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Critical Path Analysis the introduction of New TB diagnostics in the Africa region



26th March 2026

Presented by:
Dr Marguerite Massinga Loembé (project lead)

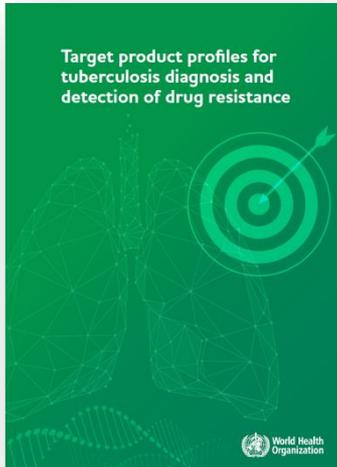
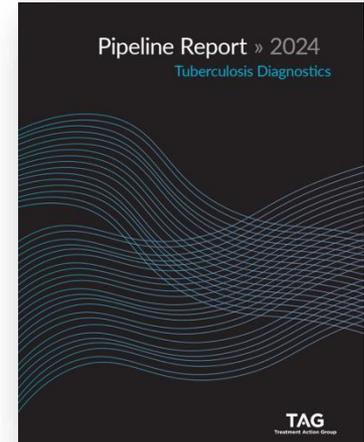


Photo credit pexels.com

Persistent gap for accessing WRDs to achieve the targets of the End TB strategy (only 48% access in 2024).

Yet **rich pipeline of new TB diagnostic tools**

Critical shifts are required to expand access to WHO recommended rapid Dx tests (WRDs), including at the decentralized/community level



Innovation

- **Swab based POC/NPOC**
- Next generation high sensitivity lateral flow assay



Predisposing, enabling, and need factors influencing rapid uptake of the world health organization-endorsed TB diagnostic technologies in Africa

[Jean de Dieu Iragena](#)  [Achilles Katamba](#), [Anandi Martin](#), [Moses Joloba](#) & [Willy Ssengooba](#)



“it took between 2 to 9 years from the endorsement of a new technology to its full implementation, with the duration increasing with the complexity of the test”



“How to **expedite the review and approval** of new TB diagnostic tools and technologies to facilitate quicker market entry & uptake in national policy while **maintaining** safety & quality **standards** ?”



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New TB Dx Critical Path Analysis project



MATAHARI

Africa Region

- Ethiopia
- Gabon
- Kenya
- South Africa

+ Nigeria

FIND 
Diagnosis for all



THE AGA KHAN UNIVERSITY



CHRF



UNIVERSITAS
PADJADJARAN

South and South East Asia Region

- Bangladesh
- India
- Indonesia
- Pakistan

Objective:

- to identify **relevant context** and **obstacles** to the introduction to the market of novel diagnostics for TB

Anticipated result:

- **Consolidated** and **usable information** and recommendations for manufacturers, technical agencies and donors to **accelerate the initial introduction and early uptake** of new TB diagnostics

Gates Foundation



Regulatory approval
Global & country levels



In country adoption & scale up





Structure

- 48 questions
- 9 thematic areas
 - *TB Diagnostic regulatory approval (Global/regional)*
 - *TB Diagnostic regulatory approval (in country)*
 - *Validation by NTP or MOH*
 - *Product Use Case*
 - *Demand Creation*
 - *Health System and Implementation Needs*
 - *Health Insurance and Pricing*
 - *Supply Chain and Procurement*
 - *Integration*

Piloting



Co-creation of outputs



- Stakeholders, steps & processes along the pathway
- Inter-dependencies
- Timelines



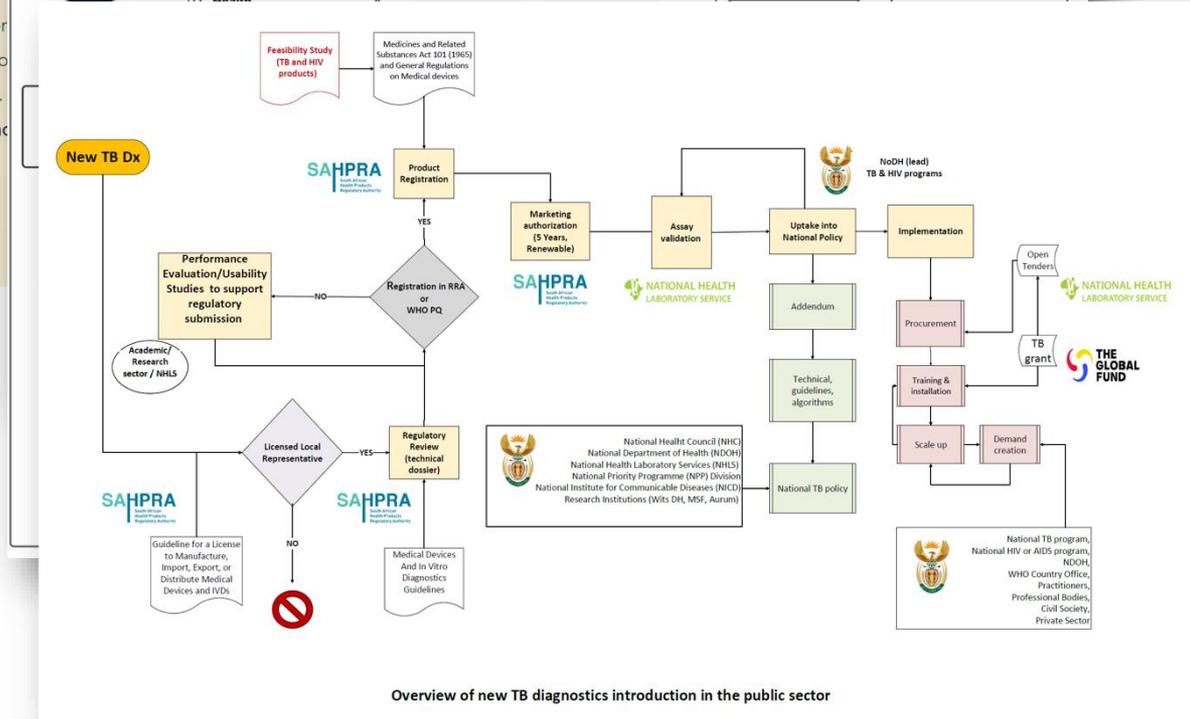
South Africa

In South Africa, new TB diagnostics are approved through SAHPRA, with WHO prequalification and ZAZIBONA easing registration, while NTP and NDoH guide policy adoption. Near POC molecular and LAM tests are prioritized for primary care and community use. Procurement and pricing are managed through NHLS and NHI, with partial donor support from USAID and the Global Fund. Digital systems and strong research institutions support integration. Learn more here:

- [South Africa Specific Critical Path](#)
- [Stakeholders Mapping](#)
- [Full country report](#)

CRITICAL PATHWAY FOR NEW TB DIAGNOSTICS

<https://www.tbdcriticalpath.org>



Overview of new TB diagnostics introduction in the public sector



	Ethiopia	Gabon	Kenya	South Africa	Nigeria	
1	Ethiopia	Gabon	Kenya	South Africa	Nigeria	
N 3	Ethiopia	Gabon	Kenya	South Africa	Nigeria	
V R						
F	4. Approval timelines					
A	Regular review	3-6 months	6 months	3-24 months	3-12 months	4-6 months (NAFDAC) 4 months (MLSCN)
ra	CRP	90 days	Not specified	90 days	90 days	90 days
2	Expedited/waiver	10 days	Not specified	15 days	90 days or less	14 days (NAFDAC)
C h	5. Marketing authorization					
g	Validity	5 years (renewable)	5 years (renewable)	5 years (renewable)	5 years (renewable)	5 years (renewable)
A	6. In country validation/verification					
Lan		EPHI (not systematic)	SRL/NRL verification	KMLTTB validation	NICD/Academia Private sector NHLS HTA unit	MLSCN validation NTBLCP QA team verification



Key findings on REGULATORY APPROVAL

- **National pathways for IVDs and MD dossier review & approval are available or being setup**
- Guidelines are readily **accessible** (online).
- Approvals of TB Dx in Africa **mostly rely on WHO (recommendation/PQ)** as a standard for quality, safety, and efficacy
- **For TB programs WHO recommendation/PQ is a pre-requisite** (for funding, procurement, TA & operational guidance)
- Private sector complies with national approval pathways but is not always bound by national policy.



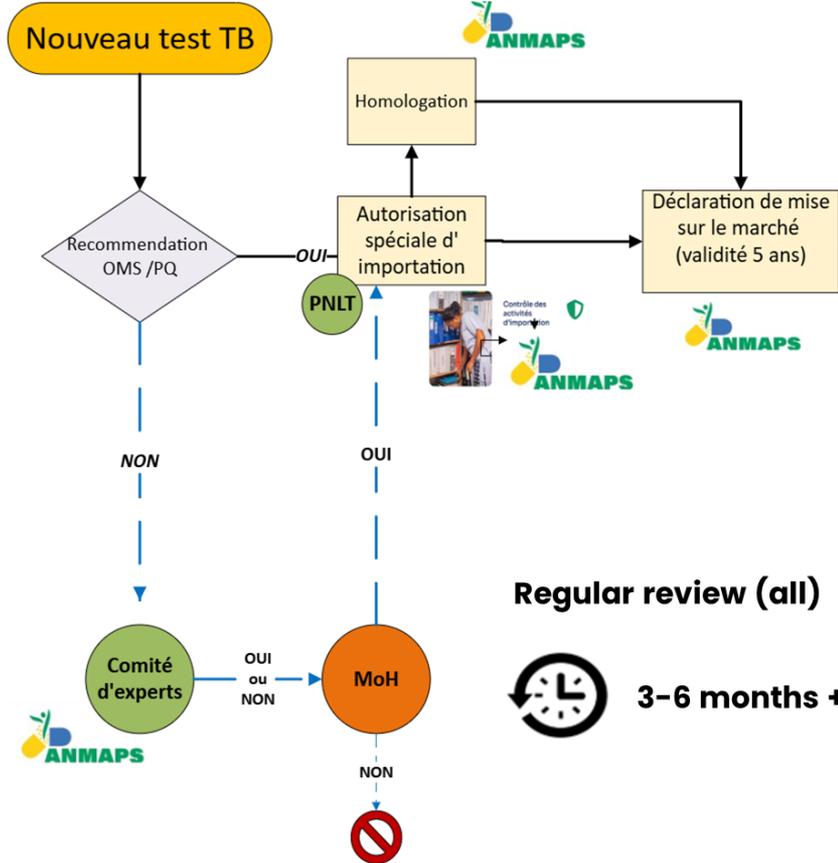
Enablers

- **Online portals** (all)
- Countries are actively engaged in capacity building & harmonization initiatives:
 - **ML3 listed** (SA, Nigeria and Ethiopia)
 - **IMDRF affiliated** (Ethiopia, Kenya, Nigeria South Africa)
 - **WHO GBT & MD** (Nigeria)
 - **AMA ratification** (Ethiopia, Gabon, Kenya)
- Pro-active **involvement of manufacturers** (ie: SAHPRA IVD & MD pathway pilot & info webinars)
- **Reliance and abridged/expedited reviews** pathways (e.g: WHO CRP)
- **Integrating & leveraging local evidence** (South Africa)

Barriers

- **Insufficient resources** (human and financial) leading to delays (all)
- **Limited awareness about regulatory requirements** (from manufacturers)
- **Rapid pace of innovation** which often **outstrips the regulatory framework**, making it difficult to keep guidelines and standards up to date
- **Potential for duplication/overlap** of regulatory entities at country level causing confusion & higher administrative burden for manufacturers (eg: NRA and Health technology assessment or Lab Councils)

**TIMELINES FOR
NATIONAL APPROVAL
ACCORDING TO REVIEW
MODALITY**



Collaborative /reliance pathways (all)

 **90 days or less**

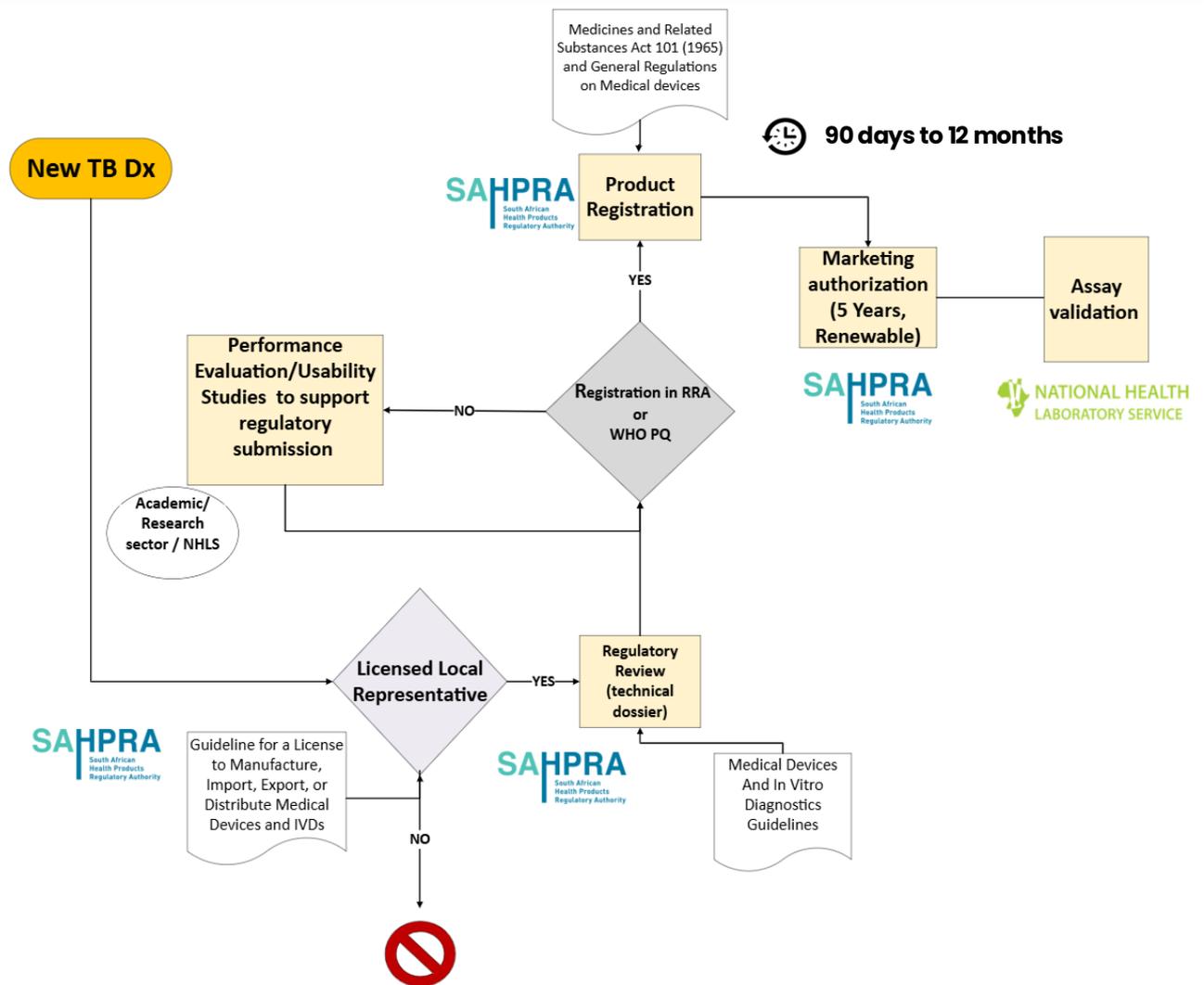
Regular review (all)

 **3-6 months +**

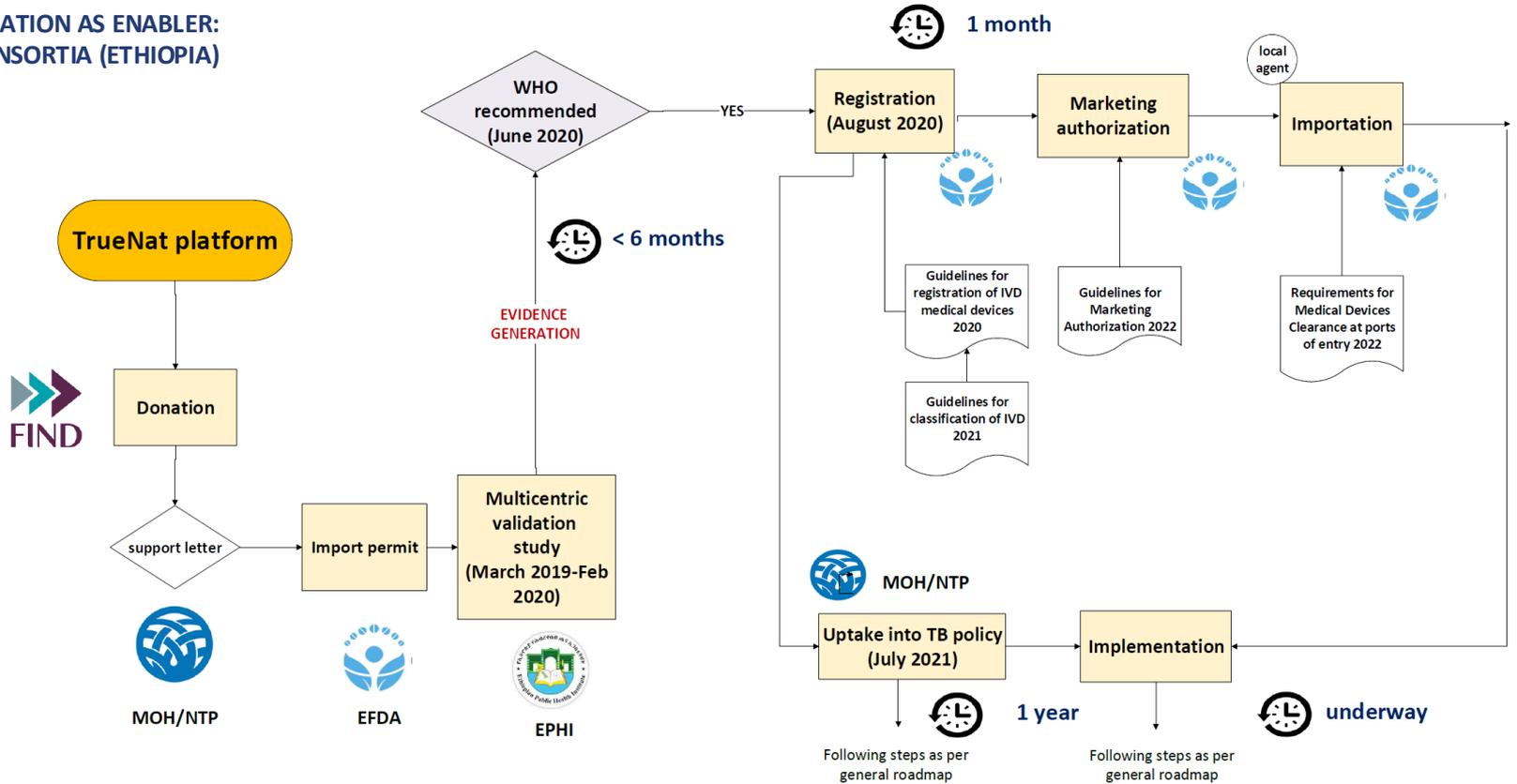
Expedited review (Ethiopia, Kenya, Nigeria)

 **10-15 days**

LOCAL EVIDENCE FROM INNOVATION HUBS, JOINT ACADEMIA/NRL RESEARCH EMBEDDED IN REGULATORY PROCESSES (SOUTH AFRICA)



**PRE-MARKET EVALUATION AS ENABLER:
INTERNATIONAL CONSORTIA (ETHIOPIA)**





Key findings on ADOPTION INTO NATIONAL POLICY

- **Local evidence accelerates uptake into national policy and informs programmatic deployment, scale up and integration strategies**

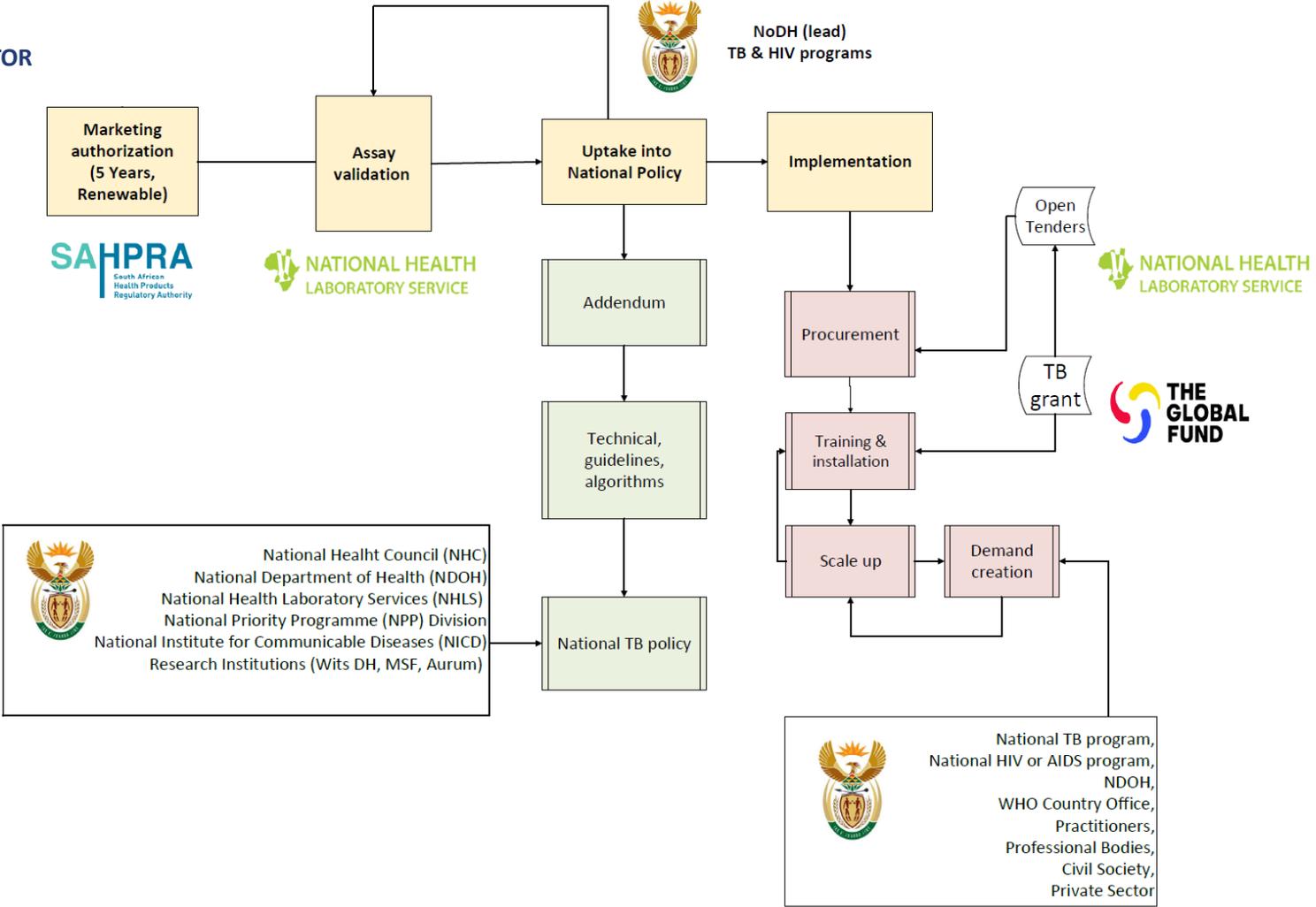
Enablers

- **National research ecosystems** (South Africa, Ethiopia, Nigeria)
- Local evidence on **performance, operational characteristics, acceptability, cost-effectiveness** either upstream and downstream of regulatory approval.
- **TWG** provide multisectoral platforms for review (all)
- **Alignment with NTP & wider health sectors strategies** (ie: Health extension program in Ethiopia, Community health strategy in Gabon)

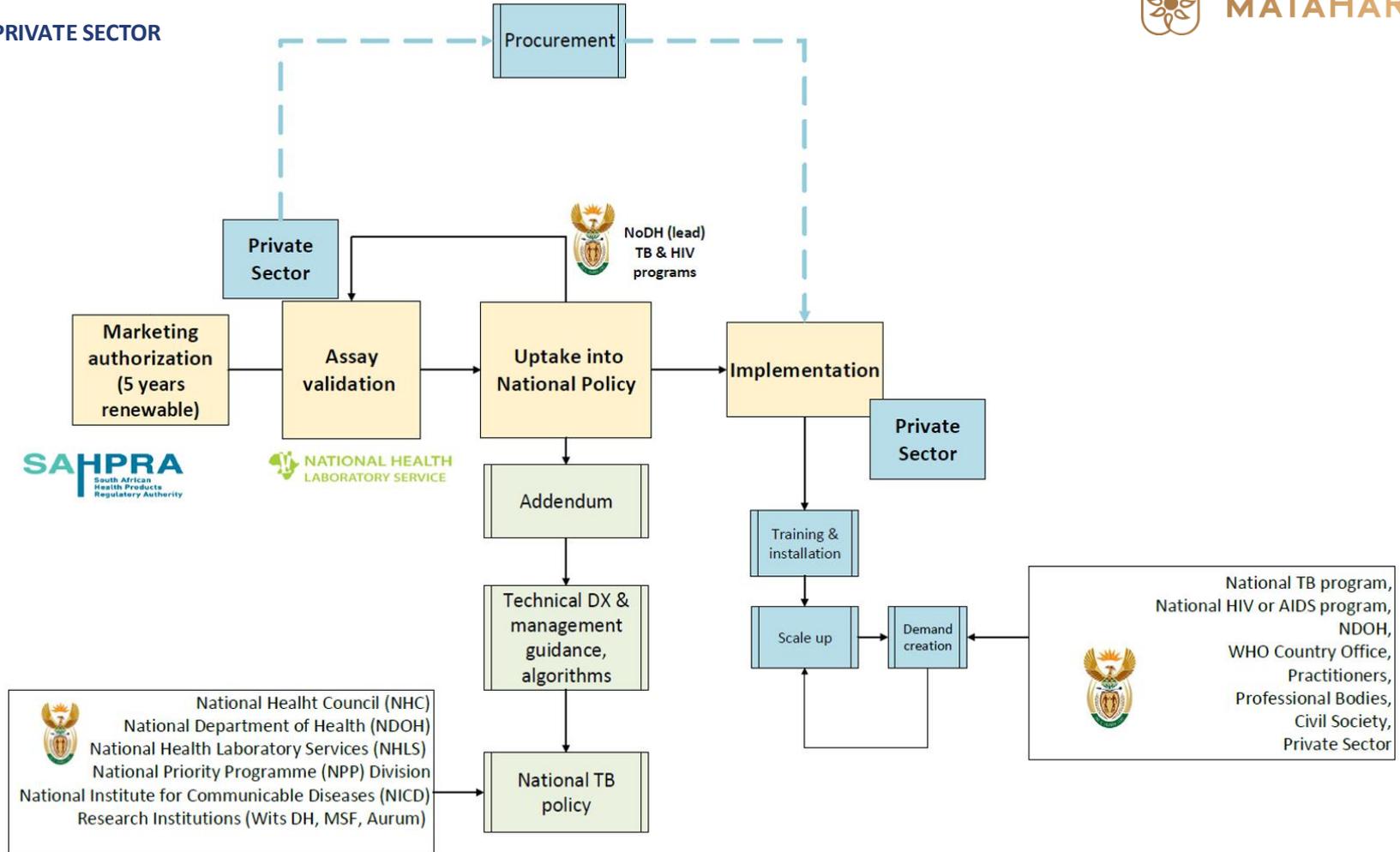
Barriers

- **Lack of overarching guidance & uncertain timelines** for in country for in-country performance evaluation and operational studies.
- Fixed, **timebound review and production cycles** for policy updates (vs ad hoc policy addendums).
- Private sector not leveraged as an entry point, where relevant

**UPTAKE VIA THE PUBLIC SECTOR
(SOUTH AFRICA)**



UPTAKE VIA THE PRIVATE SECTOR (SOUTH AFRICA)





Key findings on PROCUREMENT and IMPORT

- TB IVDs and MD are **manufactured externally and imported** (all)
- A registered/licensed local representative is required (all) and additional requirements may apply (all).
- **Donors (currently Global Fund) are the main source of funding and global pooled platforms (GDF or WAMBO) the main channels for procurement** (all)

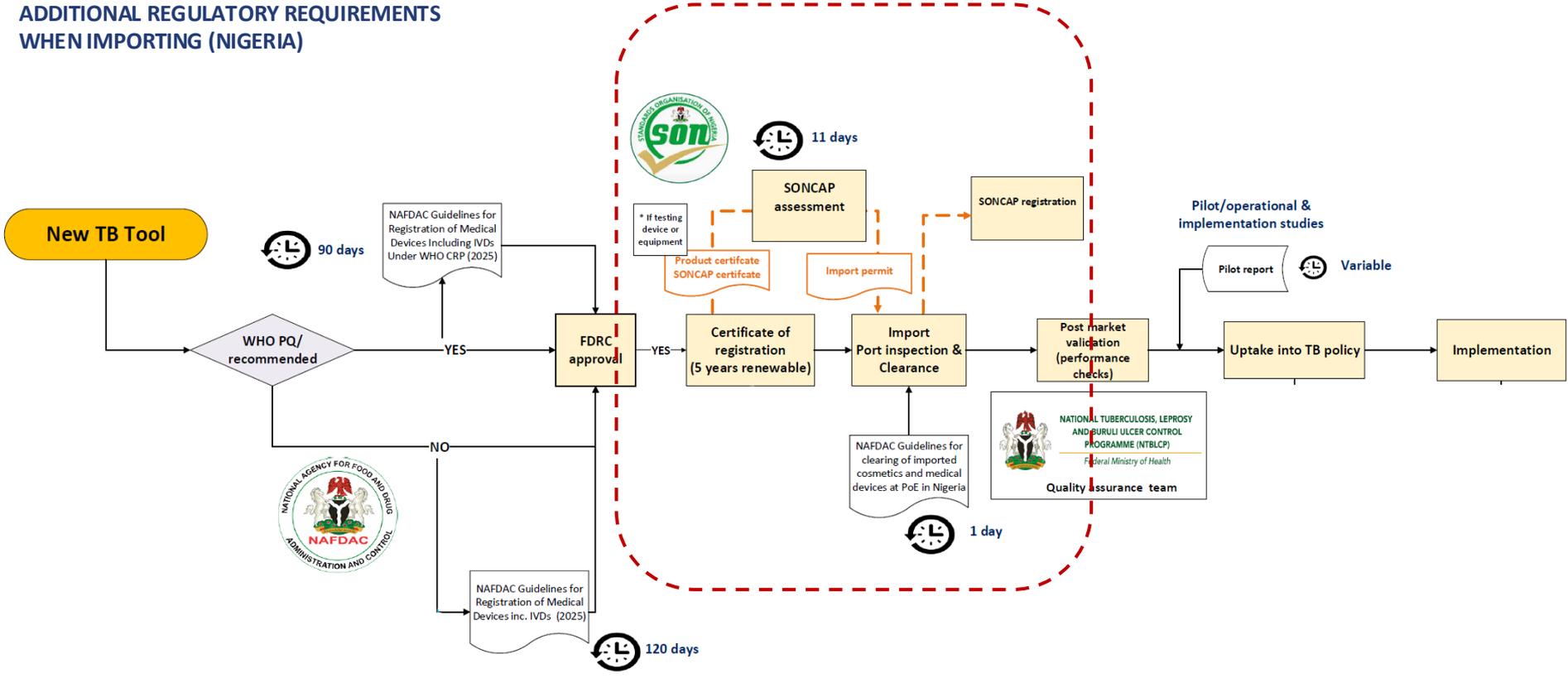
Enablers

- **Import waivers** for i.e. investigational products (Ethiopia, Gabon, Kenya, Nigeria)
- **Subsidized/volume-based pricing**
- Interim **pathways to procurement eligibility** (i.e. ERPDP from Global Fund)
- **Market access initiatives** (Global Fund/UNITAID)

Barriers

- **Misalignment between national regulators**
- **Donor dependency** (Ethiopia, Kenya, Nigeria)
- **Limited local manufacturing**
- **Access to foreign currency/exchange rate** (Ethiopia, Nigeria)
- **Small market size & limited market attractiveness** (Gabon)

ADDITIONAL REGULATORY REQUIREMENTS WHEN IMPORTING (NIGERIA)





Key findings on IMPLEMENTATION & SCALE UP

USE CASES:

- **replace microscopy** as initial test (Ethiopia, Gabon, Kenya)
- **expand access at decentralized level** and **outreach to underserved populations** (all)

Enablers

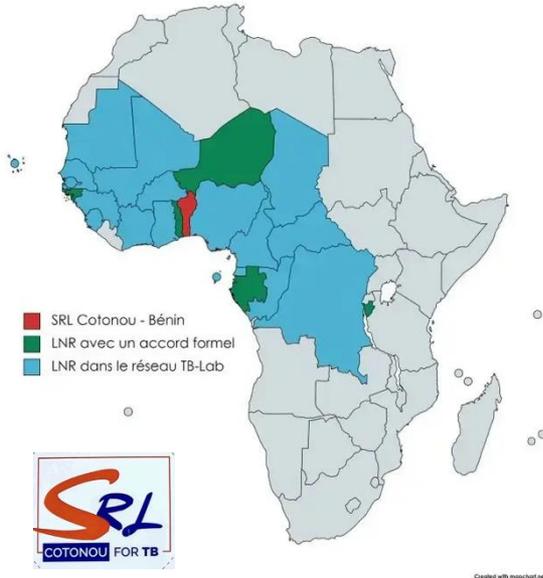
- **Targeted technical assistance** (from donors/partners or SNRLs or regional laboratory initiatives/networks) & **pilots introduction**
- In country **manufacturer support** at early market entry (installation, maintenance, spare parts etc.)
- Inclusion in **NEDL, minimum/essential service packages**
- **DNO/DNA** (informing use case /placement)
- Potential for **integration & multi-disease testing**

Barriers

- **Programmatic funding gap (all)**
- **Limitations of national lab systems**
- **Staff shortage & attrition**
- New cadre of workers to be trained (**task sharing**) at the point of service delivery (ie: PHC)
- Absence of **enabling legal/policy framework for testing outside the lab**



SUPPORT FOR PILOT INTRODUCTION



<https://dev.srlcotonou.org/reseau-international-tb/>

CHALLENGE TB



TB CARE I



Invitation to Manufacturers

4th April 2022

Manufacturers of Diagnostic Products
Are Invited to Submit
An Expression of Interest
For Product Evaluation by the
Global Fund Expert Review Panel for Diagnostic Products

Closing Date: not applicable (open Call)
Reference Number: GF/ERP/Adhoc-21/04-2022

Stop TB Partnership
TB REACH

MiniDock MTB Test



- RAPID**
Results available in as fast as 5 min
- EASY**
Hands-on time within 2 min
- SENSITIVE**
Comparable to PCR
- ACCESSIBLE**
Easy-to-collect
- ROBUST**
Same-day diagnosis & treatment

ERP Review Result – Category 2

The MiniDock MTB Test has been granted ERP Category 2 status. This qualifies the product for procurement under Global Fund-supported programs.

Source: ERP Review Outcome Letter, July 2022





STATUS OF NATIONAL POLICIES FOR TASK SHARING/SHIFTING*

Selected indicator	Botswana	Burkina Faso	Burundi	Côte d'Ivoire	DRC	Eswatini	Ethiopia	Gabon	Kenya	Malawi	Mozambique	Nigeria	Sierra Leone	South Sudan	South Africa	Tanzania	Uganda	Zambia	Zimbabwe
National policy for TS of general health services is available	Red	Red	Red	Red	Red	Red	Red	Red	Red	Red	Red	Green	Red	Yellow	Red	Red	Red	Red	Red
Acknowledges LHW for supporting general PHC activities	Green	Red	Green	Green	Red	Green	Red	Red	Red	Red	Red	Green	Red	Green	Green	Green	Red	Green	Red
NHSP Emphasizes TS for general health services	Green	Red	Red	Green	Red	Green	Red	Red	Red	Red	Red	Green	Red	Green	Red	Green	Red	Red	Red
Mentions POC testing	Red	Red	Red	Green	Red	Red	Red	Red	Red	Red	Red	Green	Red	Red	Red	Red	Red	Red	Green
Has an objective to improve POCT services	Green	Red	Red	Red	Red	Green	Red	Red	Red	Red	Red	Red	Red	Green	Green	Green	Green	Green	Green
NLSP Makes reference to TS and or LHW for POCT	Green	Red	Red	Red	Red	Red	Red	Red	Red	Red	Red	Green	Red	Red	Red	Red	Red	Red	Red
Has a costed framework, indicators & timelines for POCT	Green	Red	Red	Red	Red	Red	Red	Red	Red	Red	Green	Red	Red	Red	Red	Green	Red	Green	Green
National Essential Diagnostics Lists is available	Red	Green	Blue	Green	Red	Red	Green	Blue	Green	Green	Blue	Green	Red	Green	Red	Green	Yellow	Blue	Red

Legend: **Green**: YES, and supporting materials are provided. **Yellow**: YES, but supporting materials were not provided. **Blue**: Document in draft version. **Red**: No.

*Courtesy of Nzee Ndlovu





WHO policy statement on Xpert MTB/RIF

Dec 2011

WHO policy update on Xpert MTB/RIF in EPTB and pediatric populations

Dec 2014

WHO meeting report of a technical expert consultation on Xpert MTB/RIF Ultra

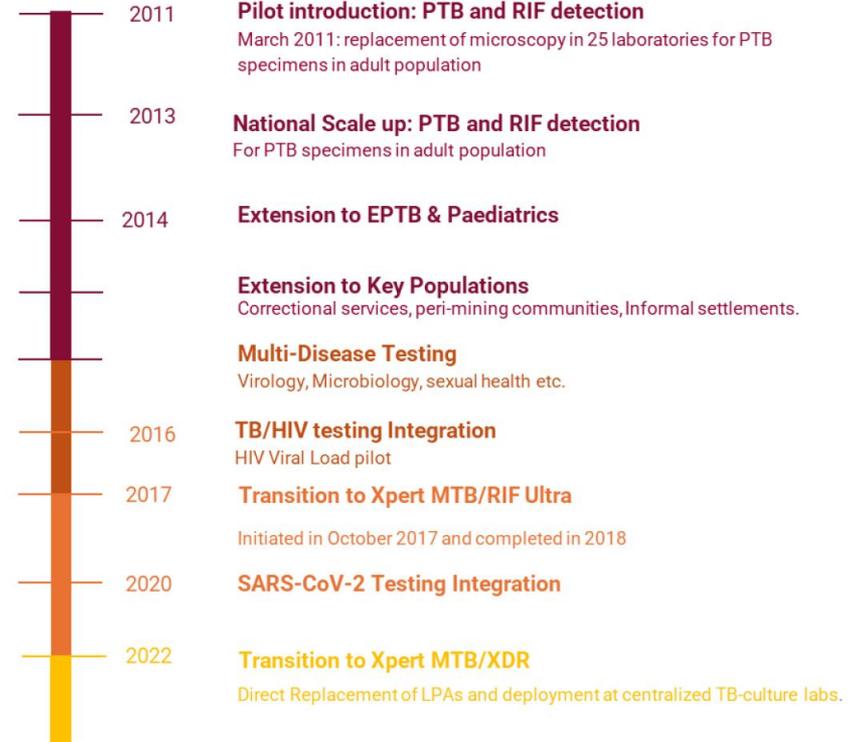
March 2017

WHO rapid communication on GeneXpert for SARS-CoV 2 testing

April 2020

WHO consolidated guidelines

Sept 2022





Xpert MTB RIF for replacement of Microscopy in high-risk groups

	Gabon	Kenya	South Africa
WHO recommendation	2010	2010	2010
Registration	2014 (SAI)	2018/2020	2010 (HTA validation)
Uptake into policy	2018	2016	2011
Time to adoption	8 years	6 years *	1 year

Truenat as initial test (mWRD) for replacement of Microscopy in all

	Ethiopia	Gabon	Kenya	Nigeria
WHO recommendation	2020	2020	2020	2020
Registration	2020	2023 (SAI)	2021	2021 (SONCAP)
Uptake into policy	2021	2024	2022	2021
Time to adoption	1 year	4 years *	2 years	1 year



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An opportunity: the Africa Medicine Agency



AMA African Medicines Agency

Marketing authorization:

The AMA shall be responsible for evaluation and decision making with regard to selected medical products for treatment of priority diseases/conditions as determined by the African Union.



Medical Devices Assessment Technical Committee (**MDA-TC**)

African Medical Devices Forum (**AMDF**)

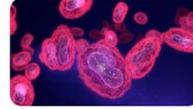
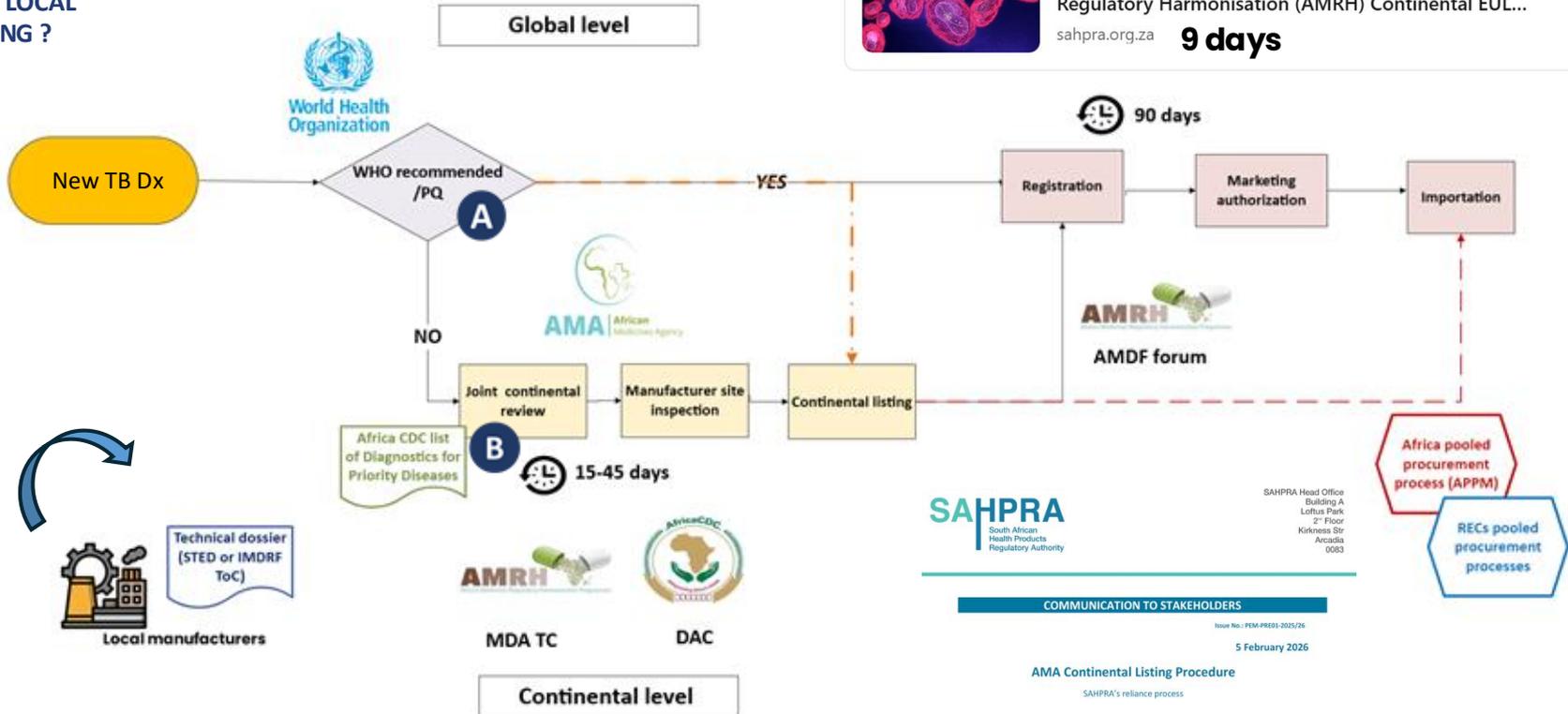


Diagnostic Advisory Committee (**DAC**)

Harmonized process for joint review & listing of medical devices and IVDs



AMA CONTINENTAL LISTING: POTENTIAL FOR SYNERGIES & INCENTIVE FOR LOCAL MANUFACTURING ?



SAHPRA Approves Mpox Test Using African Medicines Regulatory Harmonisation (AMRH) Continental EUL...
sahpra.org.za **9 days**

WHO

- Expand the roll out of the GTB+MDs benchmarking tool
- Maintain collaboration with continental stakeholders

Continental regulatory stakeholders

- Ensure alignment & synergies with existing initiatives
- Support strengthening of NRAs capacity at country level for MD & IVDs /expand pool of assessors
- Select TB as use case for the joint review and listing of priority diseases



NRAs

- Leverage the WHO GBT + medical devices and AMDF guidance to streamline & harmonize MD & IVDs guidelines (i.e. pilot in South Africa)
- Ensure transparency of the regulatory process (e.g: up to date online repositories guidelines, listing of authorized tests/devices, licensed distributors, etc.) for timely access
- Streamline the interface between NRAs and HTA/council

NTPs

- Engage with NRAs and HTA/council
- Strengthen PPM



Manufacturers

- Address documentation requirements (NRAs checklists) & language requirements
- Ensure availability of full technical dossiers
- Consider interim pathways to procurement eligibility listing, such as Global Fund ERPD open call for TB products
- Consider alternative diseases (integration) with high market attractiveness
- Stay abreast of and leverage regional pooled procurement mechanisms as alternative market entry points
- Leverage capacity of academia, regional initiatives, private sector for production of (local) evidence



OPINION | OPINION: GLOBAL HEALTH

To end TB, time for us to own our disease response and financing for health

Opinion: As the health ministers of four of the world's highest-burden TB countries, accounting for 25% of the global tuberculosis occurrence, we know ending tuberculosis is no longer a technical puzzle — it is a financing one.

By *Budi Gunadi Sadikin, Dr. Muhammed Ali Pate, Dr. Teodoro Javier Herbosa, Dr. Pakishe Aaron Motsoaledi* // 28 October 2025





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CRITICAL PATHWAY FOR NEW TB DIAGNOSTICS

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<https://www.tbdxcriticalpath.org/>