THE AGA KHAN UNIVERSITY

CRITICAL PATH FOR NEW TB DIAGNOSTICS IN PAKISTAN

DISCLAIMER: Information correct and valid as of Oct 2025

SECTION 1: Background

SECTION 2: Systems, processes, stakeholders and actors

SECTION 3: Critical tasks and dependencies for new TB diagnostics pathways

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SECTION 1 - Background to Pakistan's Tuberculosis Control Program[1, 2]:

Pakistan's health care delivery system comprises of provincial and district public health departments, other government sector organizations (eg healthcare services for veterans and the armed forces), nongovernmental organizations (NGOs) and a diverse for-profit as well as not-for-profit private sector. The Ministry of National Health Services[*], Regulations, and Coordination (MoNHSRC) functions as the federal coordination center; in June 2011 the overall responsibility for health services and implementation was devolved to 4 provinces and 1 capital territory (Islamabad Capital Territory or ICT). Provincial healthcare Commissions develop and enforce Minimum Service Delivery Standards (MSDS) to be implemented at all levels of healthcare. The public sector is the main source for the provision of preventive and hospital care to the urban and rural population; public centers provide essential free-of-cost services to populations.

Prior to the devolution of the health sector in Pakistan, the National TB Control Program (NTP) operated as a standalone national program. In 2016, the MoNHSRC merged the TB, AIDS and Malaria programs under a Common Management Unit (CMU)[†], with the programs no longer functioning as standalone programs. The NTP has been working since 2016 as part of the CMU for AIDS, TB and Malaria in collaboration with international and national partners, such as the World Health Organization (WHO), the United States Agency for International Development (USAID) and the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM). Procurement and supply chain management is carried out in coordination with the national and international stakeholders such as the Global Drug Facility (GDF) and WHO.

Public-Private Mix:

There are four main models of Public-Private Mix (PPM) for TB in Pakistan: PPM1 for general practitioners (GPs), PPM2 for NGOs, PPM3 for private hospitals, and PPM4 for parastatal or other public hospitals. PPM-engaged sectors for PPM1, PPM2, and PPM4 use GF-supported diagnostic networks and NTP/PTP labs (proportion undetermined); very few PPM3 providers (proportion undetermined) have private laboratories affiliated with hospitals and general practices (n=438 per 2019 annual TB report) that provide TB diagnostics.

TB Laboratory system:

The TB diagnostic testing system is a tiered laboratory system; no Point-of-care testing occurs currently. The 'laboratory' tiered system comprises of Microscopy centers, Genexpert sites, and labs (reference labs). The National Reference Laboratory performs WGS on selected isolates although this is not part of the program and does not inform clinical management. Culture labs

[*] https://www.nhsrc.gov.pk/
[†] https://www.cmu.gov.pk/

include reference labs (national or NRL, and 4 provincial or PRLs), district labs, and a few TB labs in the private sector. Most national labs, microscopy centers, and Genexpert sites are funded by and provide TB testing free-of-cost through funds from the GFATM. Very few private labs have their own procurement mechanisms independent of the GFATM labs and are funded through for-profit mechanisms and TB tests are available at cost to patients.

Despite extensive lab infrastructure, only 40-50% of the total TB cases notified are bacteriologically confirmed.

Funding structure:

Since 2003, since the introduction of Global Fund- supported programs, Pakistan is increasingly reliant on GFATM funds for TB program implementation, with the local (federal and provincial governments) contributing only minimally to funding TB diagnostics and medications.

Since the inception and disbursement of funds by the GF for TB to Pakistan (round2 onward, i.e. ~2004-5), all funding for diagnostics procurement and maintenance is provided through GF grants. Local funding for TB, especially for diagnostics, is decreasing and is minimal, mostly as the cost of new TB diagnostics viz Xpert and molecular tests is high. The costs for these new tests (equipment, supplies, maintenance, HR) are borne by the GF grant. Further, the distribution of such advanced diagnostics is also at the behest of GF experts; most Xpert platforms are in the public sector, GF-supported labs.

The Pakistan TB control program was reviewed in 2024 for GHI indicators. According to program review experts, diagnostic network optimization is NOT performed by NTP to optimize efficiency of Xpert testing. Moreover, TB program staff and stakeholders are more concerned with simply achieving GF targets than in root cause analyses of emerging issues and problems in TB in Pakistan including raising domestic funds to sustain control activities.

SECTION 2 – Systems, Processes, Stakeholders, and Actors:

A. **Medical Device/ IVD Industry value chains in Pakistan**:

Pakistan has a large local medical device industry mostly focused on PPE and assistive device manufacture. In vitro diagnostic platforms and kits are mostly imported. The IVD industry in Pakistan **imports equipment and packaged kits**; a few RDTs (hepatitis/ malaria) are locally assembled (which the regulatory agency classifies as manufacturing).
The IVD industry therefore has no R&D and minimal manufacturing capacity (mostly tetch transfer and assembly) ; the **IVD industry value chain** in Pakistan therefore mainly **encompasses import, distribution, marketing-and-sales, and post-marketing service functions**[3,4]. Multinational diagnostic companies (MNCs) have some presence in Pakistan to deliver these functions; **mostly** IVD equipment and reagents are **imported and distributed by a) licensed distributors/ supplier businesses**, or **b) in case of priority disease control programs, imported through GFATM or GDF mechanisms**. Becton, Dickinson and Company closed their facility and operations in Pakistan in 2016. Roche and Abbott currently have distribution and sales offices in Pakistan.

For tuberculosis, ALL IVDs for Active Case Finding (ACF) are currently imported, and none are locally assembled or manufactured. Both GFATM/ GDF mechanisms and local distributors are involved in import and services for TB; for national programs, either GFATM or GDF mechanisms are employed for import while local distributors mostly supply private hospitals and laboratories.

Suppliers and distributors function as businesses within Pakistan and are represented by the Healthcare Devices Association of Pakistan (HDAP)[‡]. HDAP membership promises suppliers access to national regulators via its group delegations.

B. **Regulatory system for medical devices and IVDs in Pakistan**:

Regulatory actors and processes:

The Drug Regulatory Agency of Pakistan (DRAP)[§] is the sole regulator and approver of medical devices and diagnostics, irrespective of the use case/ location of use (province)/ use type (essential service, private market/ compassionate use). DRAP acts as an autonomous body, and reports to the MoNHSRC. DRAP succeeds the previous federal regulatory entity, the Drug Control Organization. DRAP is therefore a young regulatory agency and works per its founding 2012 **Act** and regulates medical devices under its Medical Devices **Rules**, 2017[**]. Additional policy changes are notified frequently through **other instruments** viz Statutory Regulatory Orders (**SROs**) and **notifications**.

Organization: DRAP has **13 divisions** under the leadership of its Chief Executive Officer (CEO): 1. Licensing 2. Pharmaceuticals Evaluation & Registration (PE&R) 3. Biological Drugs 4. Controlled Drugs 5. Health & OTC 6. Medical Devices & Medicated Cosmetics (MD&MC) 7. Pharmacy Services 8. Quality Assurance & Laboratory Testing (QA&LT) 9. Costing & Pricing 10. Legal Affairs 11. HR & Administration 12. Management Information System (MIS) 13. Budget & Accounts.

Decisions are overseen by **DRAP boards** and **committees** comprising of representatives from all divisions.

DRAP currently largely focuses on regulating commercial entities and paid goods, not donated supplies; however, donated devices and products also require No objection Certificates (NOCs) issued by DRAP for seamless imports.

DRAP's medical device & IVD regulation mechanisms:

Rules: Medical Device Rules 2017

Divisions: MD&MC; QA&LT

Boards: Medical Device Board

The DRAP's MD&MC Division is responsible for the registration of medical devices & medicated cosmetics.

DRAP's Regulatory frameworks and Classification System for medical devices:

[‡] https://hdap.pk/

[§] https://www.dra.gov.pk/

[**] https://www.dra.gov.pk/wp-content/uploads/2022/10/Medical-Devices-Rules-2017-updated-upto-april-2022-2.pdf

FEATURE		FRAMEWORK	DRAP POSITION	Comments	References
					5, 6
Medical device classification		GHTF (IMDRF)/ WHO GMRF	Classification by risk class A/B/C/D	DRAP Regulatory scrutiny increases with device class	
Reliance[††]		WHO GMRF WHO RRA list (pending revisions for IVDs)	Reliant on RRAs & CABs	RRAs: USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and United Kingdom.	
Recognition[‡‡]		IMDRF	Recognizes SRAs which are GHTF founding members	SRAs: a. Pre-qualified by World Health Organization or b. CE marked by CABs notified in NANDO database of EU c. US-FDA approved d. GHTF founding countries NRAs	
***Imported* medical device/IVD assessment by class**			Increasing scrutiny by risk class		
	A			ISO 13485 compliance FSC CAB certificate of compliance from RRA	
	B			ISO 13485 compliance FSC country of origin FSC in RRA QA/ QMS certificate or CE mark	
	C				
	D			As for class B and C plus: Design examination certificate	

RRA= Reference Regulatory Authorities; CABs= conformity assessment bodies

DRAP regulation of importers of medical devices and IVDs:

DRAP issues authorizations/ licenses to MD and IVD manufacturers and importers in Pakistan.

TYPES OF DRAP AUTHORIZATION:

- Establishment licenses (for manufacturers and importers) with 5-year validities

  A manufacturer/ importer must first obtain an Establishment License to import medical devices from MD&MC division of DRAP. The authority granting the license is the Medical Device Board of the DRAP.

  Licenses are issues to MD manufacturers, or their authorized representatives (sales reps) who also act as suppliers/ distributors.
- Product registration/ market authorization
- Import permits

EUAs are also issues for MDs where necessary.

[††] https://www.dra.gov.pk/wp-content/uploads/2023/01/2nd-edition-Relaince-Mechansim-in-Regulatory-Processess.pdf

[‡‡] https://www.dra.gov.pk/wp-content/uploads/2023/01/2nd-edition-Relaince-Mechansim-in-Regulatory-Processess.pdf

PROCESSES AND REQUIREMENTS FOR DRAP AUTHORIZATION:

1. *Establishment Licenses for Medical Device (IVD) Importers*[§§]:

   Prior essential tasks before DRAP application for import license:

   - New distributor company is run by Pakistani nationals carrying Pakistani CNIC
   - Company portfolio is submitted to and approved by the Securities and Exchange Commission of Pakistan SECP[***]
   - Company is registered with the Federal Board of Revenue (FBR) and has a National Tax Number

   DRAP Enlistment process:

   1.1. Step-0 Distributor submits fee "challan" for application as specified in rule 63 (currently 25000 PKR) in any branch of Allied bank of Pakistan; "challan" is an invoice generated online, however the payment must be made in cash at a bank;
   1.2. Step-1 Application on form-2. Submitted to MD&MC division in DRAP and online as well;
      1.2.1. Application pack includes list of devices/ IVDs to be imported, National Identity Cards (NICs) of Company (importer) partners /proprietors/directors, National Tax Registration Certificate (Obtained from Federal Board of Revenue), degrees/ experience certificates and appointment letter of qualified technical team/ persons per 2017 rules, property ownership deed/ lease, and a notarized Affidavit (Undertaking) per text given in form 2.
   1.3. Step-2 Evaluation of application by MDB (medical device board) through a panel of experts which includes auditors and inspectors.
      1.3.1. Panel inspects premises (storage area/ warehouse) to verify documents, information, other requirement at the premises as per the GDP (Good distribution practices) checklist.
   1.4. Step-3 Panel reports to MDB
   1.5. Step-4 MDB meet for the approval (MDB meetings occur at unpredictable intervals)
   1.6. Step-5 Decision from MDB: License granted, deferred, or rejected
   1.7. Validity of import license: 5 years from the DOI (date of issuance)

   Establishment licenses to new businesses take ~ 18 months.

2. *Product (IVD) (Class A/B/C/D) registration*:
   Preconditions: Only importers/ distributors/ vendors that are a) Licensed importers and b) authorized sales representatives in Pakistan of the manufacturing company may apply for product registration with DRAP
   DRAP Registration process:
   1. Online application – For Class A, Checklist and form 6A; for Classes B, C, and D, checklist and form 7A.
   2. Submission of dossier with prescribed fee (invoice online and payment in cash at a bank)
      2.1. for class A with FORM-6A and data on: shelf life / stability studies, storage conditions, letter of authorization from the manufacturer specifying that importers

[§§] https://knowledgehub-isb.pitb.gov.pk/search/activity/-1/rlco/4/department/13
[***] https://www.secp.gov.pk/company-formation/registration-of-company/

are their authorized representatives, proposed MRP maximum retail price) of IVD, free sale certificate (FSC) from the country of origin (apostilled, original hard copy enclosed in the dossier, FSC in an RRA country, ISO-13485/ GMP certificate, safety and performance data sheets, Declaration of conformity if evaluated by a Conformity Assessment Body (CAB), packing labels, manufacturing and quality flow charts, declaration/ undertaking on stamp paper

2.2. for class B, C and D with FORM-7A, all documents as for class A IVDs, description of accessories, complete list of various configurations to be registered, complete description of IVD/ device with intended use, key functional elements, formulation & composition with functionality.

3. Evaluation by the MDB
4. Decision by MDB: approved, deferred or rejected
5. Approved products classes B/C/D license valid for 5 years may be imported

3. *Import Permits*:
For registered IVDs, DRAP provides import permits or No-Objection Certificates (NOCs) for import to an established importer, or a government agency, a public health agency, or hospital/ laboratory.

Documentation requirements for import of IVDs:

• Intimation of arrival of consignment of imported medical device/raw material/component of medical device on Form -11

• Copy of registration and renewal status of the medical device/ IVD

• Packing list

• Bill of landing (B.L) / Airway bill (A.W.B)

• Invoice

• Deposited “challan” (Official Receipt) of applicable fee.

• Undertaking under Rule 25 of the MDR, 2017 on stamp paper.

Import of Un-registered/Unavailable medical devices by Hospitals/Institutions

Application for import of un-registered/unavailable medical devices can be made by the Hospitals/institutions. This, however, requires special permission and prior approval from the DRAP field offices in provinces. Pre-approval is subject to FSC for the IVD (country of origin or RRA rule), hospital registration, and undertaking by importing agency as to the conditions of use, and provision to patients on ‘No Profit No Loss’ basis.

Import of Medical Devices on Donation

Application for import of donated medical devices/ IVDs can be made by the Government Institutions, Non-Governmental Organizations (NGOs), or Hospitals after obtaining prior approval from the DRAP field offices. NOCs are issued by the DRAP QA&LT Division after advice from the MDB. FSC, importing agency registrations, and certificate of donation from donor are required for MDB approval.

Note on medical devices used for imaging:

In addition to DRAP, these need Pakistan Nuclear Regulatory Authority (PNRA) approvals. This report does not focus on the PNRA pathway.

While PNRA is primarily responsible for radiation protection, in Pakistan, import and export of radiation sources and imaging equipment involving radiation can only be carried out if explicitly authorized by PNRA. Authorization is issued in the form of a "No Objection Certificate" (NOC) to the importer/exporter which is verified by the relevant law enforcement agencies at international entry/exit points. Only licensed entities are authorized to import or export these devices.

Import regulations - Ministry of Commerce:

MINISTRY OF COMMERCE IMPORT POLICY ORDERS[†††]:

The framework for imports in Pakistan is governed by the Ministry of Commerce, including guidelines for specific product categories through its import policy orders. Medical devices and diagnostic kits can be imported subject to DRAP clearance. Moreover, private importers (non-government entities) must enter into Commodity Exchange Arrangements (CEA) [‡‡‡]with suppliers (including undertakings controlled by foreign governments or public sector agencies).

For imports under credit or bilateral assistance (eg public development project by a private agency), contracts also need to be approved by Economic Affairs Division of the ministry of Commerce (not a requirement for routine imports by hospitals or government agencies).

Post-marketing surveillance by DRAP:

Good Distribution Practice for Medical Devices (GDPMD) [§§§]- Importers undergo annual monitoring and checks based on customer complaints, field corrective actions/ notices, advisory notes, recalls, and feedback from manufacturers.

Notes on device/ kit/ reagent registrations and imports from India:

Pakistan imports several medicines and vaccines from India; however it tdoes not import medical devices and especially IVDs from India; no specific regulations exist to define DRAP position on imports from India. However, in Feb 2025, MolBio applied for device clearance and DRAP deferred a decision. Minutes stated: "Referred to Authority for case-to-case guidelines regarding import of medical devices from India." It is unclear which authority the case was referred to (likely MoNHSRC and Trade Development Authority of Pakistan – TDAP). A State Bank of Pakistan Report cites several tariff and non-tariff barriers between India and Pakistan restricting imports and trade[****].

Per SBP: *"....one of the most significant obstacles to trade is Pakistan's restriction of imports from India. Although Pakistan has progressively removed all its non-tariff barriers since the 1980s, its imports from India remain restricted to items covered on a positive list. In 1986, Pakistan issued a list of 42 items that were allowed to be imported from India. This list has progressively been extended to 687 items in May 2003, 768 items in November 2004 and further to 773 items in February 2006. In addition, a 2002 Statutory Regulatory Order (SRO) permits the import from India of raw materials which are not produced locally and are required for the production of exports, including approximately an additional 1000 items. The increase in permissible items for import*

[†††] https://www.commerce.gov.pk/wp-content/uploads/2022/04/IPO-2022-SRO-No.-545I-2022-dt.-22.4-2022.pdf

[‡‡‡] https://www.sbp.org.pk/epd/1998/c50.htm

[§§§] https://www.dra.gov.pk/wp-content/uploads/2022/02/Guidelines-on-Good-Distribution-Practices-for-Medical-Devices-Approved-by-DRAP-Authority-in-38th-Meeting-held-on-17th-October-2016.pdf

[****] https://www.sbp.org.pk/publications/pak-india-trade/Chap_2.pdf

notwithstanding, the positive list approach continues to be a crucial obstacle to imports from India."

Moreover, import of Indian-origin products has been banned for a while (was allowed in 2009, banned later), per Ministry of Commerce policies.

Per ministry of Commerce policies[††††]: *"Import of the followings are banned: Namely i (a) goods of Indian or Israeli origin or imported from India or Israel: Provided that the provisions of this clause to the extent of India shall not apply to therapeutic products regulated by the Drug Regulatory Authority of Pakistan (DRAP)."*

C. **CMU/NTP approval mechanisms and algorithm updates**:

The CMU oversees NTP. All diagnostic platforms and IVDs are donated by the GFATM or other donor mechanisms.

Motivation for diagnostic updates:

CMU is advised by the WHO and GFATM during grant-making and interim periods on modifying/ updating diagnostic algorithms. Decisions on algorithm revision are taken during trilateral meetings held especially before/ during grant-making, between CMU and NTP representatives, WHO representatives, and GFATM advisors. Provincial programs (PTPs) are not routinely involved in decision-making and algorithm updates; however past CMU heads have highlighted that PTP should be involved and in future it is highly likely that they will be public PRs of GFATM with CMU as implementers of the TB control program. iNGOs in the past have initiated population-wide projects independently of CMU algorithm updates, however currently this is discouraged and iNGOs and partners working with the CMU do not initiate population wide services incorporating new diagnostics unless algorithms are updated. Pilot projects may be undertaken by partners or NTP themselves without algorithm updates; these are invariably externally funded by non-GFATM agencies (Stop TB/ TB Reach or BMGF etc).

On occasion, diagnostic company representatives or regional/ national distributors are known to approach CMU/ NTP with product updates, however without confirmed funding mechanisms, no new diagnostics are acquired by CMU/ NTP.

Currently, the Government of Pakistan does not fund the procurement of TB diagnostics.

CMU/ NTP diagnostic strategies and programmatic priorities:

The current CMU/ NTP priorities[‡‡‡‡] for the control program as listed on their website include expansion of molecular diagnostics, enhanced ACF especially in primary care, and AI-assisted diagnostics, all linked with the reporting mechanism through DHIS2[§§§§] for information management.

The program prefers using WHO PQed and/ or WHO-recommended platforms and/ or products for TB diagnosis. No bounds are set by the program for specific use cases and pathways; for ACF the program uses and adopts as reference the WHO-recommended/ WHO-verified accuracy estimates or TPP requirement.

[††††] https://www.commerce.gov.pk/wp-content/uploads/2022/04/IPO-2022-SRO-No.-545I-2022-dt.-22.4-2022.pdf
[‡‡‡‡] https://www.cmu.gov.pk/ntp-national-tb-control-programme/
[§§§§] https://dhis2.org/

When selecting new diagnostics for algorithm updates the following characteristics are considered by the program:

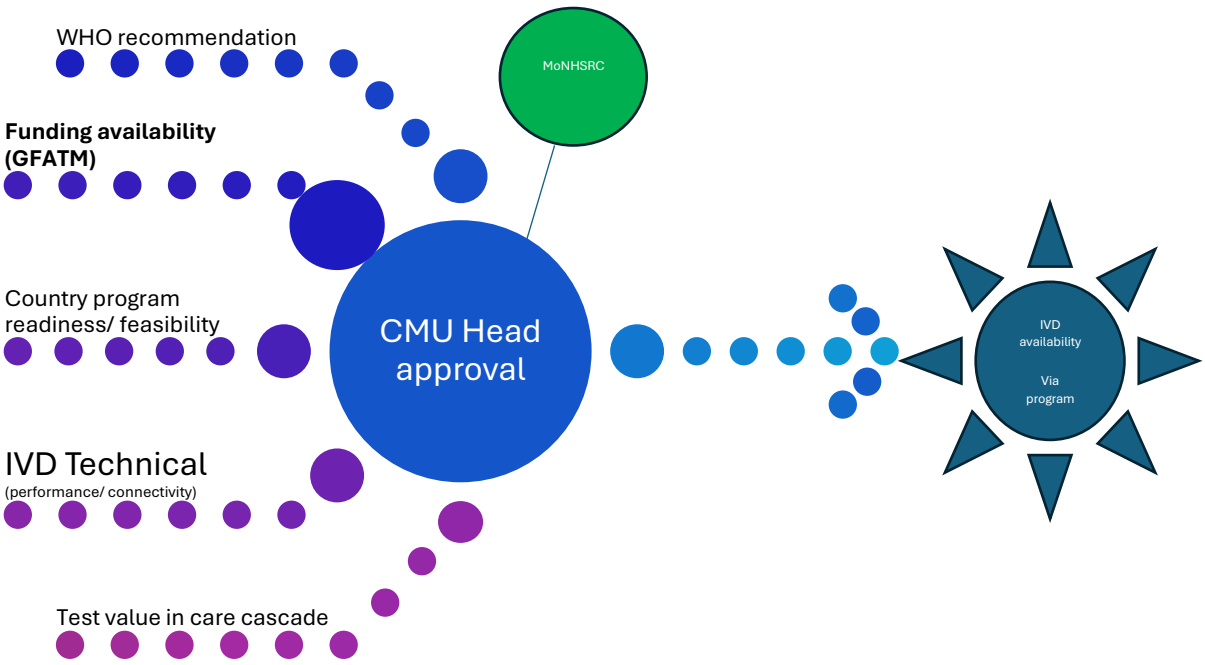
- WHO recommendation
- GFATM advice on use of test
- Availability of funding
- Use of diagnostic in care cascade and system/ program readiness to adapt
- Country pilot testing accuracy vs WHO-recommended targets

Other considerations eg in-country expert advice, diagnostic value, availability of in-country maintenance services, and total cost of ownership evaluations, and DHIS2 compatibility***** (as laid out in guidance for digital or e-reporting enabling conditions) are considered secondary to the ones listed above.

Necessity of Pilot testing:

NTP experts reiterate that pilot testing is necessary to infrastructure requirements and feasibility determination, and development of data linkage mechanisms, in addition to use-case accuracy verification.

Figure: CMU/ NTP decision-making influence map for algorithm updates



D. **Procurement mechanisms for donor-funded, publicly funded, and private IVDs**:

Procurement mechanisms vary depending on the buyer (end-user, i.e. CMU/NTP/PTP, private healthcare, or private NGO project, or an agent on behalf of the end-user), and the seller (diagnostic product manufacturers).

***** https://tbassessment.stoptb.org/pakistan.html

Since the CMU/ NTP are largely dependent on GFATM awards for diagnostic programs in TB, the GFATM procurement mechanisms comprise in large part the procurement of TB IVDs in Pakistan. Within the framework of the GFATM-permitted mechanisms, a mix of pooled, national, and direct procurement mechanisms are employed by the CMU to sustain TB IVD and diagnostic supplies.

Five main actors are involved in the procurement of TB IVDs in Pakistan:

1. GFATM (Pooled via GDF, national, and direct mechanisms, several end users)
2. CMU's Procurement and Supply Chain Management (PSCM) department
3. Public Procurement Regulatory Authority (PPRA)[†††††] (Provincial/ national procurement mechanism, public entity end-users)
    - *The Public Procurement Regulatory Authority is an autonomous body endowed with the responsibility of prescribing regulations and procedures for public procurements by Federal Government owned public sector organizations with a view to improve governance, management, transparency, accountability and quality of public procurement of goods, works and services. It is also endowed with the responsibility of monitoring procurement by public sector agencies/organizations and has been delegated necessary powers under the Public Procurement Regulatory Authority Ordinance 2002.*
4. Private labs and hospitals (private healthcare end users)
5. Diagnostic companies and distributors (sellers to end-users, public or private)

Types of procurement and use cases for TB IVDs in Pakistan:

1. Donated equipment and supplies
   Equipment and diagnostic supplies that are paid through 'donations', i.e. GFATM awards for TB are procured via GFATM funds, and all procurement mechanisms are subject to GFATM approval. Pakistan CMU/ NTP employ multiple procurement models for this, as allowed by GFATM (per procurement policies of the CMU). [7]

   Procurement for private PRs (Mercy Corps and their SRs) are done through similar mechanisms for two major reasons per our conversations with stakeholders: 1) the Private PRs and SRs are not tax-exempt and so it is cost-efficient to order through the CMU mechanisms; and 2) the private PRs and SRs do not have the capacity for procurement and supply chain management.

   TB diagnostics requested by the National Reference Laboratory NRL (on behalf of all the PRs and SRs and labs including the provincial reference labs) are run through **CMU for approval** and **ordered by the PSCM** through the following mechanisms currently:
   A. The Pooled Procurement GDF mechanism:
      PSCM order supplies through the GDF; currently this is operational for laboratory reagents and supplied without a local distributor eg the line probe assays etc, and where national and direct procurement mechanisms cannot be used (the latter two preferred by the MoNHSRC).
   B. National Procurement through PPRA – VALUE THRESHOLDS APPLIED:

[†††††] https://www.ppra.org.pk/

For orders valued at <30000 USD or <3000000 PKR, national procurement via National or International/ Limited Competitive Bidding; the latter used for diagnostic supplies not available in the national market. Currently this mechanism is used mostly for procurement of laboratory reagents.

C. Direct-from-manufacturer procurement (Single-source, non-competitive):
For some supplies where technical/ market dominance AND regulatory restrictions in country result in a single source eg Xpert (Cephied), NTP/CMU enter into direct long-term contracts with manufacturers to supply equipment/ reagents directly without going through the GDF pathway (and therefore also exiting the fold of GDF supplier management). Prices are GDF-comparable under multinational companies' Global Access Programs.

Delays in PSCM orders occur due to frequent changes in CMU and PSCM leadership and differences in management styles and proactivity of CMU and PSCM staff in office.

2. Public – government-supported (**not currently used** as most supplies donated)

This is performed through PPRA-based mechanisms by provincial departments. Currently provincial reference labs, provincial PRs (PTPs) and provincial departments of health (DoH) are not directly funded through the GFATM, NRL and NTP procure supplies. Since most TB diagnostics used in public facilities are donated and not funded by the government, large consignments use the mechanisms detailed above.

The PPRA mechanism for procurement by provinces may become the primary mechanism if GFATM funding is withdrawn; DoHs will then be responsible for public fund allocations for TB diagnostics, unless federal funds are used and disbursed. The planning phase involves developing "PC-1"s – an instrument used by the Planning Commission‡‡‡‡‡ for development projects. The PC-1 document outlines details of a proposed project, including its objectives, costs, financing, and potential benefits. PC-1s may be federal or provincial. Development and approval of PC-1 is the most critical link in procurement planning through public funds.

PPRA procurement uses value thresholds; purchases of <50000 PKR are defined as petty purchases and allow shopping. Purchases valued higher require competitive bidding processes.
The PPRA procurement systems have been evaluated for Sindh and KP provinces; highlighted areas for improvement include procurement infrastructure, HR and IT. [8, 9]

3. Private – lab-based for-profit sector

A few private laboratories in Pakistan house TB diagnostic facilities for culture as well as molecular diagnostics. These laboratories mostly develop **contractual agreements** (as opposed to long-term partnerships) **with country-based agents/ suppliers/ distributors/ vendors** of various products, acting on behalf of manufacturers. Private labs may or may not perform competitive evaluations of bids based on their internal processes. Competition is often limited as few companies have vendors with biomedical services available in Pakistan and even fewer have supply divisions in Pakistan. Costs are

‡‡‡‡‡ https://www.pc.gov.pk/uploads/downloads/PC-Forms/PC-I-Infrastructure.pdf

negotiated during contract development; based on private labs' profit margins and not0for-profit status, hospitals and labs may be eligible for lower costs as determined by Global Access Programs (especially if tests offered to populations at no cost to patients).
Private healthcare must comply with Provincial Healthcare Commission (HCC) directives/ provincial drug rules (of the province their labs are in). Currently, HCC permits are required for medicines and vaccines but not for diagnostic product/ medical device procurements and imports.
Since private labs are for-profit, procurement of supplies is under strict DRAP import restrictions and in addition to DRAP licensing of the vendor, product registration certificate, and import permits, certificates from the Ministry of Commerce and invoices are also required for import.
Private labs/ hospitals may obtain supplies directly by obtaining one-time import licenses for supplies under special use-case permission from DRAP.

4. Pilots/ research project-based

Similar to private labs procuring supplies, entities (for-profit or not-for-profit) engaged in research and pilot projects procure diagnostic supplies through distributors or directly under special use-case permissions from DRAP. Research projects must also carry an approval or exemption letter from the National Bioethics Committee[§§§§§]. Import policies may mandate Commodity Exchange Agreements if NGOs register pilot projects under bilateral assistance schemes.

E. **Shipment and Customs**:

Shipping and customs logistic processes are heavily regulated in Pakistan and therefore impact import of TB IVDs into the country. Requirements for shipping and documentation including packing methods, handling, and shipment logs, customs clearance certificates, bills and invoices are time-consuming for importers.

Customs clearance:
The ordering authority is responsible for customs clearance at ports. For the various procurement mechanisms, these authorities differ. For donated devices obtained through GFATM, whether ordered via GDF, directly from manufacturers, or national procurement mechanisms, the CMU's PSCM department is the ordering agent. For private labs and projects, either the lab/ healthcare facility or research institute orders directly (and therefore clears shipment at customs) or a licensed supplier/ distributor is responsible.
If public funds are used (to reiterate, currently public funds are not used for TB diagnosis or ACF in Pakistan), PPRA and their respective provincial/ federal procurement authorities are responsible for procurement and shipment as well as M&E.

Customs clearance requirements for import of lab equipment and IVDs:

- Commercial invoice: Invoice (from the seller i.e. manufacturer/ exporter) specifying the imported item(s), monetary value, and any other relevant transaction details.

[§§§§§] http://nbcpakistan.org.pk/

- Packing list: Contents of each package (with quantity, weight, description).
- Bill of lading/air waybill: The contract between the shipper and carrier, acting as a receipt for the goods and evidence of the contract of carriage – from manufacturer/ exporter.
- Import permit – Intimation of Import arrival for consignment clearance[******]- DRAP form 11 submission and NOC obtained from DRAP (detailed in section on regulatory approvals processes)
- Export permits and declarations from country of origin
- Certificate of free sale/ Free sales certificate from country of origin (confirming that the medical device is legally marketed and sold in the country of origin)
- Certificate of analysis (COA) verifying the quality and composition of the product
- Other certificates: eg GMP certificate, tax certificates, authorization certificate

Delays in clearance are frequent; these result in demurrages incurred (charges payable to chartered ship for failure to load or discharge the ship) and fines payable are borne by the buyer (CMU/NTP, distributor or hospital). Buyers pay around PKR 50,000 per consignment for delays. DRAP provides a 3 days' grace period for the clearance of consignment without charges; however, the customs department takes around 15 to 20 days to process and clear the consignment. [3]

Customs clearing agents (for-hire businesses) may be able to expedite complex processes if distributors do not have the capacity to do so.

Note Oct 2025 - Hidden costs and tariffs:

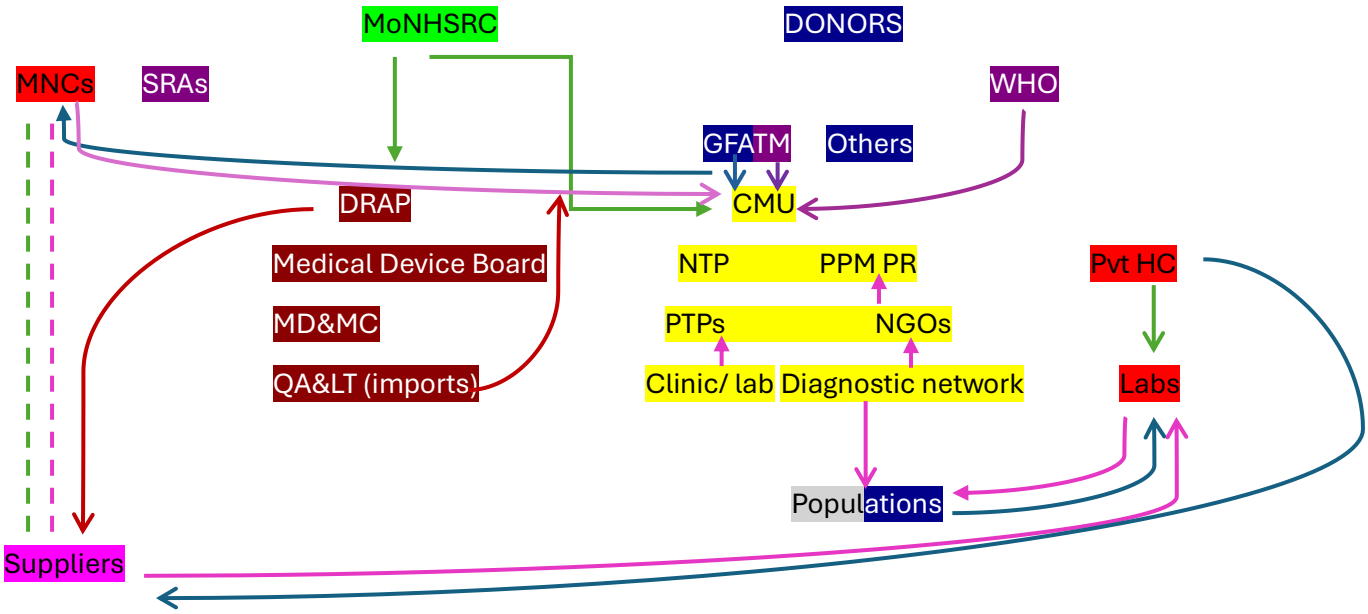
Stakeholders identified customs costs which are variable and incur a large burden on buyers especially in the private market. Buyers pay customs duties on imported equipment and disposable devices (including diagnostic kits) which is 3-5% of the Cost-Insurance-Freight (CIF) charges. An Additional Customs Duty (ACD) or Special Customs Duty[††††††] may be levied per FBR rules on imported goods at rates that are not fixed and vary between 2-11% (stakeholder input).

These costs are often hidden and always paid by the buyers and in case of the private market, borne by the distributors. Since Pakistan does not manufacture medical diagnostic kits, these costs which are designed to reduce reliance on imported products and goods, deter manufacturers and distributors from registering and importing new products due to fear of incurring additional costs.

[******] https://tipp.gov.pk/index.php?r=searchProcedure/view1&id=55

[††††††] https://download1.fbr.gov.pk/Docs/20194914412587 97FifthScheduleupdated.pdf

F. **Network diagram High-level TB IVD delivery network in Pakistan:**



Actor color key:

Red= Regulator, Green=Ministry, Blue=Payer, Yellow=TB program, Orange=Private (for-profit), Purple=Catalyst, Pink=Licensed Distributor and service agent; Grey= beneficiary

Arrow process color key: Red = Regulates; Green= oversees; Purple= advises; Blue= pays; Pink= delivers service; Dashed arrow= partial.

MNC= multinational companies (dxic manufacturers), SRA= Stringent regulatory authority, MoNHSRC = Ministry of health, GFATM= global fund, DRAP= drug regulatory agency of Pak, MD&MC= medical devices and medicated cosmetics, QA&LT= quality assurance and lab testing, CMU= Common management Unit, NTP= National TB program, PPM= public private mix, PR= primary recipient of GFATM award, PTPs= provincial TB programs, NGOs= non-governmental organizations, PvtHC= private healthcare sector

SECTION 3 - Critical Path: Regulatory and procurement process of IMPORTED TB IVDs with respect to payment models financing diagnostics in Pakistan

Critical path structure/ parameters:

Process – Actors – Dependencies (on previous tasks) – Duration (Estimated) – Barriers – Enablers

DISCLAIMER: Critical path is based on processes described above in previous sections; knowledge current as of October 2025.

Model 1: Public – donated equipment & supplies (GFATM-funded)

PROCESS/ TASK	ACTORS	DEPENDENCIES (previous tasks)	DURATION (Est)	BARRIERS	ENABLERS
Pre-Launch (Global)					
A. Certification and accreditation of new IVD	Manufacturers ISO CE/ IVDR USFDA	Unlisted tasks: Pre-clinical and clinical testing	6-12 mo for ISO 9-24 mo for CE/IVDR 6-10 for US FDA	Manufacturers reluctance to invest in certification High fee/ complex processes	
B. WHO recommendation	Manufacturers WHO GLI +/- WHO PQ	+/- A or unlisted tasks	~ 12 -18 mo		
C. GDF Cataloguing	Manufacturers GFATM GDF	A, B Unlisted: UNDP supplier registration?	?		
D. Market launch	Manufacturers Country of origin regulator (NRA) and commerce	Unlisted tasks: Pre-clinical and clinical testing IFU, labeling	Varies by country of origin and NRA rules		
Planning					
E. Program strategic priority setting (for new dx use case)	GFATM MoNHSRC CMU NTP (National coordinator) WHO	B			
F. Pilot testing	NTP PTP iNGOs or local NGOs PRs and SRs of GFATM award	+/- E			
G. Funding commitments and allocation of resources	GFATM CMU/ NTP	E, +/-F			

H. Algorithm updated	CMU/ NTP	A+ E + F + G			
Regulatory Approval					
I. NRA import certificate	DRAP CMU PSCM deptt	D (manufacturer free sales certificate country of origin)	3 days to 1 mo	DRAP fee not payable online	FSC Proactive CM PSCM
Procurement and supply chain					
J. DNA/ DNO	NRL CMU/NTP Pvt partners	G+H	12-24 mo	Limited program & partner capacity	
K. Procurement (requisition)	CMU PSCM NRL Provincial partners	G+I+J; +/-C	Based on mechanism: GDF: 1 mo Direct: 4-6 mo PPRA: varies by product and use case		
L. Shipment & Customs	CMU PSCM NGO partners	I	5 days-2mo	Delayed DRAP NOCs; incomplete documents; lack of pre-import intimation by PSCM to DRAP	
M. Distribution to network	PSCM CMU Warehouse managers PTPs Pvt partners	H, J	1 week-3 mo	PSCM, PTP, Warehouse internal communication delays	
N. Scale-up	CMU/NTP PTP Pvt partners GFATM	G, J, M	Q3yr based on GFATM funding cycles	(limited by program capacity and political will)	
O. Uptake by physicians/ populations	CMU/NTP Professional societies Healthcare commissions	H, +/- F	Ongoing		

Model 2: Public – govt-funded

This was done prior to 2003 before an increasingly GFATM funded national control program. The Government of Pakistan (Federal Ministry of Health) or provinces (departments of Health) funded programs through public fund allocations via PC-1. **The critical path analysis presented here is based on experience of diagnostics for other public programs (**Essential service by provincial governments' public health program**).**

PROCESS/ TASK	ACTORS	DEPENDENCIES (previous tasks)	DURATION (Est)	BARRIERS	ENABLERS
Pre-Launch (Global)					
A. Certification and accreditation of new IVD	Manufacturers ISO CE/ IVDR USFDA	Unlisted tasks: Pre-clinical and clinical testing	6-12 mo for ISO 9-24 mo for CE/IVDR 6-10 for US FDA	Manufacturers reluctance to invest in certification High fee/ complex processes	
B. WHO recommendation	Manufacturers WHO GLI +/- WHO PQ	+/- A or unlisted tasks	~ 12 -18 mo		
C. Market launch	Manufacturers Country of origin regulator (NRA) and commerce	Unlisted tasks: Pre-clinical and clinical testing IFU, labeling	Varies by country of origin and NRA rules		
Planning					
D. Program strategic priority setting (for new dx use case)	MoNHSRC - NTP Provincial DoH-PTPs WHO	B	12-24 mo		With ministerial planning and political commitment, the 12-24 months are synchronous
E. Funding commitments and allocation of resources	MoNHSRC (NTP) Provincial DoH PTPs	D	12-24 mo		
F. Pilot testing	PTPs	D, E	No historic precedent		
G. Algorithm updates	PTPs	B+D+E	12-24 mo		
Regulatory Approval					
H. Authorized representative registration license	DRAP Manufacturer Distributor/ authorized representative/ vendor	C	14-16 mo (upto 2 years) Validity q5 yr	DRAP registration independent of political commitment but influenced by it; if no prior distributor, regulatory approval is in addition to planning timelines	MoNHSRC influence and commitments MoNHSRC partnership with manufacturers

				DRAP fee not payable online	Reduced timelines if distributor already carries a license
I. **IVD registration**	DRAP Manufacturers Distributors	H, A+C, +/-B	6-9 mo	Lack of FSC in country of origin, Non-RRA status of country of origin Origin in India (import restriction unless sole source) DRAP fee not payable online	MoNHSRC influence and commitments FSC in RRA
J. **NRA import certificate**	DRAP Distributor/ vendor	C+H+I	3 days to 1 mo	DRAP fee not payable online	FSC FSC in RRA
Procurement and supply chain					
K. **DNA/ DNO**	PTPs		No historic precedent	Limited program capacity	
L. **Procurement (requisition)**	PTPs Provincial DoHs PPRA	D+E	1-2 years based on funding status and agreements		
M. **Shipment & Customs**	DoHs PTPs Authorized agents/ distributors	H+I	**Shipment lead times 4-6 mo** Customs ~ 1 mo	Delayed DRAP NOCs; incomplete documents; lack of pre-import intimation by PTPs/ procurement agents/ distributors	
N. **Distribution to network**	PTPs		No historic precedent		
O. **Scale-up**	PTP DoHs Pvt partners if any	D		Limited by program capacity and political will within provinces (implementers)	
P. **Uptake by physicians/ populations**	Healthcare commissions	D, N, O			

Model 3: Private – for-profit labs (Business models based on out of patients' pocket expenses) – or research use

PROCESS/ TASK	ACTORS	DEPENDENCIES (previous tasks)	DURATION (Est)	BARRIERS	ENABLERS
Pre-Launch (Global)					
A. Certification and accreditation of new IVD	Manufacturers ISO CE/ IVDR USFDA	Unlisted tasks: Pre-clinical and clinical testing	6-12 mo for ISO 9-24 mo for CE/IVDR 6-10 for US FDA	Manufacturers reluctance to invest in certification High fee/ complex processes	
B. WHO recommendation	Manufacturers WHO GLI +/- WHO PQ	+/- A or unlisted tasks	~ 12 -18 mo		
C. Market launch	Manufacturers Country of origin regulator (NRA) and commerce	Unlisted tasks: Pre-clinical and clinical testing IFU, labeling	Varies by country of origin and NRA rules		
Planning – Private sector					
D. Market Demand Creation	WHO Global guidelines developers Manufacturers Physicians and private labs	A+C, +/- B	12-24 mo	Lack of physicians awareness about latest developments	Global professional society and SSO recommendations
Regulatory Approval					
E. Authorized representative registration license	DRAP Manufacturer Distributor/ authorized representative/ vendor	C	14-16 mo (upto 2 years) Validity q5 yr	Highly regulated process: DRAP regulates commercial entities and timelines longer for new manufacturers and distributors DRAP fee not payable online	Reduced timelines if distributor already carries a license
F. IVD registration	DRAP Manufacturers Distributors	E+A+C, +/-B	6-9 mo	Lack of FSC in country of origin, Non-RRA status of country of origin Origin in India (import restriction unless sole source) Manufacturer reluctance in seeking registration in Pakistan anticipating complexities (eg DRAP fee not payable online)	FSC in RRA RRA NRA or SRA approved product Authorized distributor proactivity Manufacturer commitment in seeking registration in Pakistan
G. NRA import certificate	DRAP Distributor/ vendor	C+E+F	3 days to 1 mo	DRAP fee not payable online Some manufacturers do not obtain FSC/ do not enter free market	FSC FSC in RRA Authorized distributor proactivity
Contracting and procurement					

H. Service agreements/ contracts with labs and service provision	Manufacturer cost of production and sales	A+C+D+E+F	12 mo	Manufacturer cost of production and sales set prohibitive market costs No sales representatives to facilitate reagent rental contracts in Pakistan Labs employ contracting over partnerships	Manufacturer has CSR models to offset sales prices for LMICs Reagent rental (placement) contracts
I. Pilot testing/ lab verifications	Labs Distributors	A+C+D+E+F + H	~2-6 mo based on use case		Provision of reagents for verifications at no cost under agreements
J. Procurement (requisition orders) and costing	Labs Distributors	D+E		High supplier power for low complexity diagnostics	High buyer power for highly complex diagnostics
K. Shipment & Customs	Authorized agents/ distributors Hospitals where they act as buyers	H+I	**Shipment lead times 4-6 mo** Consignment release ~ 1week	Delayed DRAP NOCs; incomplete documents; lack of pre-import intimation by distributors. Hidden costs: Customs Duties of 3-5% of Cost-Insurance-Freight and 3-11% variable additional special duty costs deter manufacturers and distributors	Proactive distributors and buyers
L. Service availability to populations	Health care facilities Labs Manufacturers (costing mechanisms)	J+K			
M. Uptake by physicians/ populations	Healthcare commissions	D, J, L			

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