



Access Strategy and Priorities

Updated November 2023

Executive Summary

GARDP's vision is to ensure infections are treatable for everyone, everywhere. GARDP works with partners to accelerate the development of and access to treatments for drug-resistant infections that pose the greatest threat to health. GARDP's disease area strategy focuses on two areas: prevention of sepsis induced by bacterial infections and sexually transmitted infections (STIs). Since antimicrobial resistance (AMR) primarily affects the most vulnerable populations in low- and middle-income countries (LMICs), GARDP's activities focus on the needs of those groups. Access to antibiotics remains a significant challenge, with barriers across the entire product-to-patient pathway. Many of these barriers are particular to the antibiotic market and the ways that antibiotics are developed and registered.

Amongst the small group of public, not-for-profit and private sector entities active in the field of antibiotic R&D and access, GARDP bridges the gap between innovation and access. It ensures that access considerations are embedded into all aspects of our work so that patients and providers can have the treatments they need at the right time, in the right place, at an affordable price, and with the data needed to inform clinical decisions. During research and drug development, GARDP works to ensure access, for example by helping develop evidence across populations, including children, and by focusing on chemistry, manufacturing, and controls (CMC) to reduce the cost of goods or make the manufacturing process more efficient. GARDP also works to provide access to treatments for drug-resistant infections, collaborating with partners to accelerate the introduction and appropriate uptake and use of treatments.

This document outlines GARDP's access strategy and priorities. GARDP focuses on facilitating access to our portfolio of antibiotic treatments, while also recognizing that certain activities can be leveraged to improve access to other antimicrobials. By improving the enabling environment for access, GARDP in turn facilitates access to its own portfolio. In line with GARDP's focus on supporting an integrated strategy, GARDP works in collaboration and/or consultation with a number of actors, including expert and normative organizations, health systems and implementers, industry, payers, procurement and supply chain systems, regulatory bodies and civil society.

Note: This document will be updated as often as needed and at least once per year.

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1. BACKGROUND

The recent GRAM study revealed that AMR directly caused 1.27 million deaths and was associated with 4.95 million deaths in 2019.¹ This is nearly the same number of deaths from HIV/AIDS and malaria combined that same year. The data showed that 70% of deaths that resulted from AMR were caused by resistance to antibiotics often considered the first line of defense against severe infections. Critically, the GRAM study also found that most of the deaths were caused by six bacterial pathogens, and that resistance is rising across the world, especially in low- and middle-income countries (LMICs). In 2019, one in five people who died due to AMR were children under five years old.

Unfortunately, even after antibiotics are successfully developed, they are not necessarily accessible. A recent study found that the majority of the 18 new antibacterials approved and launched between 2010-2020 were accessible in only 3 out of 14 high-income countries (US, UK, and Sweden).² In low- and middle-income countries, the problem is even worse. Only 12 of the 25 new antibiotics that entered the market between 1999 and 2014 were registered in more than ten countries.³ Age, in addition to geography, may create a barrier to access. Paediatric development of novel antibiotics is regularly delayed, which limits treatment options for newborns and children.

The AMR market presents unique access challenges. Newer antibiotics are often developed to target multidrug-resistant isolates for which few or no other antibiotics are effective. They are thus categorized as Reserve antibiotics, for which the target market is often limited, resulting in very low sales and limited income for the manufacturer.⁴ Too many manufacturers in a small market may result in manufacturer exit from the market or inappropriate marketing that can harm stewardship efforts. However, a market with only one or two manufacturers is a fragile market, risking abrupt product discontinuation or shortage due to commercial or quality issues.

For small, growing markets, it is important to carefully balance supply and demand while supporting other market interventions to ensure access and affordability, including activities that can consolidate demand, make orders more predictable, incentivize broad registration in geographies where there is need, and support good marketing practices while also strengthening stewardship efforts on the ground to ensure appropriate use.

Ensuring equitable access means patients get the treatments they need at the right time, no matter where or who they are. Interventions to improve access thus must take into consideration local implementation, including registration, forecasting, guideline development, training, national and facility-based stewardship programmes and the diagnostic network.

There are also a range of public health and health system access barriers to overcome. For example, as many LMICs lack good data on local epidemiology, national programmes may not be able to prioritize new product introduction or create reliable forecasting models to determine demand. This lack of clear demand further weakens the case for product registration. Diagnostics may either not be available or may have such long turnaround times that the results are not available when needed to inform clinical decisions. Many LMICs have not developed guidance for treating bacterial infections, especially management of resistant infections, leaving clinicians without evidence-based recommendations on treatment selection and duration. Weaknesses in surveillance and local antibiograms and lack of timely diagnostics and guidance make the successful development and implementation of stewardship programmes difficult. They may also contribute to the increase of inappropriate antibiotic use. Frequent

shortages of older Access or Watch antibiotics due to market forces (described above) may aggravate the problem of inappropriate use. Finally, patients may have to pay out of pocket, especially for diagnostics, again hampering appropriate access to antibiotics. Even modest out-of-pocket payments for antibiotics can be an absolute barrier to access, especially for those who are at or below the poverty line and residing in countries in which healthcare coverage is only accessible through the private sector. High prices, particularly for new antibiotics, may also discourage government or private procurement.

Sustainable access is a key pillar of GARDP's mission. Given the challenges listed above and the relative paucity of other actors that address the AMR access space, GARDP is committed to developing a coherent strategy, strong expertise and activities that focus on access in order to meet our mission and goals.

2. ACCESS PRINCIPLES, OBJECTIVES, AND PRIORITY ACTIVITIES

GARDP wants to see a world where affordable antibiotics rapidly reach those in need, and where appropriate use is supported by evidence.

2.1 How does GARDP enable antibiotic access?

GARDP prioritizes facilitating access to its portfolio of antibiotics. GARDP works through partnerships to improve the enabling environment for access through projects like piloting improved procurement or economic models, or supporting development of interventions to combat shortages, including through SECURE, an initiative to expand access to essential antibiotics. GARDP focuses on access in LMICs where the AMR burden and access barriers are most severe, even while recognizing that access barriers also affect high-income countries (HICs).

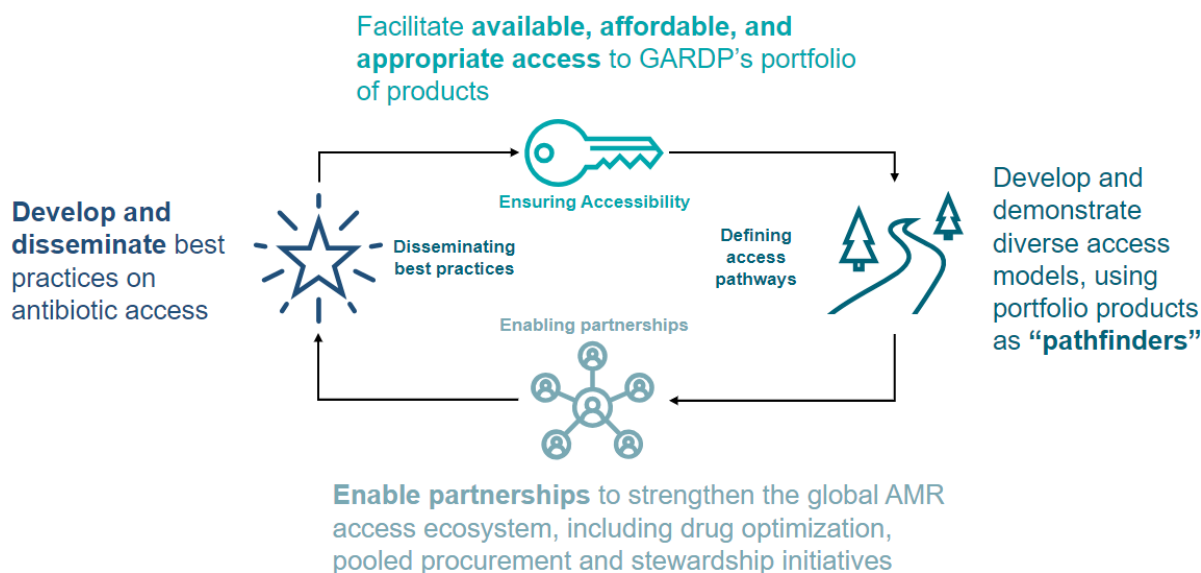


Figure 1: Our vision for access

2.2 Guiding principles of the GARDP Access Strategy

1. **Comprehensive:** GARDP analyses the entire product-to-patient pathway and builds access considerations and interventions into its work, from product research and development to patient delivery. Access considerations are thus reflected throughout R&D, policy and advocacy, business development, and implementation work.
2. **Rapid:** Accelerate equitable access so that GARDP's quality products arrive at the point of care wherever and whenever they are needed.
3. **Sustainable:** Extend the useful life of products, thereby improving access to effective treatments through optimal and rational use and stewardship programmes. Sustainable also means that the market will support ongoing and reliable production to meet demand.
4. **Integrated:** Bring together local and international actors, institutional players and the private sector, taking into account local country contexts, needs, and capabilities, to align efforts and develop partnerships for access. GARDP works in partnership and/or consultation with a number of actors, including expert and normative organizations, health systems and implementers, industry, payers, procurement and supply chain systems, regulatory bodies, and civil society.

2.3 Access objectives

- Build evidence for optimal use.
- Bring affordable, quality-assured antibiotic treatments in GARDP's portfolio to populations in need, especially children and neonates.
- License to quality manufacturers and distributors who bring the GARDP portfolio to countries.
- Support appropriate use and stewardship.
- Examine, develop and demonstrate interventions to improve the market and delivery of antibiotics.
- Develop access-oriented policy and advocacy positions.
- Support the development of networks of experts, implementers, civil society and other stakeholders to support antibiotic access across early adopter countries.

2.4 Priority activities

GARDP has three areas of access activities: 1) optimizing introduction and appropriate use; 2) sustainable, affordable, and quality-assured supply; and, 3) improving the enabling environment and market conditions for antibiotics. The priority areas represent a basic package that GARDP provides across product and portfolio areas.

GARDP's priority access activities:*

1. Optimizing introduction and appropriate use
 - a. Build evidence for optimal use, both pre- and post-registration
 - b. Provide data to relevant authorities for guideline development and Essential Medicines List (EML) inclusion
 - c. Partner with local actors to design and implement demonstration projects to support and evaluate treatment introduction and use, and build best practices
 - d. Support stewardship and appropriate use across the product lifecycle

2. Support for sustainable, affordable, and quality-assured supply through sublicensing, partners, and support for manufacturers and distributors
 - a. In- and out-license products
 - b. Secure quality-assured supply
 - c. Support WHO Prequalification (PQ) approval and national registration, through regulatory pathway mapping and developing robust regulatory dossiers
 - d. Work with suppliers to reach sustainable product pricing
 - e. Provide chemistry, manufacturing, and controls (CMC) support to manufacturers to optimize the manufacturing processes
3. Improving the enabling environment and market conditions for antibiotics
 - a. Develop, implement, and evaluate economic models and market shaping interventions, such as payment guarantees or subsidies, to ensure sustainable supply where relevant
 - b. Advocate for access-oriented policies

*For further details on these and other activities, please see section 3.2.

Figure 2 shows a simplified example of the access needs from product R&D through patient delivery and interventions that may be used to remove access barriers (with blue highlights indicating GARDP's focus). Throughout the product lifecycle, GARDP supports stewardship and environmental good practice, focusing where public health need is greatest and working in partnership whenever possible.

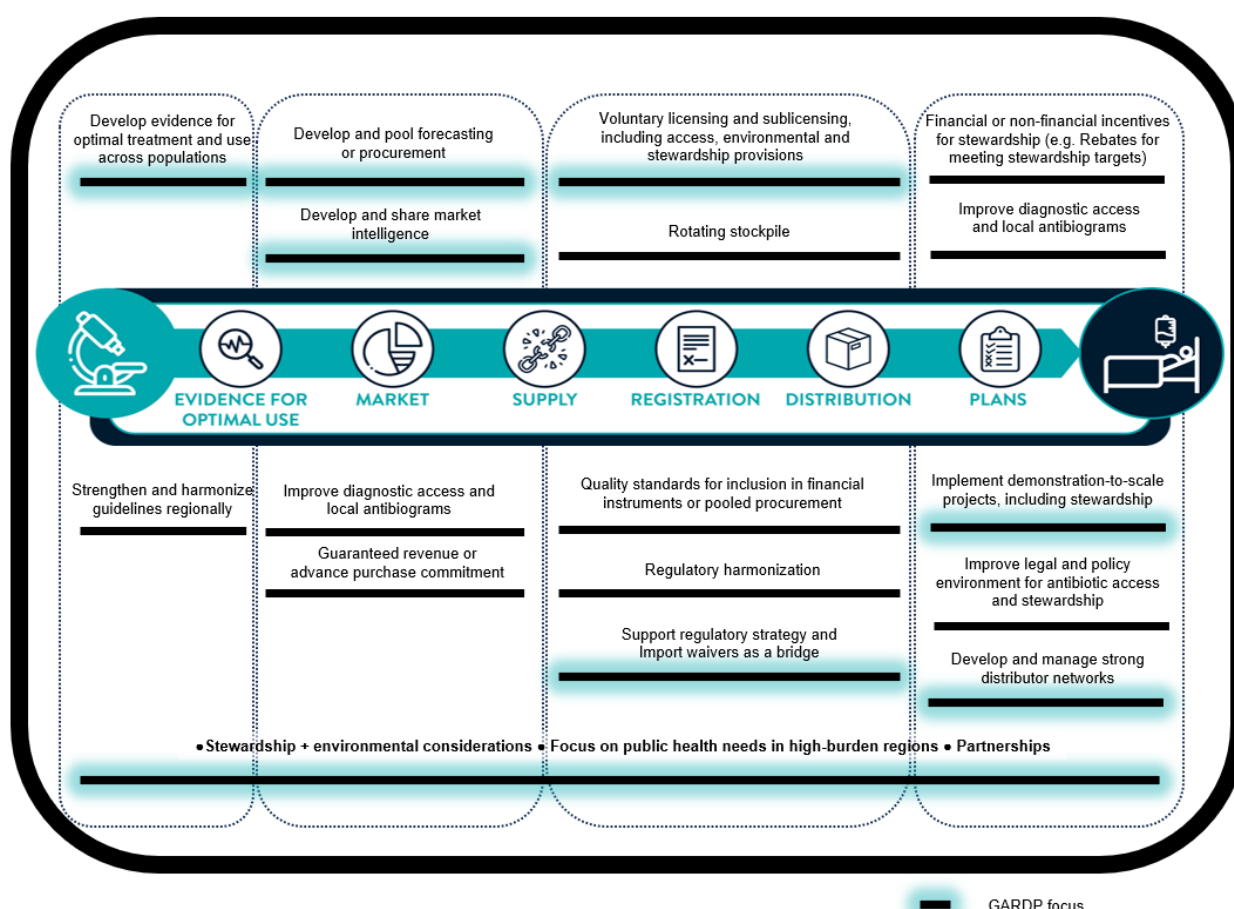


Figure 2: Access needs and interventions on the product-to-patient pathway, including GARDP's focus

3. ACCESS APPROACH

3.1 Catalyzing access: Partnering to rapidly adopt and demonstrate responsible access for new antibiotics

Based on the public health needs, priorities of countries, and other criteria (Figure 3), GARDP will identify a limited group of countries and approach local stakeholders to gauge willingness to be considered as “early adopters.” In these early adopter countries, GARDP, along with partners, can work to define a deep database of the market, health system, health economics, epidemiology, and stakeholder knowledge which will facilitate efficient product entry. In addition, GARDP can develop stable relationships with: commercial partners to manufacture and deliver GARDP products; national and regional partners; and specific health facilities. The early experiences gained by these countries will be used to generate lessons learned and identify best practices, as well as catalyse further sustainable and appropriate uptake in other geographies. Furthermore, the group of implementers, including private sector implementers and researchers engaged in early adopter countries, can form the basis of a network of regional antibiotic access champions that can support the introduction and evidence generation for future products.



Figure 3: Rubric to help guide country identification and engagement

Guided by this rubric, GARDP has developed a systematic approach to consistently evaluate potential early adopter countries for engagement. GARDP approaches this analysis with pragmatism and recognizes that partnerships may evolve based on changing epidemiology and local priorities.

3.2 GARDP positions on key areas of intervention and licensing

Wherever possible, GARDP works with and through partners to support our access work. As noted above, GARDP is working to leverage a multi-national collaborative access network of partners, including governments, procurement bodies, implementers, and civil society. GARDP collaborates with this network to 1) define key access issues; 2) achieve access objectives; 3) document and disseminate best practices and lessons learned; and 4) develop and act on shared policy and advocacy goals.

GARDP's priority areas for access interventions can be grouped into three areas: 1) optimizing introduction and appropriate use; 2) support for sustainable, affordable, quality-assured supply; and 3) improving the enabling environment and market conditions for antibiotics. The following section describes some of the key areas of intervention for access, outlines GARDP's positions, and suggests how GARDP may be involved. However, any GARDP activities will need to be tailored to the product, market situation, country context, and partner landscape.

OPTIMIZING INTRODUCTION AND APPROPRIATE USE

3.2.1 Evidence generation and dissemination

As part of its mission, GARDP develops new and existing drug products as treatments. Clinical trials are designed with access in mind, according to the R&D strategy. GARDP also focuses on working with both local partners and organizations with regional or international normative authority (e.g. the World Health Organization, or WHO) to identify gaps in post-approval evidence, including real-world evidence, that may help to improve the optimal use of novel or repurposed antibiotics. Generation of real-world evidence may include observational studies of product introduction, guideline inclusion, assessment of the impact of stewardship models, costing and cost-effectiveness, ongoing surveillance for resistance, and modelling resistance development. GARDP may collaborate with local partners to carry out studies and disseminate evidence through learning networks such as REVIVE, publications in peer-reviewed journals, and conferences. Whenever possible, GARDP publishes in open-access journals or pays for open access to GARDP-authored articles.

3.2.2 Guidelines and Essential Medicines Lists (EMLs)

GARDP works closely with the WHO AMR Division to support applications to update the WHO EML, including through evidence summaries, applications and letters of support, as relevant. The WHO Model EML serves as a guidance for national EMLs and signals a product's importance; inclusion in the WHO Model EML is one precondition for inclusion in the WHO PQ programme. Additionally, product inclusion in national EMLs is important, as inclusion in national EMLs often signal a product for regulatory prioritization or inclusion in national budgeting. GARDP works with WHO to understand and respond to evidence needs to inform guidelines. GARDP also works with Ministries of Health (MOHs), expert groups and other stakeholders, especially in early adopter countries, to help provide information to support MOHs when considering guideline change.

In addition, GARDP participates in AMR drug optimization work led by WHO and the development of target product profiles to help guide research and resources.

3.2.3 Demonstration projects

GARDP works with partners at the regional or local level to support planning and implementing demonstration projects of product introduction. In general, these projects may include a limited number of sites within a given country to support initial product use. For these demonstration projects, GARDP may provide more intensive support for quantification, product introduction planning, design and rollout of training materials. It may also design and implement evaluation approaches. Ideally, product introduction and use will be documented using clear monitoring and evaluation indicators or by using more stringent implementation science approaches such as the RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) framework. Evidence and lessons learned from these demonstration projects will be used to inform subsequent phased product introduction. To help disseminate this information, GARDP may partner with existing training and mentorship networks, including international networks such as Project ECHO. Such networks provide a mutual learning platform for the early adopter network to share information, best practices, and challenges, thus learning from each other in real time. GARDP collaborates with partners to strengthen stewardship programmes, in line with technical and operational guidance described in the WHO practical toolkit, “Antimicrobial Stewardship Programmes in Health-Care Facilities in Low- and Middle-Income Countries.” Support for operational research may also help to document the outcomes of stewardship models in LMICs. The learning and implementation networks described above can also help share lessons learned and best practices for implementing stewardship programmes.

3.2.4 Stewardship and antibiotic conservation

The GARDP Disease Area Strategy lays out many of our key tactics and strategies for stewardship, which is integral to our work. GARDP endeavours to ensure appropriate stewardship of our product portfolio, either working directly or through partnerships, including:

1. Updating treatment and use guidelines and protocols
2. Developing real-world evidence to inform optimal use and demonstrate effective stewardship models
3. Investigating and evaluating the impact of payment models that de-link payment from procurement volume to enable stewardship and remove commercial incentives to sell and use excess antibiotics
4. Working with manufacturer partners to adhere to WHO’s Ethical Criteria for Medicinal Drug Promotion
5. Comparing actual use to antibiotic forecasts to identify and support investigation of potential overuse
6. Support for training and mentorship on optimal use
7. Collaborating with diagnostic developers and other entities for diagnostic development and/or diagnostic system strengthening

GARDP’s support for stewardship runs across all activities from development to implementation. A range of stewardship levers, both pre- and post-regulatory approval, are shown in Figures 4 and 5.

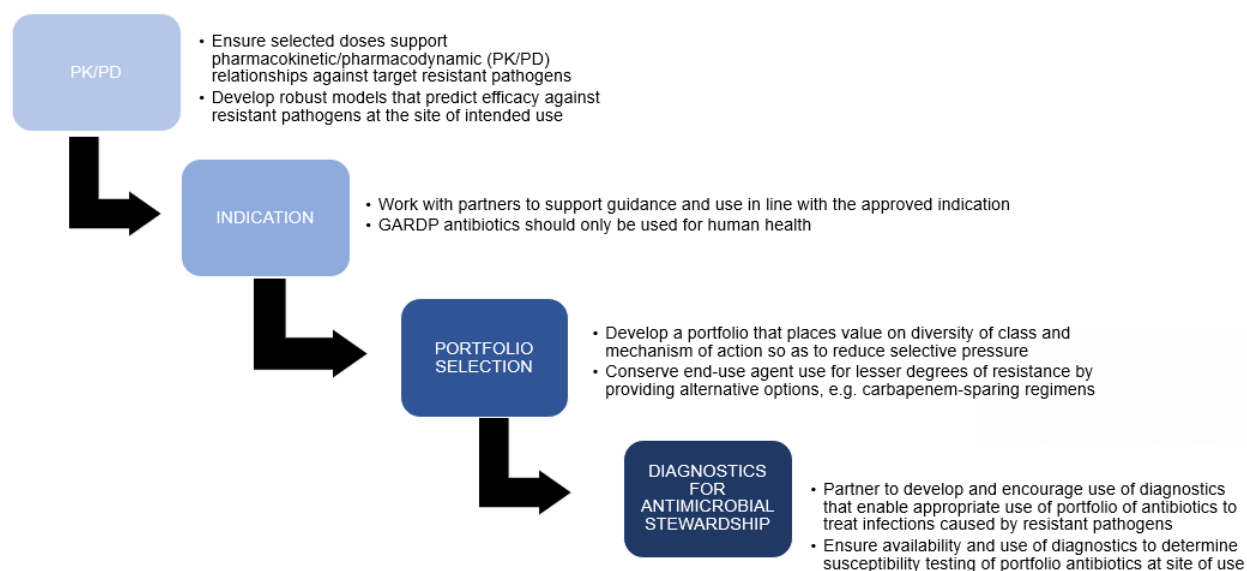


Figure 4: Pre-regulatory approval stewardship levers

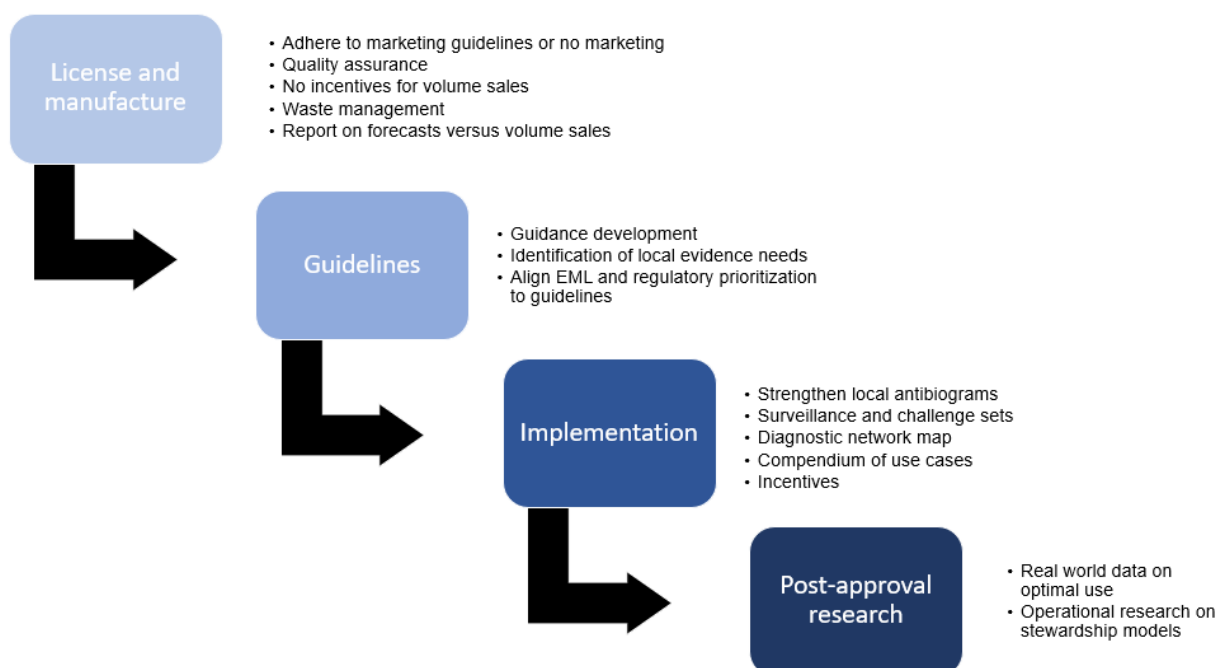


Figure 5: Post-regulatory approval stewardship levers

SUPPORT FOR SUSTAINABLE, AFFORDABLE, QUALITY-ASSURED SUPPLY

3.2.5 Public health-oriented licensing and sublicensing

GARDP works to ensure access through public health-driven in- and out-licensing agreements which GARDP executes and manages. GARDP aims to include provisions in both in- and out-licensing that support sustainable and affordable access. These provisions may differ somewhat for different compounds and market situations.

Overall access-oriented licensing principles

- Non-exclusivity or managed exclusivity, depending on the market situation, to meet the objectives of access, sustainability, and stewardship
- Provisions related to Chemistry, Manufacturing, and Controls (CMC):
 - Freedom to select the manufacturers and launch CMC activities to potentially optimize the cost of goods (CoGs).
 - GARDP will ensure the quality of the product by obtaining stringent regulatory approval and/or WHO Prequalification Programme approval. WHO-listed national regulatory authorities will also be included once these are identified. As the WHO process to identify WHO-listed regulatory authorities progresses, we will readjust our quality-assurance standards accordingly.
 - Good environmental standards that comply at a minimum with standards proposed by the AMR Industry Alliance. GARDP is in the process of assessing these standards and their implementation. When new standards are released (e.g. by WHO), GARDP will update its policy.
- Minimal or no royalties for any low-income countries, and for as many lower middle-income countries and upper middle-income countries as feasible
- Commitment to collect and report all post-marketing surveillance data transparently
- Appropriate management and transfer of all research assets, data, compounds, and associated intellectual property, scientific expertise, and relevant manufacturing capacity to one or more third parties should the original owner become insolvent, to the extent permissible under the country's bankruptcy law
- Commitment from the market authorization holder to rapid registration, including using all regulatory pathways that can accelerate registration, such as the WHO Prequalification Programme, the WHO Collaborative Registration Procedure, or regional or continent-wide registration programmes
- Reduce or eliminate volume-based incentives for sales staff and/or appropriate product marketing

Principles specifically related to in-licensing

- In-licensing should include the widest possible geographic scope
- Commitment to share or allow referral to the evaluation dossier of US-FDA or EMA
- Commitments to launch with or without the support of GARDP, in a timely manner, paediatric and neonatal trials, where relevant
- Commitment to share their Stewardship Action Plan (in case of financing by CARB-X) and any other high-level commitments to sustainable access (through financing by other third parties)

Principles specifically related to out-licensing

- Commitment to share (and if needed, update, with the support of GARDP) the sublicensee's stewardship strategy / programme
- Commitment to agree on a pricing strategy with the goal of reaching an affordable and sustainable price
- Sublicensee agrees to transparently sharing its commercial decisions with GARDP, including distribution marketing, pricing, volumes and timing of launch
- Respecting environmental standards and monitoring environmental health practices using frameworks like the RAMP/SIWI

3.2.6 Quality assurance

GARDP supports access to quality-assured products. GARDP recognizes traditional Stringent Regulatory Authorities⁵ and WHO Prequalification. WHO-listed national regulatory authorities (WLAs) will also be included once these are identified. As the process to identify WLAs progresses, we will readjust our quality assurance standards accordingly. Where required to assure access, GARDP may also engage with independent experts to perform quality assurance audits as a temporary mark of quality assurance while awaiting one of the above approvals.

3.2.7 Regulatory support and streamlining

GARDP landscapes and defines regulatory pathways for products. In some cases, GARDP also provides technical support to market authorization holders (MAHs) for dossier preparation and to liaise with the national regulatory authority (NRA) for advice. In some cases, for example when demand is very low or sporadic, GARDP works with local entities to import the product under regulatory waivers or special import licenses. In most cases, these waivers will be used as a temporary bridge to full registration. GARDP also attempts whenever possible to accelerate regulatory approval and to streamline approvals by using innovative regulatory pathways or regulatory harmonization schemes. Leveraging these regulatory efficiencies may reduce transactional costs, accelerate approval, and expand approval to less attractive markets (e.g., via PQ). For example:

- Leverage WHO Prequalification (PQ), the European Medicines Agency EUM4All, or Swissmedic Marketing Authorization for Global Health Products (MAGHP) Procedure, according to product characteristics and regulatory needs. GARDP will also work with developing regulatory authorities, such as the African Medicines Agency.
- Identify, analyse, and work with regional regulatory schemes, preferring submission via these pathways when possible.
- Work with relevant WHO departments to support release of WHO PQ expressions of interest and, if necessary, support submission of PQ dossiers.
- Utilize or work with entities that submit regulatory dossiers to use the WHO or stringent regulatory authority (SRA) collaborative procedures for accelerated registration.

3.2.8 Sustainable product pricing

GARDP's Chemistry, Manufacturing and Controls (CMC) team works with drug developers and manufacturers to identify and implement manufacturing efficiencies to improve affordability, reduce hazardous products, and make the process more environmentally-friendly. GARDP's CMC work also decreases cost of goods estimates to determine affordable and sustainable price points. GARDP also provides CMC support for capacity development for distributed manufacture.

GARDP is committed to ensuring that each of our products is affordable in all countries in which GARDP is authorized to market the respective product, while ensuring that prices are sustainable for our manufacturing and distribution partners (affordable and sustainable pricing).

GARDP develops price-point analyses that will inform affordable and sustainable price points for each of its products in several indicative geographies. These analyses take into account a range of factors, including cost-effectiveness analyses and a country's health system's ability to pay.

GARDP requires manufacturers and distributors with which it works to set affordable prices, ideally using ceiling prices based on a cost-plus approach. The ceiling prices should be informed in part by GARDP's price-point analysis and should not undermine affordability and sustainable use of a product in that market. The Cost of Goods, upon which cost-plus prices will be set, will be verified through a third-party audit of the manufacturer.

IMPROVING THE ENABLING ENVIRONMENT AND MARKET CONDITIONS FOR ANTIBIOTICS

3.2.9 Economic models and market shaping activities

Many of the target antibiotics in the GARDP disease area strategy may be lower volume per geography or per purchaser, leading to the risk of a fragmented or unattractive market. Such market fragmentation may lead to access barriers such as lack of suppliers, higher prices, long lead-times, and unreliable supply. Given the lack of international funding, strong training and stewardship programmes in many LMICs, and centralized procurement agencies, demand may be more sensitive to price, and uptake may be slow and uneven.

GARDP analyses the market and product characteristics for each product in order to identify opportunities to improve the market. Market shaping activities should always consider the public health need according to pathogen and resistance mechanisms, and consider the principles of stewardship. Depending on the treatment, epidemiology, country and market context, these interventions may include:

1. Support for development and sharing of forecasts.
2. Harmonizing guidelines for preferred treatments within a given region or within a group of buyers to consolidate the market around a smaller set of antibiotics.
3. Pooled forecasting procurement to consolidate demand.
4. Development and testing financial tools to help shape the market. For example:
 - a. Advance purchase or volume commitments, including subscription models.
 - b. Development grants or prizes, including for meeting regulatory goals.
 - c. Subsidies: Especially to rapidly reduce market entry prices, where achievement of a certain volume is expected.
 - d. Capital expenditure investments.

GARDP works with external partners including economists to evaluate the use of these instruments or others and test which instrument may be best fit for various AMR product market conditions.

Finally, with partners, GARDP works on cross-cutting initiatives like SECURE to improve market conditions for antibiotics.

3.2.10 Advocacy for access-oriented policies

GARDP takes a leadership role in advocating for funding and in developing policies that aim to accelerate global access to antibiotics, including through early access. In this role, GARDP works to fill critical innovation and knowledge gaps to support data-driven policies for equitable access to antibiotics. GARDP will work with civil society partners to help improve our access analysis and approach as well as to achieve success for our access objectives.

GARDP also collaborates with networks such as the Global Accelerator for Paediatric formulations (GAP-f) to accelerate access to paediatric formulations of critical antibiotics to patients in need.

4. ACCESS REVIEW

This strategy and approach is a living document and will be updated as needed. The document will be reviewed at least once a year.

¹ Murray CJ et al. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis, The Lancet, Vol 399, Issue 10325, 2022, p. 629-655, ISSN 0140-6736, [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0). (<https://www.sciencedirect.com/science/article/pii/S0140673621027240>)

² Outtersen, K., Orubu, ESF., Rex, J., et al. (2022). Patient access in 14 high-income countries to new antibacterials approved by the US Food & Drug Administration, European Medicines Agency, Japanese Pharmaceuticals & Medical Devices Agency, or Health Canada, 2010-2020. Clin Infect Dis. 2022 Apr 9;74(7): 1183-1190. DOI: 10.1093/cid/ciab612

³ Kållberg C, Årdal C, Salvesen Blix H, Klein E, M Martinez E, Lindbæk M, Outtersen K, Røttingen JA, Laxminarayan R. Introduction and geographic availability of new antibiotics approved between 1999 and 2014. PLoS One. 2018 Oct 16;13(10):e0205166. doi: 10.1371/journal.pone.0205166. PMID: 30325963; PMCID: PMC6191083.

⁴ <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2022.02>.

⁵ Fifty-first report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2017 (WHO technical report series ; no. 1003). Licence: CC BY-NC-SA 3.0 IGO.