

POSITION OF FIFARMA¹ ON POOLED PROCUREMENT OF PHARMACEUTICALS

FIFARMA is committed to supporting local, regional and global efforts to improve access to medicines and health systems sustainability, as the Research and Development pharmaceutical industry continues driving innovation to provide new treatments and vaccines for unmet health needs.

FIFARMA recognizes the ongoing challenges that governments in Latin America face when providing health access to an expanding and aging population, as well as the importance of addressing gaps in access to medicines. To expand access to quality medicines and health care in a meaningful way, all stakeholders, including governments and the private sector, need to address the underlying regulatory, infrastructure, financing, and supply chain barriers that can impede access.

FIFARMA is aware that governments in the region may view pooled procurement, which refers to mechanisms by which multiple countries consolidate purchasing efforts for a pharmaceutical product to achieve a common lower price, as broad based answer to some of these challenges.

However, broad or mandated use of pooled procurement does not address the underlying barriers that impede access to innovative medicines and can negatively impact patients' safety. Only under exceptional circumstances, such as epidemics, should pooled procurement be carefully and sparingly utilized one of many tools available to facilitate access to medicines and vaccines. Ultimately, pooled procurement does not address true barriers to access.

NEGATIVE EFFECTS OF POOL PROCUREMENT

FIFARMA's concerns regarding pooled procurement are highlighted below:

1. **Pooled procurement mechanisms can compromise patient safety by placing patients under an increased and unjustified risk when they:**
 - a. ***Bypass local regulatory requirements:*** Latin American countries have stringent local legal and regulatory requirements for participating in public bids to ensure safety and efficacy for patients and reliable supply. These requirements include both pre-market obligations (sanitary registration) and post-market obligations (pharmacovigilance, local patient and physician support, appropriate labelling/packaging, stability requirements, etc.). The possibility that products purchased by international pooled procurement may bypass these local regulatory processes (both pre-market and post-market) would create significant increased risk for patients and healthcare professionals, putting budgetary or commercial concerns ahead of international best practices in health. Moreover, the WHO Pre-qualification system that some pooled-procurement mechanisms apply

¹ FIFARMA represents national pharmaceutical associations and research-based pharmaceutical companies operating in 32 countries in Latin America and is officially recognized as a stakeholder by PAHO and the Development Centre of the OECD Emerging Market Network. FIFARMA and its members are committed to acting ethically and responsibly to make medicines and vaccines available to patients in the region.

to some products was not designed to substitute local regulatory processes, particularly in a country with fully functioning regulatory agencies.

- b. ***Compromise Clinical Decision-Making:*** By focusing solely on the lowest bid and limiting access to innovative technologies, pooled procurement could compromise patient health by jeopardizing the continued treatment for certain products (particularly biologics) where substitution/switching of treatment is not clinically advisable. Switching products without patients input might compromise safety, adherence and health outcomes.
 - c. ***Increase the risk of supply interruption:*** When products are imported from suppliers without a local presence, or stock and infrastructure, there is an increased risk that patients will have their medicine supply interrupted, potentially causing treatment failure and health deterioration. Further, procurement initiatives may lead to a decreasing supplier base, which may further debilitate the ability of governments to ensure a safe, effective and predictable supply of medications, including for vulnerable populations.
2. **Pooled procurement may lead to higher prices for lower income countries.** Pooled procurement undermines a manufacturer's ability to differentiate among countries and institutional payers based on differentiating factors, including ability to pay, thus forcing price convergence when differential pricing would better meet patient needs. Particularly, procurement mechanisms that drive a single price across Latin America create an obstacle for implementation of differential pricing and strategies aimed at maximizing affordability and access to patients in lower income nations.
 3. **Pooled procurement may create an unstable investment environment, potentially jeopardizing supply and creating negative effects in the local economy.** International and domestic pharmaceutical companies currently have complex supply chains that can provide a reliable source of necessary medicines across Latin America. Pooled procurement that covers an entire continent can have significant unintended consequences as locally established companies (that pay taxes, create jobs and invest in the local economy) are placed in an unfair competitive disadvantage vis-a-vis companies that have not been required to register their products local, which may force them to restructure their regional footprint and exit certain markets, shrinking the supplier base overall, eliminating local jobs and driving competition out of the market². Consequently, this could lead to supply insecurity and shortages for health systems and patients that depend on critical medicines as well as an incentive for sole suppliers to raise prices in the future. Furthermore, potential violations of international intellectual property obligations when procured products infringe locally-patented products can create a disincentive for future investment in country.
 4. **Pooled Procurement may not be financially advantageous when compared with local negotiations** as payments may need to be made in advance by the country to the procuring international organization; countries may need to assume the exchange rate risk involved in the transaction; there

² The experience of other pooled procurement arrangements implemented in other regions of the world, e.g., UNICEF, PAHO has shown that the buying power of pooled procurement can shift market balances and result in a shrinking supplier base overall. For example, an analysis of UNICEF procurement of measles vaccines over the period 1992-2001 has shown a drastic reduction of the number of suppliers from 10 to 3.

may be administrative and other type of fees; and countries may need to create infrastructure to distribute the product and assume the risk for its integrity throughout the supply chain.

GUIDING PRINCIPALES FOR POOLED PROCUREMENT MECHANISMS

To address these concerns and to promote the development of a stable biopharmaceutical sector that can steadily invest in research & development, and develop and ensure access to the technologies that

address the unmet and emerging public health challenges of our time, pooled-procurement mechanisms should be guided by the following principles:

- **Pooled procurement mechanisms should not compromise good clinical decision-making, which is essential for the individual patient.** All medicines – including those used to treat the same condition – have different safety, tolerability, and efficacy profiles. As such, procurement must ensure sufficient variety of products and avoid forced medicine switching for patients whose health conditions are well-controlled on an existing medicine. Procurement should allow prescribers to choose the most appropriate medicine for their patients by ensuring continued treatment for patients already initiated on a therapy and should avoid limiting supply of medicines in a therapeutic area not awarded a contract.
- **Pooled procurement arrangements should foster effective competition and not distort it by artificially limiting the number of suppliers** to avoid jeopardizing the sustainability and supply of innovative medicines. Winner-takes-all models risk leaving the market without sufficient supply if manufacturing issues arise and can lead to fewer suppliers returning to bid as contracts are renewed. Over time, reduced competition can reverse savings potential and limit the quality and variety of products offered, and increase overall healthcare costs.
- **Any pooled procurement should apply scientifically sound award criteria and should not solely be focused on price** to minimize the potentially negative effects of joint procurement on the structure of the market for medicines.
- **Tenders should meet regulatory standards of individual participating countries.** All products procured through pooled mechanisms should be registered in each participating country to ensure compliance with local regulatory and pharmacovigilance standards.
- **Tenders must safeguard against supply interruptions.** Interruptions in supply can harm patient health and increase costs to governments. As such, government purchasers must ensure that suppliers are capable of ensuring a reliable product supply and develop contingency plans for alternate suppliers to avoid risks of shortages. Moreover, safeguards must be established to ensure that supply is not diverted from countries not participating in the tender.
- **Pooled procurement strategies must not violate intellectual property rights.** Pooled procurement strategies must respect intellectual property rights both within and across countries. If a procured product potentially infringes a patent in force in one or more jurisdictions participating in the pool – or if a procured product would potentially infringe a patent pending in one or more jurisdictions

participating in the pool – the procurement authority, participating governments, and/or suppliers should not procure the product through the tender process without the prior consent of the patent applicant or holder.

- **Procurement schemes should be transparent and robust.** Tendering procedures should be transparent, contain robust selection criteria beyond price (e.g., product quality), and include a medical committee in decision-making.
- **Total transaction costs must be considered.** Multi-country tenders require overhead expenses that may not be applicable to single-country tenders; such as complex inventory management and extra-territorial transportation expenses including taxes, repackaging fees, currency exchange adjustments, and more. Procurement agencies must account for these additional expenses, beyond a manufacturer's price, in the contracting process and when determining if pooled procurement represents a savings opportunity.
- **Volume projections must be honored.** Projecting the amount of a product needed to supply multiple countries over a tender period can be complex. Given that winning manufacturers must ramp up manufacturing capacity and make other investments necessary to meet the terms of the contract, participating government payers must honor volume commitments made in the bidding process.
- **Pooled procurement groups should be comprised of similar peers.** Participating countries should be as similar as possible in their burden of disease, health priorities, infrastructures, supply chains, ability to pay, and budgeting processes. Moreover, the group of participating countries should be reviewed periodically to ensure "peer" status is maintained.
- **Publication of final tender terms must remain confidential.** Tendering processes that publish offer terms (i.e., transaction prices) should be avoided, as they may constrain a competitive response by bidders and therefore limit the benefits of competition.