Principles for Pooled Procurement of AMR Products

The AMR Industry Alliance Principles for Pooled Procurement provide recommendations for purchasers in low- and lower-middle-income countries (LMICs) seeking private sector participation in pooled procurement mechanisms (PPMs) for antimicrobial resistance (AMR) products, including antibiotics and diagnostics.

These principles highlight key private sector considerations as LMICs address the multifaceted challenges of ensuring the availability and reliability of supply across AWaRe categories, including regulatory issues, inadequate demand forecasting, unsustainable procurement practices, and the absence of economic models that account for the full value of products.

Pooled procurement mechanisms offer one avenue to improve access in LMICs, but address only one aspect of a broader set of market challenges. In general, the absence of economic models that consider the full value of AMR products is a significant burden, as it hinders ensuring that products are both accessible across income levels and utilized throughout the entire patient pathway. Effective reimbursement reform for antibiotics and diagnostics as well as R&D incentives for novel antibiotics are essential to stabilizing the antimicrobial resistance (AMR) product ecosystem. Specific for antibiotics, the lack of market-based R&D incentives has resulted in a steadily shrinking clinical pipeline, market failures for smaller companies, and the continued loss of AMR R&D expertise.

Additionally, progress needs to be made on antibiotic and diagnostic access and utilization in both higher and lower-income settings, as diagnostics are not consistently or comprehensively assessed through value assessment or reimbursement frameworks.

In lower-income settings, novel access models may include Pooled Procurement Mechanisms (PPMs), which aim to maintain the ongoing availability of affordable, high-quality health products while also improving the quality of care in the local market over time.

The Alliance makes the following recommendations to purchasers in LMICs seeking private sector participation in these PPMs:

1. Provide accurate demand forecasting and clear, transparent tender calendars.

The predictability of demand and multi-year tenders can facilitate manufacturer participation, and PPMs can help by improving the reliability of countries' forecasts. Investments in diagnostic access, utilization, and sustainable surveillance capacity are a prerequisite to enhancing understanding of needs and improving demand forecasting.

Once the need has been quantified, a well-structured PPM should include systematic, multi-annual tender calendars, which will enable companies to incorporate PPM participation into their medium- to long-term planning of manufacturing volumes.

Any PPM will likely initially suffer from inaccurate demand forecasting due to a lack of data on resistance and antimicrobial consumption. This situation may require additional mechanisms, such as revenue guarantees or flexible funding options, while the associated capacity is being developed.

2. Ensure rational and appropriate use of antibiotics supported by robust stewardship programs.

A unique characteristic of antibiotics and other antimicrobials is that, over time, resistance to existing treatments will develop, which may also impact the effectiveness of different products within the same class, or even those outside it. Ensuring that antibiotics, once procured, are used appropriately through effective utilization of diagnostics and in line with the most recent treatment guidelines adapted for national contexts will be essential to slowing down that process.

This will likely require additional initial programmatic country support and long-term capacity building to properly introduce and manage treatments as part of overall patient care, informed by robust stewardship programs supported by access to diagnostic testing. Investments in diagnostic tools and laboratory capabilities to support diagnostic and stewardship efforts will be necessary for the long-term success of any PPM.

3. Increase transparency in decision-making and tender awarding.

Tender decisions should be based on clear and transparent criteria to ensure fair competition and uphold good legal and ethical practices. The criteria for awarding tenders should encompass the full value that products bring to patients and society, with consideration given to proposed or tested models for assessing this value for both antibiotics and diagnostics.

Additionally, multiple supplier tenders for off-patent antibiotics and value-based assessments for decision-making can foster a healthier market environment and encourage greater company participation compared to a "winner-takes-all" approach. Furthermore, tender criteria should take into account factors beyond price, such as supply security to minimize the risk of stockouts, sustainability, including responsible manufacturing processes, and reliability and quality assurance. Clear assessment criteria by which these factors are considered should be included in tender processes, such as independent certification in line with the AMR Industry Alliance Manufacturing Standard.

4. Establish clear criteria and guidelines for country pooling.

An aggregated demand mechanism across multiple countries or populations will enhance the scale and reliability of supply, and appeal to suppliers who may be interested in accessing markets not served by a local presence and/or cannot manage procurement across various geographies. Defining country pools for procurement is both important and complex. Manufacturers may set differentiated access pricing for different procurers based on national monetary measures (e.g., Gross National Income, GNI, and Gross Domestic Product, GDP), geographic locations, and other criteria, such as target populations, disease burdens, and development status.

To enable broad manufacturer participation, the PPMs should align with policies concerning pricing and related areas. Ideally, all stakeholders – including potential buyers and suppliers – need to be consulted on the scope of new PPMs to ensure they achieve the desired results for patients.

5. Create or utilize an appropriate structure to ensure the success of small volume tenders.

Aggregating demand for antibiotics and diagnostics significantly enhances supply reliability, while collaboration with partners and countries facilitates the appropriate integration of these treatments into patient care. A PPM that aggregates demand may serve as a particularly effective strategy for supporting higher-volume access to and certain Watch category generic antibiotics, capitalizing on economies of scale. However, for lower-volume reserve antibiotics, pooled demand may still prove inadequate to attract suppliers.

Additional mechanisms, such as revenue guarantees that explore the assessment of antibiotics' societal benefits in greater detail, may need to be examined to ensure sustainable access to lower-volume reserve antibiotics.

6. Ensure accountability measures to govern technical and financial capacities.

Any PPM must ensure accountability among all relevant parties through mechanisms that support the technical and financial capacity of countries for reliable orders and prompt payments. Clauses ensuring volume commitments

or rotating funding to guarantee orders would also need to be included.

7. Allow non-exclusive, voluntary participation with flexible procurement options.

Participation in PPMs should be voluntary for countries and companies. It should not be linked to exclusivity, and countries should be able to directly procure additional supplies from outside the PPM if desired, whether from participating or non-participating suppliers.

8. Regulatory harmonization and reliance-based regulatory practices.

To maximize the availability of products eligible for a tender, PPMs should support regulatory harmonization and reliance-based approaches by recognizing regulatory approval by a Stringent Regulatory Authority or using a Regulation Waiver, for a smoother and more timely product registration and supply.

In addition to making PPM participation more attractive for suppliers, this approach can also help optimize the eventual regulatory process undertaken as a country moves towards a sustainable and independent infrastructure.

9. Mobilize sustainable funding streams for high-quality products in cases where donor funding is needed.

In cases where PPMs require additional mechanisms to mobilize sustainable streams of procurement funding, it is essential to note that, unlike in several other infectious disease areas, there are currently no donor-funded mechanisms to support access to antibiotic products, which could play a crucial role, either catalytic or otherwise. Beyond the funding for the procurement itself, funding will needed to support the PPM operations. Consideration should also be given to long-term financial sustainability and building towards eventual independence.