

# SECURE's Economic & Procurement Tools to Address Access Challenges for Antibiotics

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**SECURE is developing economic and procurement tools to incentivize suppliers of antibiotics to enter more country markets. The goal is to significantly improve the appropriate use of, and access to, antibiotics. SECURE also aims to provide catalytic financing support to countries for the purchase of antibiotics where affordability is a critical barrier.**

To inform the design of SECURE's procurement and economic interventions, an analysis was undertaken with the support of Boston Consulting Group to model the impact and costs of different economic and procurement tools. A key aim of SECURE is to create market efficiencies and predictability, for example by aggregating antibiotic demand across multiple countries through pooled or coordinated procurement mechanisms. The goal is to optimise pricing and availability for countries by creating a more attractive market for suppliers, while ensuring appropriate stewardship.

This report focuses on the economics of antibiotic product procurement as a building block within SECURE's business model and does not represent a comprehensive description or costing of all other SECURE interventions <sup>1</sup>. For more about our other interventions please refer to the SECURE 2023 Development Phase update on the SECURE website.

The model estimated the impact of different packages of economic and procurement tools on access to, and costs of, different antibiotic products. The analysis used several different antibiotic 'archetypes' <sup>2</sup> and evaluated the purchasing costs to participating countries as well as costs incurred by SECURE to set up and operate the system. The model also considered the feasibility of implementing different packages of tools by pressure testing the models with key stakeholders including procurement entities and suppliers.

## Challenges with Access by 'Antibiotic Archetype'

Based on our analyses that included stakeholder assessments and market intelligence (secondary data), three 'antibiotic archetypes' were identified along with their associated key access challenges that could be addressed by SECURE (see figure 1):

- **Archetype 1: High volume, off-patent antibiotics characterized by low margins. These antibiotics were often in the "Access" category.** Recurrent shortages, stemming from inaccurate forecasting, manufacturing constraints, or suppliers ceasing production, were identified as the most significant barriers.

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<sup>1</sup> For more about the other SECURE interventions please refer to Newsletter Development Phase no 1.

<sup>2</sup> Antibiotics that share common features in terms of categorisation as per WHO AWaRe index and similar access challenges or market dynamics.

- **Archetype 2: Antibiotics that are of medium volume, possibly off-patent. These antibiotics were often classified under the "Watch" or mid-volume "Access" category, notably those for paediatric use.** Challenges to access include factors such as cost considerations relative to national budgets, omission from procurement policies, and frequent product shortages.
- **Archetype 3: On-patent, typically recently introduced, that are used at low volume and are highly priced. These antibiotics are typically Reserve or lower-volume Watch antibiotics.** Key challenges hindering access to these products involve prices, financial constraints and inconsistent and segmented demand, leading to limited registration across essential geographical areas.

## Economic models explored to solve access barriers

This analysis tested a range of potential procurement and economic tools to solve issues described in the above archetypes. The initial analysis was focused on low- and middle-income countries (LMICs), with the assumption that high-income countries (HICs) may be modelled and included at a later date.

The analysis estimated the impact of different tools for a small country, with a total population of 12 million, of which 75% (9.3 million) rely on public sector health services. This country was added into a pooled procurement mechanism with an assumed pool of 100 million public sector population. Tunisia was selected as the small country for modelling purposes due to availability of data for the required variables. One sample antibiotic was chosen to represent each archetype in order to use real pricing data to model. Public sector tender prices as well as estimates for consumption volumes for sample antibiotics were available from a representative country to assist in the modelling. This is why the 100 million pool was modelled on the public sector population only.

The assumption is that SECURE would partner with an existing procurement entity or entities (including existing regional pooled procurement entities). These would provide services to support country forecasting, pooling of orders, and contracting with suppliers on price and terms. It would also involve running tenders or direct negotiations on prices, decisions on allocations, ordering and payments, supply and logistics with warehouses containing the stockpiles and transportation to the ports of entry of countries. Thereafter the model assumes that the country would take control of the last mile processes of distribution.

### Purchasing options explored included:

- Coordinated procurement, ranging from pooled forecasting to pooled procurement and ensuring supplier diversity through multiple supplier selection
- Developing regional or international stockpiles of antibiotics
- Supplier guarantees (e.g. revenue or volume guarantees).

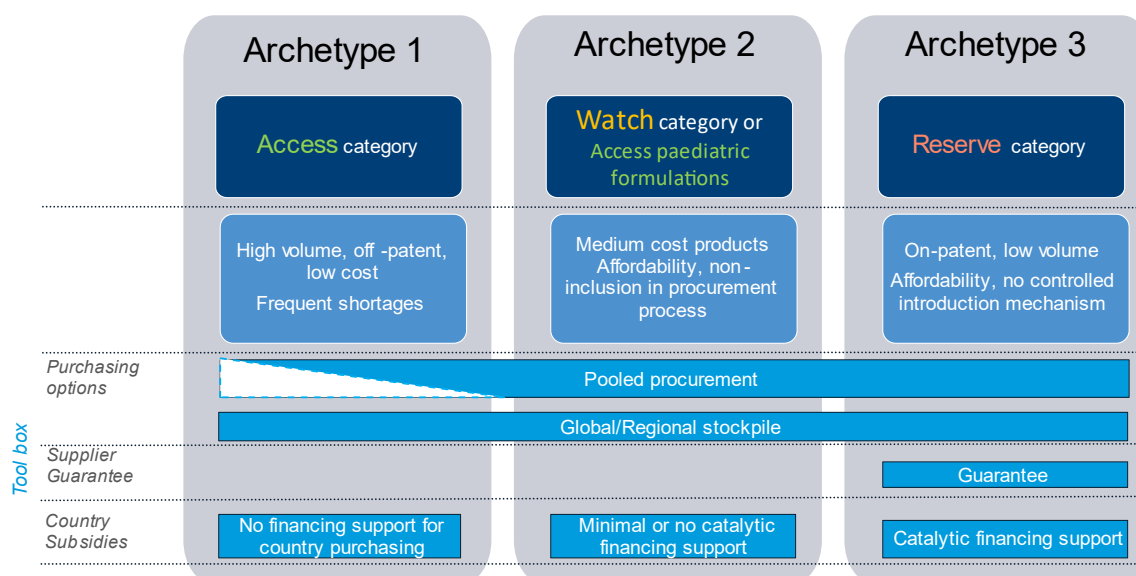
### Financing models for countries (see definitions at end):

- Time-limited catalytic subsidy payments for product procurement to improve affordability and reduce entry barriers.

Ultimately, the goal is for countries to become self-financing in the future, driven by a growing and more stable antibiotic market generated through early adoption activities and increasing commitment from countries.

For each antibiotic archetype, individual economic tools were identified as potential solutions. Various combinations of economic tools were tested and those which could help to address key access barriers most feasibly were chosen (see figure 1 below). While a broader range of economic tools and combinations of tools were evaluated, this note will describe the packages of tools which were found to have the highest potential in terms of feasibility and cost.

Figure 1 – Antibiotic Archetypes and Barriers to access with economic tools to support access.



**Conditions necessary for the models:** Testing and comparing outputs across different scenarios was only possible by standardising and adding conditions for each model to work. These conditions are critical to achieve the desired impact when implemented. Some of these conditions include:

- The willingness of countries and manufacturers to adopt pooled procurement using an existing procurement entity contracted by SECURE
- Establishing mechanisms to implement stewardship, availability of diagnostics for laboratory sensitivity testing and monitoring systems for pharmacovigilance
- Mechanisms to accelerate or harmonize drug registration processes of selected prioritized products across a range of countries including the development of standardized packaging/labelling.
- The existence of a functional in-country distribution and cold chain (where needed) to ensure the drugs reach the patients

This model and its findings are based on a small set of antibiotic archetypes using individual drugs with limited data availability and include informed assumptions on the potential benefits of interventions. The model is meant to demonstrate the potential costs, benefits, and feasibility of the interventions. Therefore, refinement of the model with larger local data sets of countries and their specific antibiotic prices is needed to confirm assumptions, expected impacts and costs.

## Scenarios showing good potential for SECURE to flexibly address country-specific needs.

Provisional findings indicate that SECURE has high potential to support access to antibiotics by implementing the following tools: pooled procurement, supplier guarantees, temporary catalytic product subsidies or financing support to countries, and stockpiles. It is important to note that the most economically attractive stockpiles in the analysis were revolving stockpiles linked to pooled procurement mechanisms. The supplier guarantee would be based on either a minimum revenue or volume that is sufficiently attractive to register the product in the countries making up the pool and structured in such a way as to ensure appropriate use. In the case of the volume guarantee, volumes would be based on forecasts of demand based on appropriate use. Should the minimum revenue needed for suppliers exceed estimated demand, i.e. more volume would need to be guaranteed than what would be required for appropriate use, a revenue guarantee would be more appropriate. In either case of a volume or revenue guarantee, should the demand exceed the minimum levels determined, then it will be paid for at a unit cost at the agreed price. This is similar to the Sweden model of revenue guarantee. Benefits of supplier guarantees include improved affordability for countries, incentivized market entry and predictability of demand for suppliers, surety of supply and quality-assured products available in countries.

Ultimately, a balanced portfolio of “Access”, “Watch” and “Reserve” antibiotics to enhance stewardship and match national treatment guidelines would need to be created. See a brief summary of the most viable scenarios in figure 2 below. It provides the key results for the package of tools applied to each antibiotic archetype using a sample antibiotic. Results are shown in terms of overall cost savings to those participating in pooling, potential product price discount, and estimated cost of implementing the contracting of the mechanism to a procurement entity over 5 years.

Figure 2 – Scenarios showing good potential for SECURE to flexibly address country-specific needs

Antibiotic Archetype	Tools	Antibiotic example (single drug per archetype)	Pooled Country savings over 5 yrs <sup>1</sup>	% discount potential <sup>2</sup>	Costs of procurement mechanism over 5 yrs <sup>3</sup>
<b>1. Registered, medium price, medium volume</b>	Pooled procurement + Stockpile	“Access” antibiotic (amoxycillin oral solution)	15.2 million USD	30%	12.3 million USD
	Pooled procurement + stockpile + with catalytic subsidy	“Watch” parenteral antibiotic (azithromycin IV) (subsidy applied at 20% and declining thereafter)	46.7 million USD	37%	26.9 million USD
<b>2. Non-registered, high price, low volume</b>	Pooled procurement + stockpile + supplier guarantee + catalytic subsidy	“Reserve” antibiotic (Ceftazidime/avibactam IV) (subsidy applied at 95% and declining thereafter)	8.6 million USD	90%	2.9 million USD + 2.2 million USD <sup>4</sup>

1. Savings calculated at average LMIC price for a small country (e.g., Tunisia) for an individual antibiotic and summed up for the entire 100 million population pool

2. Discount based on average LMIC price for antibiotic

3. Mechanism includes contracting with an existing procurement entity – service fees, stockpile, warehousing and wastage costs

4. SECURE Supplier guarantee liability for the countries in the pool

Please note : These numbers are indicative only with large uncertainty margins and are meant to illustrate the potential benefits and costs of different tools.

#### A. Scenario to address access issues for selected Access Antibiotics such as paediatric formulations and for Watch Antibiotics (Archetypes 1 and 2)

The package included here aims to creating a predictable, more efficient and sustainable market for suppliers, while also providing insurance against shortages. This could also improve the quality of products available to the countries at an affordable price by adhering to quality assurance standards.

The tools applied include:

- Procurement: Pooled procurement with multiple vendors
- Revolving stockpile linked to the pooled procurement mechanism to protect against shortages or unpredicted outbreaks at regional or global level
- Catalytic subsidy as an option for higher priced Watch antibiotics. SECURE subsidises 20% of cost for drugs in year 1, reducing to 5% in year 5 and then continues as a self-financing scheme thereafter.

For a single watch drug (based on *azithromycin parenteral*), countries could save 37% in product costs (a total of USD 46.7 million over 5 years for the 100 million pool) through price reductions resulting from pooling and subsidies. This mechanism has the highest cost due to larger drug volumes, as well as warehousing and stockpile costs with a need for USD 26.9 million over 5 years for a pool of 100 million population.

For a medium-volume paediatric drug such as *amoxicillin oral solution*, this mechanism would enable countries participating in the mechanism to save approximately 30%. The cost to SECURE would be USD 12,3 over 5 years for the 100 million pool.

#### B. Scenario to address key access issues related to on-patent, often newer, low volume products usually in the Reserve category (Archetype 3)

The package to improve access to Reserve antibiotics focuses on creating a market for the supplier that is more coordinated, predictable, and consolidated (with relatively larger volumes) to improve affordability and expand availability. Interventions to reduce introduction barriers were also included for these products which often are more expensive or more difficult to introduce.

The tools applied include:

- Procurement: Pooled procurement
- Revolving stockpile linked to the pooled procurement mechanism
- Supplier guarantee - The guarantee was based on about 4,200 standard units (SU) of product equal to a revenue of about USD 430k similar to what was done in the Sweden model
- Catalytic subsidy: SECURE subsidises 95% of the cost for drugs in Year 1 and Year 2; 79% in Year 3 and thereafter a decline of 5% per annum

A single small LMIC participating in a pool of 100 million public patients would have a flexible supply of product, even with very low demand. For a single product (modelled based on *Ceftazidime/avibactam IV*), savings are estimated at USD 0.812 million over 5 years - due to minimal volumes needed) with the potential to receive the drug at a more than 80% discount based on the estimate of an average LMIC price. Total savings for the entire pool of countries would potentially amount to USD 8.6 million. It would cost USD 2.9 million to establish the mechanisms for the pool of countries, comprising procurement services, catalytic subsidy as well as a supplier guarantee. SECURE

would need to provide an additional guarantee liability of USD 2.2million, if purchases by countries don't meet the volume required.

Key stakeholders have confirmed that this model would improve market attractiveness for manufacturers and support access and affordability for these antibiotics into geographies previously not considered attractive. The risk with increased accessibility is inappropriate use and therefore stewardship interventions are a critical component in this scenario. Participating parties can help support stewardship by implementing a new product introduction strategy for phased and monitored introduction, appropriate use and training of prescribers. SECURE should also work with countries to ensure that demand does not shift use in favour of Reserve antibiotics as they become more available, and their affordability improves.

### *C. Models found to be less feasible*

Several other procurement and economic packages were tested which were found to be less feasible. This included using a rotating stockpile for emergency supply without pooling to address global shortages of high-volume "access antibiotics". The costs to run such a stockpile were estimated at USD 60 million for 5 years for a single product (modelled on *cefixime oral tablets*) for the pool of 100 million population. This is not likely to be economically feasible or effective, as the choice of stockpile size will depend on the severity of expected shortages and the ability to predict which antibiotics and which countries may be prone to shortages, so that the stockpile can be placed in the correct region.

Therefore, other non-financial interventions would be needed to address global shortages of high-volume Access antibiotics. For example, countries can optimize their access antibiotic portfolios and procurement to support market consolidation. SECURE can support countries with improved market intelligence and more reliable forecasting models and can advocate for national regulatory authorities to address shortages by supporting supplier mapping, requiring suppliers to report anticipated shortages and disseminating information on forecasted demand.

LMICs may not find it feasible to agree to upfront supplier guarantees for reserve antibiotics given their low historical demand and their limited public health funds. Such subscription or supplier guarantee models may be tried as innovative pilots with interested countries once the SECURE mechanism is functional with proven benefits. Alternatively, the pooling entity can administer the supplier guarantee while the country continues to purchase products on a per unit cost as normal. Especially if the pooling entity is a non-profit or public entity, this structure will serve as an additional layer of de-linkage as the pooling agent will have no profit motive to sell more volume.

### **Risk for mitigation**

Risks are related to the set-up of the procurement entity and mechanisms. Countries may be uncertain about the potential benefit of such mechanisms resulting in lack of national political will to participate. The sustainability of the mechanisms may require that country subsidies are continued over a longer period to allow countries to continue accessing certain antibiotics. The benefits of market consolidation and improved predictability combined with tools such as supplier guarantees may not be sufficient to incentivize suppliers to participate or to agree on price reductions.

Operating risks, such as inaccurate forecasts and delayed payments by countries, impact the certainty and liquidity of the procurement entity. Financial risks for the mechanism are substantial once the models scale up as additional countries are added. There is also a risk that forecasts are incorrect, or countries don't buy the products for which supplier guarantees are provided, thereby requiring the

guarantor to step in and pay. Countries might not adhere to forecasting and stewardship monitoring mechanisms, undermining the ability to preserve the effectiveness of these antibiotics.

## Key takeaways and next steps for SECURE

SECURE can play a key role in improving access to appropriate essential antibiotics. Two packages of interventions tailored to key access issues of common drug archetypes were deemed feasible and provide a very promising financial case to begin SECURE's implementation. Savings were shown for countries as compared to their average cost baselines, while the cost to create the mechanism with an existing procurement entity is deemed to be reasonable and sustainable compared to other scenarios tested. Discussions on specific access challenges and possible economic solutions with countries, potential manufacturers, distributors, and procurement entities will help to further refine the economic model. These are planned for the latter half of 2023.

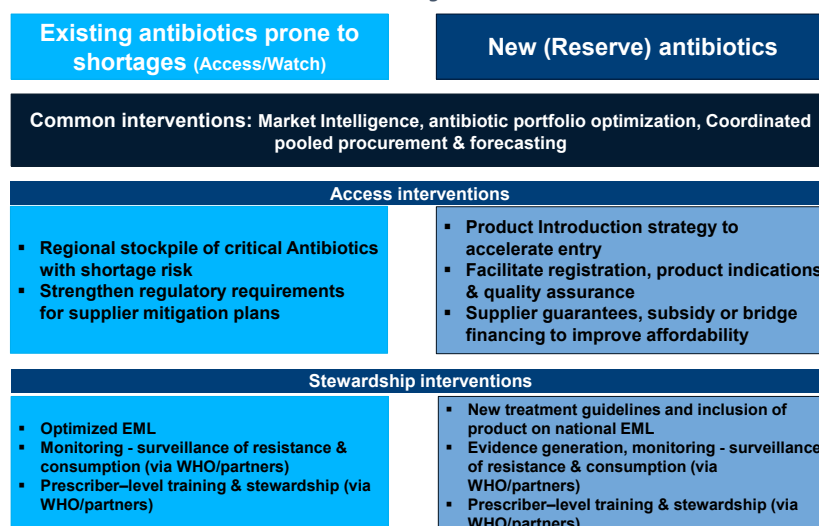
It is important to note that SECURE will work directly with, as well as through partnerships with organizations and countries to encourage their solidarity in establishing regional procurement mechanisms. Stakeholders' supported use of existing international or regional pooled procurement entities and the selection of the right entity or entities will be crucial to SECURE's success.

It is crucial to tailor and combine the economic tools with the broader SECURE interventions (please refer to SECURE Update Development Phase on our website and summarized in figure 3 below) which addresses individual product and country needs, particularly as we advance to the next phase of the SECURE initiative. A critical next step is to narrow the product portfolio to a small set of antibiotics with importance to public health and well-known access challenges, widely applicable to many countries and which can be modelled, so that we can understand actual funding requirements. This more concrete and granular data will facilitate discussions with potential partners in the implementation phase, including participating countries.

Determining the most practical stewardship levers which can be included within the SECURE interventions or those that require in-country partner support will go hand in hand with the portfolio decisions and require a country-specific lens. These again would form part of the country discussions.

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.

*Figure 3 – SECURE interventions tailored to existing and new antibiotics*





## Summary of economic tools with definitions

**Coordinated procurement** options included informed / coordinated buying whereby entities share market research & other data, but contract and buy separately; joint contracting in which multiple entities negotiate prices together but purchase independently; and pooled procurement with central contracting & purchasing where multiple entities purchase antibiotics together to cover their needs in a coordinated fashion.

**Stockpiles:** Options examined include rotating stockpiles with annual replenishments or revolving with continuous resupply and replacements as drugs were used by countries. These could be managed regionally or globally and payment to the manufacturer would be on consignment (i.e. when drug is delivered) or upfront. In the case of a revolving stockpile, the stockpile would be managed by the pooled procurement entity.

**Revenue guarantee:** In a revenue guarantee model, a supplier is guaranteed an annual revenue for supplying product based on the needs of the country. The guarantee is set at a level that ensures a viable business case for the supplier. It is anticipated that the revenue guarantee will initially result in overpayment for the product as volumes needed will be (initially) lower than the revenue amount. Should the demand exceed the ceiling volume agreed as part of the revenue guarantee, then it will be paid for at a unit cost at the agreed price. The guarantee used in our model was based on the Sweden model of about USD 430k per annum.

**Volume guarantee:** A minimum volume is guaranteed to the manufacturer (at an agreed price), to ensure a minimum scale for production for the manufacturer (and being able to offer a specific price). Technically the physical exchange of the product is anticipated and can be matched to the volume guaranteed. If the demand is higher than the guaranteed volume, then it will be paid on a unit basis. Often this is used to offset uncertain or fluctuating demand.

**Time-limited catalytic financing:** For certain higher cost products, a time limited subsidy was used to offset initial higher prices and enable countries to participate in the pool. With increasing demand and corresponding lower prices, it is envisaged that the subsidy could decrease over time. Full subsidy was also considered but was determined to be less feasible due to high costs and resulting lack of sustainability.

Other subsidies may take the form of a grant to support country activities during the period of new product introduction where additional new processes need to be established, including stewardship. However, these were not included in the analysis.