1).

Figure 1 – Antibiotic Archetypes with barriers to access



- B. **Analysis of economic and procurement tools.** SECURE developed a model of different economic and procurement tools to assess the benefits and cost of various access interventions for the three priority antibiotic access archetypes described above. The analysis evaluates the costs for SECURE to contract an existing procurement entity to provide procurement services, with additional support for subsidies to participating countries and/or guarantees to suppliers (depending on the product archetype). The model and tool were pressure tested for feasibility with global stakeholders.

Based on provisional findings, a set of economic and procurement interventions were identified to enhance access to these antibiotics. These include pooled procurement mechanisms, supplier market-entry incentives through small scale guarantees, enhanced affordability via temporary catalytic financing for countries, and assurance of steady supply via stockpiles. It is crucial to tailor and combine these interventions to address individual product and country needs, particularly as we advance to the next phase of the SECURE initiative. It is envisioned that, in collaboration with countries, a small portfolio of "Access", "Watch", and "Reserve" antibiotics will be identified by late 2023 to test the SECURE model. This will align with treatment guidelines and drug resistance indicators.

For more about the other SECURE Economic model please refer to SECURE Update Economic Model September #2.

- C. As noted above, projects are being **incubated as SECURE global interventions**. These include the development of an antibiotic forecasting model, cost of goods analysis for select antibiotics, a landscaping review of best practices in regulations that would mitigate against shortages, and development of WHO operational guidance on the introduction and preservation of new Reserve antibiotics. SECURE is also carrying out consultations with regions and countries to validate and refine the proposed interventions and gauge interest in participating in an early implementation phase that will serve as a proof-of-concept of the SECURE model.

