



Private Roundtable on Pharmaceutical Manufacturing and Supply Chain Resilience in Africa

Summary Notes
October 29-30, 2020

Hosted by the Center for Global Development (CGD) in partnership with the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), United Nations Economic Commission for Africa (UNECA), and the African Leaders Malaria Alliance (ALMA)

Meeting co-chairs

- **Dr. Ibrahim Assane Mayaki**, Chief Executive Officer, African Union Development Agency (AUDA-NEPAD)
- **Ms. Joy Phumaphi**, Executive Secretary of African Leaders Malaria Alliance and Co-Chair of the UN Secretary General's Independent Accountability Panel for Women, Children, and Adolescent Health
- **Dr. Vera Songwe**, United Nations Under-Secretary-General and Executive Secretary of the Economic Commission for Africa (ECA)
- **Prof. Prashant Yadav**, Senior Fellow at the Center for Global Development and Professor at INSEAD

Discussion summary

Note: Below is an informal, high-level summary of the group discussion. The notes are not meant to be exhaustive but to highlight the broad set of issues and themes that emerged.

1. **Co-chairs highlighted current momentum with high-level political interest due to COVID-19, combined with African Continental Free Trade Agreement (AfCFTA), as a window of opportunity with significant potential to accelerate progress in regional manufacturing. They amplified that it will be important to ground theoretical and aspirational goals in actionable items for each partner organization to take forward.**
 - a. Improving access to medicines is a broad agenda of which regional manufacturing is one component.
 - b. Important to move regional pharmaceutical manufacturing from nascent industry to more mature and developed stages.

2. Participants noted prior and ongoing efforts to strengthen pharmaceutical manufacturing in Africa, led by UNECA, AUDA-NEPAD, and other leaders in the region, including:

- a. African Continental Free Trade Agreement (AfCFTA)-led efforts, such as an initiative to develop a scalable, sustainable pharmaceutical strategy to increase local production of MNCH products and other essential medicines.
- b. [Africa Medical Supplies Platform \(AMSP\)](#)—established by the Africa CDC, African Union, UNECA, and Afreximbank—creates a centralized digital tool to help streamline the supply chain for medical supplies, reduce fragmented purchasing, and achieve economies of scale.
- c. [Pharmaceutical Manufacturing Plan for Africa \(PMPA\)](#), developed by NEPAD (now AUDA-NEPAD), proposes a package of technical solutions to strengthen the continent's ability to produce high-quality, affordable pharmaceuticals.
- d. [African Medicines Regulatory Harmonisation \(AMRH\)](#), an initiative of AUDA-NEPAD, works to improve access to quality, safe, and efficacious medicines by offering an enabling regulatory environment for pharmaceutical sector development in Africa.

3. The discussion examined the main challenges for regional manufacturing, including:

Supply-side challenges

- a. Limited working capital/financing for manufacturing at scale
 - i. The local cost of working capital when raised in local markets is a significant obstacle.
 - ii. There is limited visibility into capital flows, hindering the ability to quantify gaps in the forms of capital required.
- b. Local administrative, regulatory, and legal challenges
 - i. Import/export restrictions and other burdensome or problematic local purchasing requirements (including rules around cash flow and local currency for tenders) create barriers to entry and limit competition, particularly for quality-assured generics.
 - ii. Disincentives include dependency of NRAs on charging for dossier development/approval and waivers requested by procurers on 'emergency' basis, among other challenges.
 - iii. A lack of flexible governance arrangements for global pooled procurement (e.g., mismatched budgeting cycles) leads to non-subsidized purchasing.
- c. Cost-competitiveness of certain product categories and importance of reaching economies of scale.
- d. Lack of availability of APIs and other key materials
 - i. API availability is not only a barrier to regional manufacturing, but also an important component of supply chain security, as reinforced by COVID-19.
- e. Infrastructure and labor challenges
 - i. Challenges related to infrastructure and skilled labor offer potential opportunities to develop more advanced systems, including continuous manufacturing for specific molecules and technical assistance for training in good manufacturing practices.

Demand-side challenges

- a. Market fragmentation with unorganized demand and high transaction costs
 - i. Regional markets are critical to scale and competitiveness; supply chains need to evolve and align with regional scale.
 - b. Preferences and perceptions related to quality may reduce demand and lead some purchasers and patients to [pay more for branded generics as a proxy for quality](#).
 - c. Prevalence of out-of-pocket payments is not conducive to long-term sustainability of a stable manufacturing market.
 - i. Underscores the need to integrate manufacturing efforts with health insurance and financing systems at the national level (i.e. making the market more attractive and sustainable for regional manufacturers through health financing/UHC reforms that pool demand and ability to pay).
 - ii. Important to avoid health financing disincentives for investors, e.g., retail price controls if not designed well.
 - d. Lack of market size information and weak market data infrastructure hinder domestic and international manufacturers from making larger investments in the African market.
 - e. Need to address [procurement inefficiencies](#), including registration processes, payment delays, and anticompetitive behavior, to ease institutional and legal barriers.
 - i. Suboptimal procurement outcomes due to institutional inefficiencies are compounded by limited [procurement capacity and expertise](#).
 - f. There is little competition in the supply of essential medicines in LMICs, exacerbating that purchasers in LMICs often face high—and highly variable—prices for basic medicines.
 - i. Some markets may be dominated by a single or a small number of suppliers, which may lead to inflated prices.
4. **While there was insufficient time to fully develop, vet, and prioritize policy recommendations and a future research agenda, a number of key policy opportunities and ways forward emerged that deserve additional discussion and development:**
- a. **Continental and regional efforts (long-term):** Clear need to advance the [African Medicines Agency](#), continue implementing the AfCFTA, and strengthen other regional efforts to bolster regulatory harmonization, expedite evidence review, and drive competition.
 - b. **Continental and regional efforts (short-to-medium term):** Potential cross-country initiatives to address issues related to quality and fragmentation include:
 - i. Rigorously evaluating and elevating the influence of existing efforts for potential future investment, which will help to build the evidence base of strategic practices for procurement, quality assurance, and overall supply chain resilience.
 - ii. Systematic donor support to incentivize participation in regional regulatory activities and explore how regional regulation fits within overall international quality regulatory initiatives.
 - iii. Addressing purchaser and patient perceptions of regional pharmaceutical quality through quality assurance/standardization/regulatory investments to promote sustainable demand.
 - iv. [Pooled purchasing](#) through centrally negotiated prices to aggregate demand, increase purchaser bargaining power, and better organize procurement-related functions like horizon scanning and information-sharing about the supplier landscape.

1. Pooled purchasing is one potential way to defragment NCD medicines procurement, among other actions.
2. Understanding why some purchasers may decide not to participate in pooled mechanisms is also important.
- v. Expanding our conceptualization of regulatory harmonization to include packaging (e.g., languages, logos, special labeling) is also important for pooling mechanisms.
- c. **Country-level procurement reforms:** Development partners should help governments to lead [in-country procurement reforms](#) and ease institutional and legal barriers to effective procurement. Procurement reforms to improve national procurement agendas could consider the following dimensions:
 - i. Tendering and contracting modalities that enable supplier diversification, long-term framework agreements, auctions, or joint purchasing via pooling mechanisms as described above.
 - ii. Multi-year procurement plans that take into account manufacturers' perspectives and ability to supply on time for delivery in a specific country (i.e. including long-term contracts with manufacturers in procurement plan).
 1. This would also help to advance collaboration between governments and manufacturers in the co-creation of policies.
 - iii. Streamlined product regulation (as discussed above).
 - iv. Expansion of revolving funds that allow countries to borrow money in advance for orders and pay back interest-free later (during a given window after commodities are received) to smooth over mismatched budgeting cycles, reduce risks of stockouts, and enable purchasers to take advantage of subsidized pricing.
- d. **Global procurement practices:** Global procurers should shift their procurement criteria and tender design for consolidated purchasing to include supply diversification, capacity, and other dimensions of supplier delivery performance and security beyond cost, which may improve the comparative advantage of local manufacturers.
 - i. In situations in which all manufacturers are pre-qualified, competition focuses on price; currently, other dimensions related to diversification and supply security are often covered separately or not at all.
- e. **Support to local manufacturers** to address key issues:
 - i. Better understand and take action related to various levers for cost-competitiveness (e.g., exchange rates, reliance on importation, tax structure). For example, closely collaborate with finance and revenue authorities to overcome challenges related to VAT exceptions, as imported APIs, excipients, and other materials are not just used for pharmaceutical products.
 - ii. Increase access to affordable working capital through new instruments.
- f. **Public goods to facilitate investments that improve access to affordable, high-quality health products:**
 - i. Invest in better market intelligence and information sharing to clarify who is doing what in this space, ultimately helping to identify deals and align opportunities with capital (including ways in which DFIs could underwrite investments). For example, an assessment of manufacturers' capabilities and financing needs across the continent would be beneficial.
 - ii. Develop criteria to evaluate investment opportunities by product class (e.g., complex versus simple production; opportunities with consolidated purchasing, as in the case of ARVs and potentially contraceptives, etc.). This would inform a

common understanding of the tipping point for DFIs and private capital to invest in regional manufacturing.

- g. **Mechanism for coordination:** while procurement funders, development finance institutions, other development partners, pharma manufacturers, and policymakers should each channel their efforts to overcome challenges in different ways, a mechanism for continued coordination and alignment on paths forward is critical as an immediate next step.
- h. **Numerous areas of further analysis are needed to make progress on** many of the opportunities identified above, including but not limited to:
 - i. Insights on who wins tenders/criteria used by procurers to shortlist manufacturers, including the track record of local manufacturers in existing tender processes (with the aim of making existing pools more friendly to regional manufacturing and informing where to focus efforts to boost competitiveness).
 - ii. More granularity on how to build up local manufacturing (could be in the form of a menu of models/approaches), including associated capital requirements, forms of financing, timelines for returns, whether they go to investors, national governments or industry, etc.
 - iii. Analytical work on specific types of innovative financing instruments.
 1. Effective modalities for private sector engagement should be examined and employed, including blended financing models (e.g., volume guarantees and subsidies).
 2. There is also a need for new instruments to reduce the cost of working capital when raised in local markets.
 - iv. Analysis of manufacturing trends across the African continent (as opposed to further segmenting them).
 1. One specific area of interest is whether manufacturers trend towards backward (e.g., control of APIs) or vertical integration (e.g., distributors) as a way to expand and strengthen competitiveness in Africa.

Related resources

- Tackling the Triple Transition in Global Health Procurement: Final Report of CGD's Working Group on the Future of Global Health Procurement (Rachel Silverman, Janeen Madan Keller, Amanda Glassman, and Kalipso Chalkidou, June 2019). <https://www.cgdev.org/better-health-procurement>
- Should sub-Saharan Africa make its own drugs? (Michael Conway, Tania Holt, Adam Sabow, and Irene Yuan Sun, Jan 2019). <https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs>
- African Medicines Regulatory Harmonisation Programme Newsletter (AUDA-NEPAD, 2020). <https://www.nepad.org/publication/amrh-1st-quarter-2020-newsletter>
- Complementary fact sheets to final report of CGD Working Group on Global Health Procurement:
 - A Changing Role for Global Cooperation. <https://www.cgdev.org/sites/default/files/Procurement-factsheet-global-cooperation.pdf>
 - Building an Enabling Environment for Quality Generic Competition. <https://www.cgdev.org/sites/default/files/Procurement-factsheet-generics-competition.pdf>
 - Supporting Country-Led Procurement Policy Reform. <https://www.cgdev.org/sites/default/files/Procurement-factsheet-country-policy-reform.pdf>

- Professionalizing Procurement and Facilitating Shared Learning.
<https://www.cgdev.org/sites/default/files/Procurement-factsheet-professionalizing-shared-learning.pdf>
- Pharmaceutical Manufacturing Plan for Africa (2012).
<https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa>
- Africa Medical Supplies Platform. <https://amsp.africa/>
- Aggregating Demand for Pharmaceuticals is Appealing, but Pooling Is Not a Panacea (Cassandra Nemzoff, Kalipso Chalkidou, and Mead Over, May 2019).
<https://www.cgdev.org/sites/default/files/aggregating-demand-pharmaceuticals-appealing-pooling-not-panacea.pdf>
- Can Better Procurement be the Key to Financing UHC? Potential Savings from Health Sector Procurement Reforms in Low- and Middle-Income Countries (Kalipso Chalkidou, Janeen Madan Keller, Mead Over, and Alex Jones, November 2020). <https://www.cgdev.org/publication/can-better-procurement-be-key-financing-uhc-potential-savings-health-sector-procurement>