Enabling a Market-Based Approach to Manufacturing Quality-Assured Health Products in Africa:

A Differentiated Coordination Approach

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Africa is at an inflection point in the journey of building regional value chains for sustainable health product manufacturing. Right now, there is a rare combination of opportunity, political will, donor commitment, knowledge, and resources that could enable maximum value addition for local manufacturers on the continent.

The successful transition to a robust, sustainable African manufacturing industry that delivers significant product range and volume at required standards of quality and competitive prices will require a framework and approach that expedites change and maximizes success.

This paper highlights the coordination and collaboration necessary to place local[1] manufacturing and procurement of quality-assured health products on the right trajectory—in Africa and for Africa. This opinion piece, organized by Unitaid, benefits from the input of multiple stakeholders in both the public and private sectors from across the health and industrial development industries in and beyond Africa.

DIFFERENTIATED MARKET-BASED APPROACH FOR AFRICA

In African markets, multiple challenges inhibit successful and sustainable local and regional production, including quality and regulatory compliance, unstable economies, poor access to finance and forex, power supply and infrastructure challenges, and trade-health policy incongruence.

The proposed approach herein enables continent-wide collaboration and coordination that synergizes focus and investments, accelerating progress to a positive market dynamic of scaled enterprises that deliver a secure supply of best-priced, quality-assured health commodities for Africa.

Actualizing a market-based approach anchored in a differentiated coordination model focuses on two key areas:

- Regulatory/quality assurance policies and mechanisms
- Procurement/market shaping policies and mechanisms

[1] In the context of Africa, the definition of "local" may be extended to include domestic (national or subnational), regional, and continental within the territory of the member countries of the African Continental Free Trade Area.

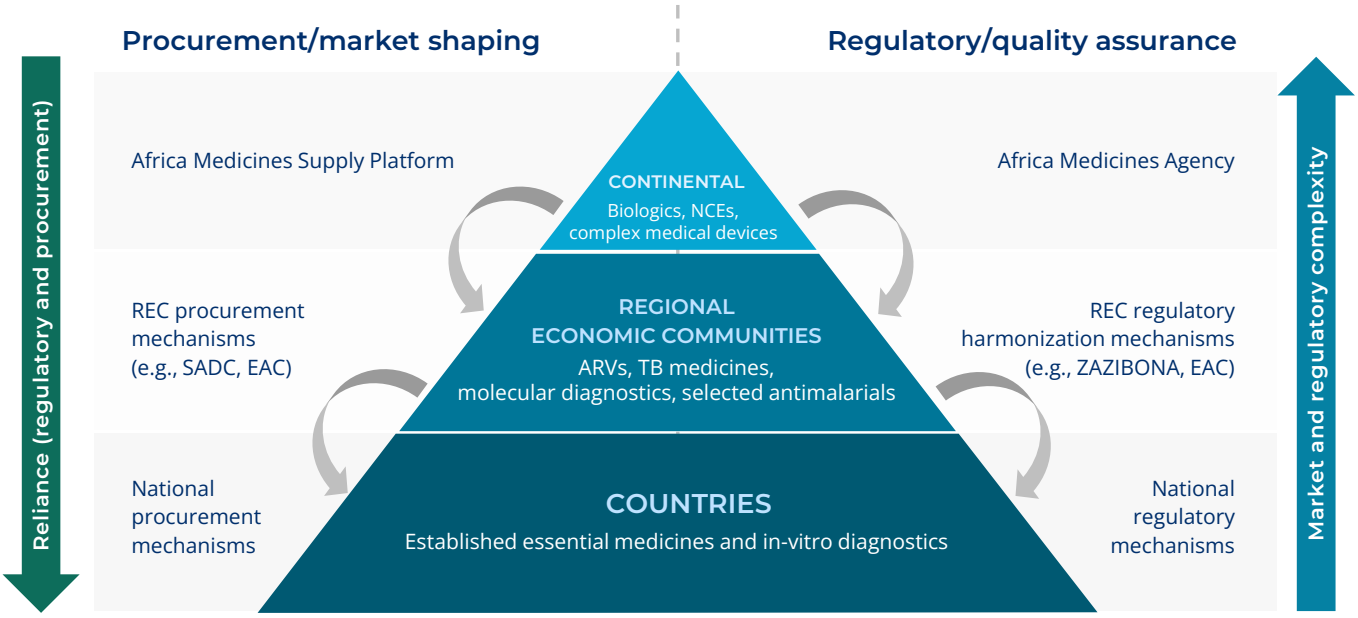

Figure 1: Framework for differentiated coordination of procurement and regulatory mechanisms

Figure 1 presents the framework for a differentiated approach to the coordination of regulatory and quality assurance mechanisms on the continent by matching them against procurement and market shaping initiatives. This framework streamlines the ecosystem toward ensuring equitable access to quality-assured essential health products across a balanced manufacturing base and enables the enhancement of the required capabilities for regional and even continental value chains.

The framework as envisioned can accommodate progressive changes to the interpretation of manufacturing over time and flexibility in approach for the differences in scale requirements across product groups. It is also relevant for products/therapeutic areas that are commercially competitive at a global level and those where low- and middle-income countries specifically need more suppliers to respond to clear public health needs.

The underlying principles on which the framework is anchored include:

- Optimization of existing or prospective national, regional, and continental mechanisms
- Promotion of specialization and value contribution of all mechanisms
- Removal of redundancies and overlap in roles and scope of operation
- Reduction of nationalism and protectionism in policy, regulations, and practice
- Promotion of reliance and recognition of the policies and operations of procurement and regulatory mechanisms
- Facilitation of inclusive participation, coherence, and ownership across member states, industry partners, development institutions, and other supporting institutions
- Facilitation of capacity building and systems strengthening through peer learning, technical assistance, and mentorship
- Modification of existing policies at the country level and in procurement practices of all institutions to align with African Continental Free Trade Area principles and give preference to products manufactured within the continent while respecting the rules of origin and acceptable levels of value addition

Adoption of the proposed differentiated framework will enable the practical considerations that must be addressed in formulating a comprehensive strategy and time-based deployment plan. These include the selection of products, the definition of "manufacture",[2] the scale and value of any price premiums that may become apparent, and the methods and means of ensuring effective and sustainable funding models for regulatory systems that positively impact market dynamics.

Continental Coordination and Collaboration

The African Medicines Agency (AMA) charter has been signed by 30 countries and the instrument ratified by 23 of the 55 AU member states. The African Medical Supplies Platform (AMSP) and African Pharmaceutical Technology Foundation (APTF) are excellent initiatives with the potential to transform access to and manufacturing of health products in Africa. As global bilateral and multilateral institutions that provide solidarity and offer significant incentives and scale of demand to manufacturers in Africa, African institutions such as the Africa Export-Import Bank and African Development Bank are designed and resourced to provide short-, medium-, and long-term support and incentives to industry. African institutions must broker strong partnerships with both regional and global institutions to leverage funding to the continent for capital investment and systems strengthening initiatives.

Continental leadership to ensure Africa's access to innovation and next generation technologies in real time is predicated on ensuring consistent growth in manufacturing capabilities across Africa, linked to an enabling structure for speedy regulation and market entry for the products produced. Market shaping for accelerated and equitable access should be central to the mandate of institutions at this level and within the context of, and alignment with, global value chains of the respective products.

Regional-Level Collaboration

Regional collaboration should be anchored within the regional economic communities (Common Market for Eastern and Southern Africa, East African Community, Economic Community of West African States, and Southern African Development Community) and other voluntary cooperation initiatives. The scope of regional collaboration should include products for which the aggregated demand is large enough to sustain economies of scale in the presence of a competing number of manufacturers. The regional level, ideally, should set product number and volume thresholds that guide the devolution of products to country mechanisms. The coordination of regional collaboration should be managed by the continental mechanisms, with support from global regulatory and procurement mechanisms.

The products coordinated at the regional level could also be devolved from the continental or global levels. For example, the World Health Organization (WHO) prequalification (PQ) program[3] should progressively devolve regulatory review and oversight of new submissions for selected

[2] Manufacturing of health products can be defined as all activities, including some or all value-added manufacturing operations, leading to the production of the respective health products. These include the synthesis of API, antigens or antibodies and other constituents of in-vitro diagnostics, and final formulation of finished pharmaceutical and diagnostics products.

[3] There has been considerable recent discussion on the role of WHO PQ. Respecting the views of all parties consulted, we maintain that the WHO PQ programme remains most relevant and important in the context of seeking decentralization of responsibilities and a differentiated approach.

categories of medicines currently within its remit to qualified regulatory mechanisms in the Africa region (and other regions) and provide technical support to fast-track the transition. Through reliance, regional approval could then flow down to countries and negate repetitive, costly, and time-consuming processes. Regional mechanisms could also specialize to optimize resources while ensuring mutual recognition across countries.

Ultimately, regional mechanisms should be further reinforced by reliance procedures and fast-track registration for WHO PQ cross-listing, providing African manufacturers with access to global markets.

For procurement and market shaping, the regional institutions should either lead initiatives by themselves or collaborate with other regions directly or through continental and global mechanisms and institutions. Global donors and their procurement partners should also establish required interfaces such as channeling procurement through regional structures and ensuring that procurement policies enable these mechanisms.

Country-Level Collaboration

Country procurement and regulatory mechanisms are at various levels of maturity with respect to capabilities and resources. Mature countries should be incentivized to play leadership roles at the regional and continental levels with support from normative and technical institutions (e.g., AMA, APTF, WHO), while others should be incentivized to continue to strengthen capacity. Countries need to conduct robust self-assessments to define maturity levels and the best approach to resource optimization, including cross country/region regulatory harmonization (common markets). The overall objective is to ensure that governments provide universal access to required health products to their citizens irrespective of the level of regulatory maturity.

Product selection for procurement and regulatory policy and practice at the country level should be defined and updated at predetermined intervals (e.g., three to five years), in alignment with national essential medicines lists and based on available resources. Regulatory and procurement approaches should include extensive use of reliance and recognition, freeing up limited national resources to be devoted to downstream activities such as compliance and post-market surveillance.

The overall objective is to ensure that governments provide universal access to required health products to their citizens irrespective of the level of regulatory maturity.

Countries should assign resources to and ensure collaboration with regional and continental mechanisms as appropriate. Furthermore, there should be transparent and consistent communication of the overall approach, including pathways to submission of dossiers and bids for defined products to the regional and continental mechanisms; such communication would include details of the countries' approaches to reliance across these mechanisms.

AREAS OF ACTION

The targets of collaboration and coordination must become the primary focus of all efforts by all players, particularly national governments and their regulators, donors and their procurement agents, and manufacturers and their investors and partners. Significant effort must be made to align incentives and to level the playing field—all in the aim of achieving a successful transformation to where African manufacturers contribute a considerable proportion of the continent's total needs and governments are confident in the resilience of their health care systems.

Leveraging Existing Achievements

Africa has demonstrated the ability to coordinate and collaborate for significant health benefits. During the COVID-19 pandemic, the preparatory and response efforts of various governments and continental institutions, largely directed and coordinated by Africa Centres for Disease Control and Prevention (Africa CDC), were commendable. Africa CDC's leadership facilitated continent-wide access to COVID-19 diagnostics and trained laboratory experts even before the first SARS-CoV-2 cases were reported on the continent. Their further engagement with heads of states, national ministries of health, and country pandemic response mechanisms led to coordinated design and execution of key strategies. Africa CDC's engagement with stakeholders beyond the continent secured support from foundations, bilateral and multilateral government agencies, and development finance institutions, resulting in initiatives such as the AMSP, African Vaccine Acquisition Task Team, and Partnership for African Vaccine Manufacturing.

Complementary to the work of Africa CDC were remarkable efforts by governments and Regional Economic Communities (RECs). WHO, for example, singled out the professionalism of the Nigeria Centre for Disease Control. Africa also leveraged the budding African Medicines Regulatory Harmonization initiative with support from WHO and some of the more mature national drug regulatory institutions to speed the review and approval of vaccines for COVID-19 using the African Vaccine Regulatory Forum as a platform.

A range of vital initiatives—AMA, AMSP, APTF, and United Nations Economic Commission for Africa and the transatlantic bridge linking these efforts in Africa, the Caribbean, and Latin America—work in pooling procurement and act as catalytic agents in ensuring alignment of their own efforts and those of their partners.

Unfortunately, not all of the lessons learned were positive. Despite all the preparatory efforts and investments across the continent, local health products' manufacturing capacity saw little investment and was poorly utilized throughout the response as Africa's overdependence on imports from other regions undercut significant manufacturing capacitation efforts.

Leveraging Existing Capacity

The pharmaceutical sector in Africa dates back more than 100 years when Lennon, the antecedent of Aspen in South Africa Ltd, was the largest pharmaceutical manufacturer in the Southern Hemisphere. In the 1930s, the first manufacturing entity was set up in Kenya, with other countries following suit. However, the sector currently operates below its potential as Africa still imports more than 95% of its active pharmaceutical ingredient (API) needs (often from competitor manufacturers) and more than 70% of all pharmaceuticals consumed on the continent. Today, the sector is organized into regional industry bodies—the West African Pharmaceutical Manufacturers

Association, Federation of East African Pharmaceutical Manufacturers Associations, and Southern African Generic Medicines Association—all under the structure of the Federation of African Pharmaceutical Manufacturing Associations (FAPMA). FAPMA has the potential to provide a central mouthpiece for advocacy and promote collaboration among regions to address the shared challenges facing the sector.

Most African manufacturers are primarily active in their respective countries; few have achieved regional or continental scale. African manufacturers are generally outperformed by their counterparts from China or India, where ex-factory unit prices are preferred by price-focused procurement agencies. African manufacturers compete with global manufacturers that have established brand recognition, enjoy significant export and import incentives (which lower their net average cost per unit), have quality certifications and preferential access to capital and buyers, and may be fully integrated and have greater economies of scale. In an unfathomable contradiction, in recent years most of these private businesses from other continents have been (and many continue to be) advantaged to improve their scale, range, quality, and price by extensive support from their own and donor governments and other international organizations through subsidies, grants, and even guarantees of production offtake (volume guarantees).

This market imbalance will continue to exist, or worsen, in the absence of active intervention. Enabling a competitive market dynamic could be achieved through collaborative and coordinated interventions such as pooling of API and excipients to guarantee availability and cost of these inputs. More immediate benefit could be achieved by extending the same advantages to African manufacturers as have been provided to Indian and Chinese manufacturers. These tools have proven effective in stimulating investments in capacity and improvements in quality in those markets and could be equally effective when applied to African manufacturers.

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Confronting the Issues of Quality and Price

Quality standards for procuring health products have been set by global role players (e.g., WHO PQ, US Food and Drug Administration [FDA], European Medicines Agency, high-income country regulatory bodies). They are based on audit and compliance frameworks for a limited range of products and are biased against smaller suppliers. As a result, many African manufacturers have chosen not to apply for these certifications largely because they do not see potential to participate in the product categories currently under the purview of global public health agencies, such as antiretrovirals. Their products are thus, in the eyes of many, often deemed to be of lower quality simply because their facilities and products were never assessed by these global authorities. An insistence on quality requirements like the US FDA or WHO PQ, without giving African manufacturers the time and incentives that have been provided to non-

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African manufacturers currently dominating the market, will perpetuate this imbalance.

Procurement policies by governments and global health agencies have been designed and even legislated to focus primarily on product price. These policies have sustained the market access imbalance for manufacturers in Africa, excluding most of them from donor-funded procurement estimated at more than $3 billion annually. Sufficient rigor must be applied to define and quantify the additional benefits of manufacturing closer to the point of use and its impact on sustainable product security, and procurement methods must be modified to incentivize investment in local capacity and quality.

By reversing the narrative of substandard quality and high costs that continues to erode the brand equity of a sector with potential to support needs in Africa and beyond, the international development community can become a catalyst for positive change.

Aligning Incentives

African manufacturers have remained resilient, even in the face of the challenges to successful and sustainable local and regional production outlined earlier. But they have been constrained to build their strategies and investments around their local private markets and national government tenders, where they have the best understanding; brand equity; and, on rare occasions, enabling policies. The call to African governments to support their local pharmaceutical manufacturing sectors, accentuated by the COVID-19 pandemic, has led to a few countries designing and implementing regulatory and procurement policies focused on growing their local manufacturing capacity. These policies have offered some early wins.

However, for most manufacturers, without off-take from international funders/buyers, the addressable markets remain insufficient in scale and reliability, limiting the ability to access the funding to extend their capacity or reach across the continent. Incongruously, many of these policies, focused on buying local or restricting importation, continue to be circumvented by global donors/procurement institutions seeking waivers based on their diplomatic status and institutional procurement and quality assurance policies.

CONCLUSION

Diligent and focused collaboration and coordination of all efforts by all players can achieve a successful transformation to where African manufacturers contribute a considerable proportion of the continent's total health product needs and governments are confident in the resilience of their health care systems. It is the responsibility of national governments and their regulators, donors, procurement agents, manufacturers, investors, and partners to ensure that all efforts are made to align incentives, level the playing field, and align policies and practices to ensure optimized scale and effective quality within countries and regions and across the continent.

Actualizing a market-based approach, anchored in a differentiated coordination model focused on regulatory/quality assurance policies and mechanisms and procurement/market shaping policies and mechanisms will enable continent-wide collaboration and coordination that synergizes focus and investments, accelerating progress to a positive market dynamic of scaled enterprises that deliver a secure supply of best-priced, quality-assured health commodities for Africa.

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