



## AFRICA-SOUTH KOREA ROUNDTABLE

# WORKING TOGETHER ON LOCAL PRODUCTION OF DIAGNOSTICS

14 June 2022

### Roundtable objectives

The COVID pandemic has brought to the forefront the difficulties faced by many African countries when it comes to equitable and sustainable access to diagnostic tests. Considering that most countries in Africa rely exclusively on imported diagnostic tests and related products, they are often last in line for securing supply and procurement agreements. This gap in regional diversity of the production and procurement of medical tools is not new, and applies to many diseases beyond COVID, including but not limited to malaria, HIV, TB and neglected tropical diseases (NTDs) that are endemic on the continent, and for which there are few or no local manufacturers.

There is a need to diversify the global diagnostics market by increasing the number of regional and local manufacturers, and to create an enabling environment through strengthening procurement mechanisms and national and regional regulatory authorities. In 2021, Doctors Without Borders/Médecins Sans Frontières (MSF) published an extensive analysis report and provided recommendations for the improvement of local production of diagnostics.<sup>1</sup>

Given the longstanding expertise of South Korean manufacturers in developing and manufacturing diagnostic technologies, and the large potential of developing a diagnostics industry in Africa, there are opportunities to forge mutually beneficial partnerships. On 14 June 2022, MSF hosted a roundtable to bring together manufacturers and stakeholders from Africa and South Korea to discuss the challenges, potential and opportunities offered by increasing local production of diagnostics. Participants emphasised the need for all people to have access to diagnostic testing, with improving access to testing at the primary health care and community level being the highest priority.

This report summarises the discussions, and offers recommendations in five key areas for improving access to diagnostics.

### Key recommendations

#### 1. *Manufacture local, buy local*



Sustainable demand for locally manufactured products is one of the main hurdles faced by local manufacturers. Manufacturing diagnostics locally may not deliver more affordable tests initially but should increase sustainability in access and create a local industry with important indirect benefits, such as employment and infrastructure development, and potential for cost savings in the longer term.

#### Recommendations

- **Locally manufactured diagnostic products that are quality assured should be prioritised for local public procurement.**

<sup>1</sup> MSF. Local diagnostics to meet local health needs. [Online]. 2021 Jul 8 [Cited 2022 Aug 31]. Available at: <https://msfaccess.org/improve-local-production-diagnostics>

- **Systems to create visibility of national and (sub-)regional funding mechanisms for procurement of diagnostics should be established.**
- **Systems should be established to reliably predict and pool demand, especially for diseases which represent a small and unpredictable market for manufacturers, such as NTDs (e.g. visceral leishmaniasis) and outbreak-prone diseases (e.g. measles).**

## **2. Strengthen the regulatory environment**

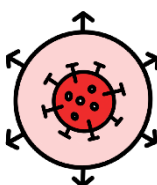


Efficient and well-resourced regulation is essential to help maximise access to safe, effective, and quality assured diagnostics necessary for both individual patient management and disease surveillance.

### **Recommendations**

- **National and (sub-)regional regulatory processes should be strengthened and harmonised across countries; all regulatory processes, as well as WHO prequalification, should be expedited to help ensure rapid access to quality assured diagnostics.**
- **(Sub-)regional networks that can evaluate locally manufactured diagnostics and generate local data should be expanded; shared use of (sub-)regional data for national regulatory processes across countries within the region should be considered.**

## **3. Manufacture beyond COVID**



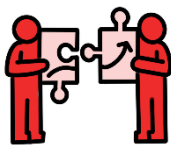
The COVID pandemic has shown that to adequately respond to health emergencies, countries should not rely solely on importation of diagnostics. While the importance of a sustainable local industry for diagnostics became apparent during the COVID pandemic, support to local manufacturers should go beyond COVID and prioritise local public health needs.

### **Recommendations**

- **(Sub-)regional and national essential diagnostics lists based on the WHO Essential Diagnostics List should be established.<sup>2</sup>**
- **Investments in local manufacturing of diagnostics that meet local health needs should be prioritised, including for diseases with small and unpredictable markets but with high local impact, such as NTDs.**
- **Locally manufactured diagnostics should meet immediate local public health needs to ensure uptake; manufacturing processes should have the flexibility to adapt and respond to emergency needs.**

<sup>2</sup> WHO. The selection and use of essential in vitro diagnostics - TRS 1031. [Online]. 2021 Jan 29 [Cited 2022 Aug 31]. Available at: <https://www.who.int/publications/i/item/9789240019102>

#### 4. Train to grow



South Korean manufacturers have long-standing expertise in diagnostic technologies and innovation, creating an excellent avenue for support and training to both start-ups and established manufacturers in Africa. African manufacturers can in turn inform South Korean manufacturers on the local public health contexts, opportunities and market dynamics, at national and (sub-)regional levels as well as form partnerships for clinical trials.

##### Recommendations

- **Partnerships between manufacturers in Africa and South Korea should be bi-directional and grounded in mutual exchange of knowledge and benefits.**
- **South Korean manufacturers are well-placed to take the lead in setting up (sub-)regional training hubs for local manufacturers of diagnostics in low- and middle-income countries (LMICs). There are specific needs for hands-on training in quality management systems and regulatory aspects for manufacturing diagnostics.**
- **African manufacturers face a gap in access to equipment for manufacturing and scaling up production capacity. Countries, (sub-) regions and global actors should invest in the local production of equipment to close the machinery gap.**

#### 5. Work together



Opportunities for intra- and interregional partnerships to manufacture diagnostic end products, raw materials and equipment or components were identified at the roundtable. The skillset and talent are widely available in African countries to build a strong diagnostics industry, but that alone is not enough.

##### Recommendations

- **Existing local industries within and beyond the health sector could be used to manufacture materials needed to scale up local production of diagnostics, including sharing large equipment.**
- **Local diagnostic industries should be developed through intra- and interregional partnerships in production of both raw materials and end products, in research and development and clinical trials; reliable demand and ensuring a sustainable market will be prerequisites for capital investments.**

## **Call to action**

As an international medical humanitarian organisation, MSF sees first-hand how insufficient access to diagnostics hinders effective medical care. The recommendations stemming from the roundtable and summarised in this brief help pave the way to building sustainable partnerships between manufacturers and actors in the African region and South Korea that can lead to increased local production of diagnostics. Technical follow-up steps by manufacturers and relevant stakeholders, including governments as well as regional and global actors, will be needed to translate these high-level recommendations into concrete actions.

**Participating organisations:** Africa CDC, African Union, African Centre of Excellence for Genomics of Infectious Diseases, African Society for Laboratory Medicine, AIDS & Rights Alliance for Southern Africa, Amref Health Africa, Bioneer, Cambridge University, CapeBio, Concern Worldwide, Das Labor, FIND, Humasis, Institut Pasteur de Dakar, i-SENS, Kanco, Kenya Medical Research Institute, Kogene, Korea Medical Devices Industry Association, Lateral Flow Laboratories, LifeAssay, Médecins Sans Frontières, Meditech, Mico Biomed, Mologic, Noul, Open Society Foundations, Open Society Initiative for Eastern Africa, OptiBio, OSANG Healthcare, Right Fund, SD Biosensor, SolGent, South Centre, Stop TB Kenya, Sugentech, Sungkyunkwan University, The Aurum Institute, UN Development Programme, UN International Centre for Genetic Engineering and Biotechnology, University of the Witwatersrand, Usamru-k, Villgro Africa, World Health Organization

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