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## **BUILDING FOR SUSTAINABILITY: Accelerating Regional Manufacturing For Diagnostics**

A FIND & Unitaid Consultation with Diagnostics Manufacturers

13 – 14 April, 2023

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### Background

The global health community is in agreement about the urgent need to establish resilient health systems worldwide, especially following the COVID-19 pandemic, which highlighted the inequitable access to health technologies due to their manufacturing being concentrated in a small number of regions. While these centralized manufacturing facilities have achieved important economies of scale, the lack of complementary regional facilities has meant that many countries have been entirely dependent on a limited set of global suppliers and manufacturers for their diagnostics capabilities. Not only has this resulted in a lack of resilience in many health systems, but it has also meant that the health needs unique to low- and middle-income countries (LMICs) are frequently underserved.

Together, FIND and Unitaid are committed to supporting efforts to create an ecosystem that enables a decentralized manufacturing model for diagnostics that meets the needs of LMICs in a sustainable way. This will help increase access to testing in LMICs, which is essential given its vital role in helping to meet global healthcare goals.

### Meeting objectives

On 13<sup>th</sup> and 14<sup>th</sup> April 2023, FIND and Unitaid convened a meeting with 22 diagnostics manufacturers from 13 countries, representing diverse geographical regions in Africa, Asia, the Americas, and Europe. These manufacturers varied in their maturity, product offering, size and approach to LMIC markets. The primary objective of the meeting was to foster cross-regional collaboration, knowledge exchange, technology transfer, and manufacturing partnerships for diagnostic technologies related to LMIC health priorities. The long-term vision is to ensure all regions are adequately prepared for potential epidemic and pandemic diseases while simultaneously establishing a sustainable and resilient ecosystem in LMICs for the regional manufacturing of rapid diagnostics.

The outcomes of this two-day convening of diagnostics manufacturers successfully brought together various stakeholders to discuss strategies for strengthening regional research and development (R&D) and manufacturing networks for health technologies. Across six priority areas, recommendations were made by manufacturers, as outlined in this document, providing concrete actions that should be considered for establishing an enabling ecosystem that supports the sustainable regional production of diagnostics in LMICs.



## PRIORITY 1:

### Finance, Investments, and Incentives

Substantial investments in the diagnostics industry are necessary to drive the sustainable manufacturing of tests in LMICs. The demand is high in LMICs for infectious disease diagnostics, particularly point-of-care and polymerase chain reaction (PCR) tests. However, underinvestment and sub-optimal government support pose risks for new actors entering the diagnostics landscape. Investments and grants are both vital for transforming the diagnostic manufacturing landscape. Inadequate investments and the lack of enabling policies hinder manufacturers' capacity to scale up or expand production. Tax regimes that impose higher rates on locally produced health technologies compared with the rates imposed on imports undermine local production ambitions.

Good governance, both within and beyond the health sector, reduces risks and attracts investment. Public-private partnerships, with the public sector creating an enabling environment and signalling investment priorities, offer opportunities for attracting manufacturers to new markets. Investments from beyond the public sector, including by commercial and development banks, as well as new incentives for the emerging private sector, are crucial for developing, scaling up and sustaining regional manufacturing capacities.



### RECOMMENDATIONS ON FINANCE, INVESTMENTS AND INCENTIVES:

- National governments and development partners **should support the creation of regional diagnostics industry networks, facilitating funding, pooled procurement of raw materials, training, and knowledge exchange, and advocating for regionally manufactured products.**
- National governments should **review their policies, with a view to the creation of enabling environments for diagnostics industry investment.** In particular, it is necessary for countries to re-evaluate their tariff and non-tariff barriers on raw materials, as well as tax concessions and incentives for potential investors.
- National governments should **increase investment in public utilities and infrastructure; reduce trade barriers; and cooperate to facilitate regional trade, raw material flow and supply resilience.**
- Regional development partners, development banks and donors should **support revised policies** aligned with these recommendations.



## PRIORITY 2:

### Developing and Scaling-up Manufacturing Capacity

New models and strategies are urgently required to address the resources, technology and materials challenges faced by manufacturers during the scaling-up process. Governments must make sustainable investments in robust manufacturing infrastructure, including reliable water and electricity supplies. Efforts should be made to train and retain a skilled workforce, necessitating engagement from policymakers and employers. Regulatory infrastructure for medical technology manufacture will require considerable investment to remove current barriers to geographic expansion.



### RECOMMENDATIONS ON DEVELOPING AND SCALING-UP MANUFACTURING CAPACITY:

- Development partners, private investors and donors should **invest adequate resources in a variety of business models, supporting the entire value-chain of diagnostics production, including regional R&D, manufacturing infrastructure, capacity strengthening and early-stage financing** for small and medium-sized enterprises.
- Governments, development partners (including multilateral development banks) and private investors should **provide early-stage financing and support to small and medium-sized enterprises.**



### PRIORITY 3:

## Regulation

Slow and inconsistent regulatory pathways create uncertainty, negatively affecting investment decisions. Finding the correct balance in the regulation of medical technologies is a common challenge faced by manufacturers. While they acknowledge the importance of product regulation, manufacturers express frustration with product regulation systems, particularly in relation to unclear processes, long timelines, a lack of guidance, and inconsistent standard requirements across markets.



### RECOMMENDATIONS ON REGULATIONS:

- National governments should **establish transparent, harmonized and accelerated regulatory pathways for regional manufacturers of diagnostics.**
- Multilateral agencies should collaborate with others to **develop regional regulatory mechanisms and policies that multiple national authorities can rely on, fostering harmonization.**
- At the regional and multilateral levels, countries **should invest in fast-track regulatory processes for regionally manufactured products and strengthen global regulatory processes**, including World Health Organization (WHO) prequalification, to enhance access.
- Multilateral actors should ensure that **global and regional procurement instruments consider a wider array of regulatory authorities, to supplement WHO prequalification.**



### PRIORITY 4:

## Adoption of Regionally Produced Diagnostics

Manufacturers consider the likelihood of adoption when deciding on new product introductions and geographic expansions. They identify two main challenges: first, governments and the public's perception of the quality and desirability of home-grown medical technologies compared to well-known imported brands, and second, limited investment in technologies to optimize product reach, including digitization and process automation. Access beyond urban areas is often neglected.



### RECOMMENDATIONS ON THE ADOPTION OF REGIONALLY PRODUCED DIAGNOSTICS:

- Manufacturers highlight the lack of reliable information in support of the quality of new products and the maturity of regulatory authorities as barriers to consumer confidence and demand. Therefore, diagnostics industry associations and partners, as well as multilateral agencies, **should support evidence-generation and advocacy to increase trust in regionally made products.**
- Buyers and institutional procurers, such as donors, ministries of health and private health networks, should **establish preferential procurement policies for quality-assured regional manufacturers through plurilateral and/or bilateral guidelines.**



## PRIORITY 5: Procurement

Understanding procurement and supply dynamics is crucial for promoting sustainable regional manufacturing of diagnostics in LMICs, especially for small and medium-sized enterprises that lack the capital, leverage and networks to compete with established global brands. In many LMICs, including many countries in Africa, there are opportunities for increased manufacturing of diagnostics but information gaps hinder progress.



### RECOMMENDATIONS ON PROCUREMENT:

- National governments and development partners should **establish global, regional and national procurement guidelines that favour regional manufacturers** based on the overall benefits they offer beyond product costs. National governments should **align their tendering processes with policies that support local manufacturing**.
- Multilateral agencies **should assist in gaining a better understanding of markets**, including assessing potential demand for priority products; they should also **support evidence-generation and the adoption of new diagnostic technologies**.
- **Regional industry associations should assist with connecting manufacturers with distributors**; global multilateral agencies and donors can support these efforts.



## PRIORITY 6: Innovation and Development

Investing in innovative products or regionally needed products without market commitments in advance or supported market-entry can pose considerable risks for manufacturers. Some of the challenges faced by innovators include insecurity of supply due to import permit requirements, limited execution capacity and skilled personnel, and a lack of competition in the market. To stimulate innovation, increased private-sector engagement can facilitate access to early small investment and financing support, while greater government backing can help overcome infrastructure and transport barriers.



### RECOMMENDATIONS ON PROCUREMENT:

- Developers should proactively **establish and strengthen R&D and manufacturing partnerships** in diverse locations, including in LMICs, to facilitate technology transfer and **maintain a balanced product portfolio** aligned with global and regional health needs.
- National governments should develop and share **national diagnostic strategies with dedicated budgets for R&D**, with the aim of **promoting industrial parks, simplifying business registrations and attracting investments**, while also addressing infrastructure and transportation barriers.
- Multilateral agencies should **facilitate public-private partnerships between manufacturers in countries of differing incomes**, promoting technology transfer, mentorship and capacity strengthening. This includes **fostering collaboration between established and potential manufacturers**, including **North-South, South-South and triangular cooperation**.
- Multilateral agencies should also **facilitate knowledge sharing** among manufacturers and continue to support them throughout the product development process.

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