Written responses to remaining audience questions of the webinar 'SECURE: Improving access to antibiotics through new economic models' by Kim Faure, Alexandra Cameron, Yewande Alimi, Joël Denis & Jennifer Cohn, moderated by Javier Guzman.
Originally broadcast on 14 February 2024. See webinar recording here: https://revive.gardp.org/secure-improving-access-to-antibiotics-through-new-economic-models/

Question asked	Response from the speakers
What gives you the confidence that countries will continue after 5 years to become 'self-sustaining'?	The principle of ensuring that countries become financial self sustaining is a key principle for SECURE and was important in the approach we took for the modelling work. This means that each country would incorporate the costs of antibiotics into their health budgets over the period of the mechanism which was initially assumed to be 5 years as a base assumption. This would obviously need to be tailored to the country or group of countries within which we will pilot as they will have their own economic and financial challenges. However, this model must be tested and refined. SECURE is also based on co-development and as such, there will be responsibilities for all partners, including participating countries, to work towards a successful and self-sustaining model.
In the total Secure Project cost , how many manufacturers of anti-infectives were considered and how will you ensure Quality standards?	Our key informants indicated that efficiencies in procurement occur with 3 to 4 suppliers. However, this is obviously dependent on the type of product as with generics the number might be easy to reach, however with patented products this may not be possible (outside of the potential for licensing) – hence other supplier incentives and interventions were tested. SECURE plans to work with existing procurement entities and SECURE will adhere to the procurement entity's requirement. For example, many international procurement entities require SRA or WHO PQ as quality assurance. However, as SECURE is interested in working with regional pooled procurement entities, PQ or SRA approval may not always be required by the procurement entity. In these situations, SECURE may work with third parties, such as QUAMED, to assess the quality of the manufacturing site and perform a dossier assessment. Another option may be to expand WHO PQ to include products SECURE is focusing on and incentivize manufacturers to submit to PQ in order to be part of SECURE. Finally, the WHO's national regulatory authority benchmarking work is an exciting development and WLAs may also be relied upon for quality assurance.

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It is observed that the input cost of medicines continue to increase (cost of Raw materials and manpower cost). How will you ensure that the prices remain stable without demotivating the suppliers?	SECURE aims to make the market attractive for the supplier whilst still improving affordability for the countries. Hence, it's a continual partnership between the suppliers who are engaged within the mechanism by the SECURE contracted procurement entity. Rules around price increases which are substantiated will need to be set and agreed with the countries in the pool to ensure reasonableness and fairness without compromising quality or access to the antibiotics. In addition, SECURE aims to work with countries and regions to focus and harmonize formularies, thus consolidating markets. This may actually lead to higher volumes, thus decreasing Cost of Goods Sold. Consolidated orders and long-term agreements will also lead to manufacturing efficiencies which suppliers have said will lead to lower manufacturing costs in the medium term.
Interesting numbers on financials were reported as results of the economic modelling. Can some numbers on the predicted effects on antibiotic access in the test population also be shared? I.e. what is the access now in that population and how will it likely increase? For example, will 100% of this population have full access to "Access" drugs? If the model is based on the assumption that 100% of the population will have full, unlimited access on all the antibiotics included in the portfolio, how can it be ensured that this goal will be reached with the proposed methods?	SECURE aims to work with countries to firstly understand their current demands and unmet needs for antibiotics to treat infections. This process would be part of any initial engagement process with the countries who agree to working with SECURE. We are in the process of developing forecasting models which will assist us in the determining demand, however the process cannot be perfect from the outset. It will require reiterations and continued adjustments to get to accurate forecasted demands for the country. As part of the modelling, we assumed countries ramp up their drug availability over the 5 years. to enable suitable stewardship mechanisms to be embedded. The model assumes that the countries in the pool would achieve the demand of the benchmark country which was modelled on the average LMIC utilization of antibiotics as reported on WHO GLASS and from tender and procurement data from some other LMICs where it was available. Please refer to page 9 onwards in the report for more details on the model assumptions. However, SECURE and its interventions will not solve all access problems. For example, many infections may go undiagnosed because of inadequate access to health care or poor access to diagnostics. In-country supply chain issues may lead to stockouts. All of these issues require additional input from incountry partners working alongside and in addition to SECURE.
Are there any specific barriers to access for antibiotics for children?	Many countries have reported specifically paediatric formulation access challenges. In addition, some antibiotics do not have labels that include

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	approved pediatric dosing while others do not have optimal pediatric formulations (e.g. see https://www.who.int/news/item/24-03-2023-who-releases-priorities-for-research-and-development-of-age-appropriate-antibiotics). GARDP as a key parter to SECURE, prioritizes R&D of antibiotics for children. Access challenges of pediatric formulations would be a key area for SECURE to unpack with each country when their needs are determined during initial engagements.
Will newer antibiotics be intentionally prioritized over generics in the antibiotic portfolios of countries, or will the higher cost of the newer drugs still favor the procurement of generics despite their higher resistance rates?	SECURE will not prioritize originator products over generic products. Where generic products are available, these will be considered for SECURE interventions if they lead to improved sustainable access to quality assured products. In addition, GARDP works on licensing for on-patent antibiotics to help expand availability of generic products. SECURE will work with the countries to understand their specific public health needs and their access challenges to antibiotics. We believe that a balanced portfolio of "access," watch" and "reserve" products is possibly the best solution as it will improve both access for empiric treatment as well as escalation treatment for drug resistance where it is needed. In this way we can improve stewardship and protect the effectiveness of newer and reserve antibiotics more effectively.
How can we overcome the high prices of Antibiotics in Low income countries especially in Africa?!	Based on our modelling work and the inputs from key opinion leaders, various economic and procurement tools may improve affordability for LMICs. Our modeling shows that the greatest discounts come from the combination of pooling, long term agreements and supplier diversity. The impact is greatest for the "watch" and "reserve" antibiotic categories, however the mechanisms may also provide some cost savings for "access" drugs although the benefits may be more around reliable supply and quality assured products. Please refer to executive summary and outputs in the report for more details.
How will the challenges of stewardship and access to diagnostics be addressed?	SECURE is focusing on antibiotics with access challenges as a first step. We would in the future look to collaborating with other partners who are better placed with an understanding of the complexity of diagnostics. Through the partnership with WHO, we are engaging countries globally to develop guidance on the introduction of new and reserve antibiotics including

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	the stewardship mechanisms which are already part of WHO Guidance with the technical implementation support of WHO Country offices. We also want to ensure a balanced portfolio of "access," watch" and "reserve" products is possibly the best solution as it will improve both access for empiric treatment as well as escalation treatment for drug resistance where it is needed. In this way we can improve stewardship and protect the effectiveness of newer and reserve antibiotics more effectively. This would translate into a new/reserve product introduction strategy which would include treatment guidelines, monitoring mechanisms to ensure appropriate use, controlled access to only higher level facilities who have the necessary diagnostics and stewardship processes in place.
Within the report have there been any considerations toward fostering innovation of new antimicrobials? Ensuring there is a long term access to novel antimicrobials for all.	SECURE is primarily focused on supporting LMICs to improve access to existing antibiotics where there are access challenges. We did test pull incentives such as subscription models for suppliers which incentive drug R&D however our key informants indicated that the complexity of determining the value of the antibiotics to set a subscription price and the increased cost to LMIC's, who are already resource constrained would likely be unattractive as an initial pilot for SECURE. However, GARDP as a key parter to SECURE is a non-profit product development partnership focused on development and access to novel and innovative antibiotics. Please see www.gardp.org for more information. Please also refer to page 13 in the report.
Could you elaborate on the process of portfolio selection - the challenges of understanding burden of disease and resistance profile - what are the data sources - is data generation part of the work required to set up this programme?	SECURE is based on co-development with participating countries and regions. Countries will determine which antibiotics are priorities to meet local and regional public health needs. Of these priority antibiotics, products with access barriers that SECURE can solve will be considered for inclusion in a portfolio. Products that are identified as priorities with access barriers that are also needed across several countries or regions will be further prioritized. SECURE will work with the country governments as well as with the clinicians to understand their specific public health needs, using their existing data sources (acknowledging there may be gaps) to unpack their access challenges to

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	antibiotics. We would also collaborate with other NGO's and in-country support partners who are already involved in strengthening or gathering the necessary data for decision making. Countries who are interested in participating in the SECURE initiative, would be engaged on an antibiotic portfolio optimization and prioritization exercise to harmonize the antibiotics needs to improve efficiency of procurement. For the initial pilot, we feel that it would be prudent to engage in countries where data already exists or is being collected and there is an understanding of their gaps and needs as well as the political will to explore mechanisms to improve access. We will use these pilots to continuously learn how best to improve engagements in countries where data sources are maybe not as rich and regional approaches may need to be taken around common access challenges based on common burden of diseases. We believe that a balanced portfolio of "access," watch" and "reserve" products is possibly the best solution as it will improve both access for empiric treatment as well as escalation treatment for drug resistance where it is needed. In this way we can improve stewardship and protect the effectiveness of newer and reserve antibiotics more effectively.
If all the newly developed antibiotics are made available to all, then will it not reduce the efficacy of the new antibiotic? As the resistant will grow at a faster speed. How will the stewardship be introduced here?	SECURE aims to ensure a balanced portfolio of "access," watch" and "reserve" products which meets the countries needs as it will improve both access for empiric treatment as well as escalation treatment for drug resistance where it is needed. In this way we can improve stewardship and protect the effectiveness of newer and reserve antibiotics more effectively. Through the partnership with WHO, we are engaging countries globally to develop guidance on the introduction of new and reserve antibiotics including the stewardship mechanisms which are already part of WHO Guidance with the technical implementation support of WHO Country offices. This would translate into a new/reserve product introduction strategy which would include treatment guidelines, monitoring mechanisms to ensure appropriate use,

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	controlled access to only higher level facilities who have the necessary diagnostics and stewardship processes in place.
Has secure started to identify potential interested countries in which to implement?	We have had some initial discussions via the WHO Regional Offices in the following regions: PAHO, AFRO, EMRO and WPRO. We would welcome any countries who are interested to participate to engage with us and we are more than happy to share more details with their relevant stakeholders. Please contact Kim Faure the SECURE Project lead on kfaure@gardp.org or +27 82 565 1388 (South Africa)
I would like to know how SECURE arrived at the specific portfolio of antibiotics derived from the Access/Watch/Reserve categorization (any input from governments? Which governments? Any input from CSOs?)	For SECURE implementation, countries and regions will lead the development of the portfolios. SECURE is based on co-development with participating countries and regions. Countries will determine which antibiotics are priorities to meet local and regional needs. Of these priority antibiotics, products with access barriers that SECURE can solve will be considered for inclusion in a portfolio. Products that are identified as priorities with access barriers that are also needed across several countries or regions will be further prioritized. For the presentation, an example antibiotic portfolio of Access/Watch/Reserve antibiotics to treat hospital based infections was created using information from GRAM Study for Sub Saharan Africa on the commonest pathogens and resistance levels to key antibiotics. This was cross referenced to the African Antibiotic Treatment Guidelines for Common Bacterial Infections and Syndromes. The purpose was to demonstrate the feasibility of the proposed solutions, using a portfolio of antibiotics how the economic and procurement tools would impact the different categories of antibiotics, impact on cost savings for the pool of 100 million population and how much it would cost to establish the procurement mechanism with SECURE support to contract an existing procurement entity and support on subsidies.