PQT UNIT

16 May 2023

WHO Regulation and Prequalification Department

World Health Organization

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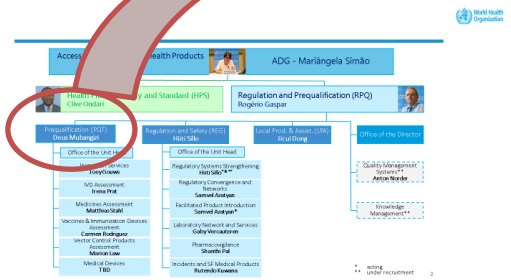
1 **Team's mandate, activities and achievements**

2 **Priorities, Challenges and Opportunities**

Structure of the Prequalification Unit



Prequalification Unit

Unit Head's office

Vaccines Assessment

Medicines Assessment

Diagnostics Assessment

Inspections

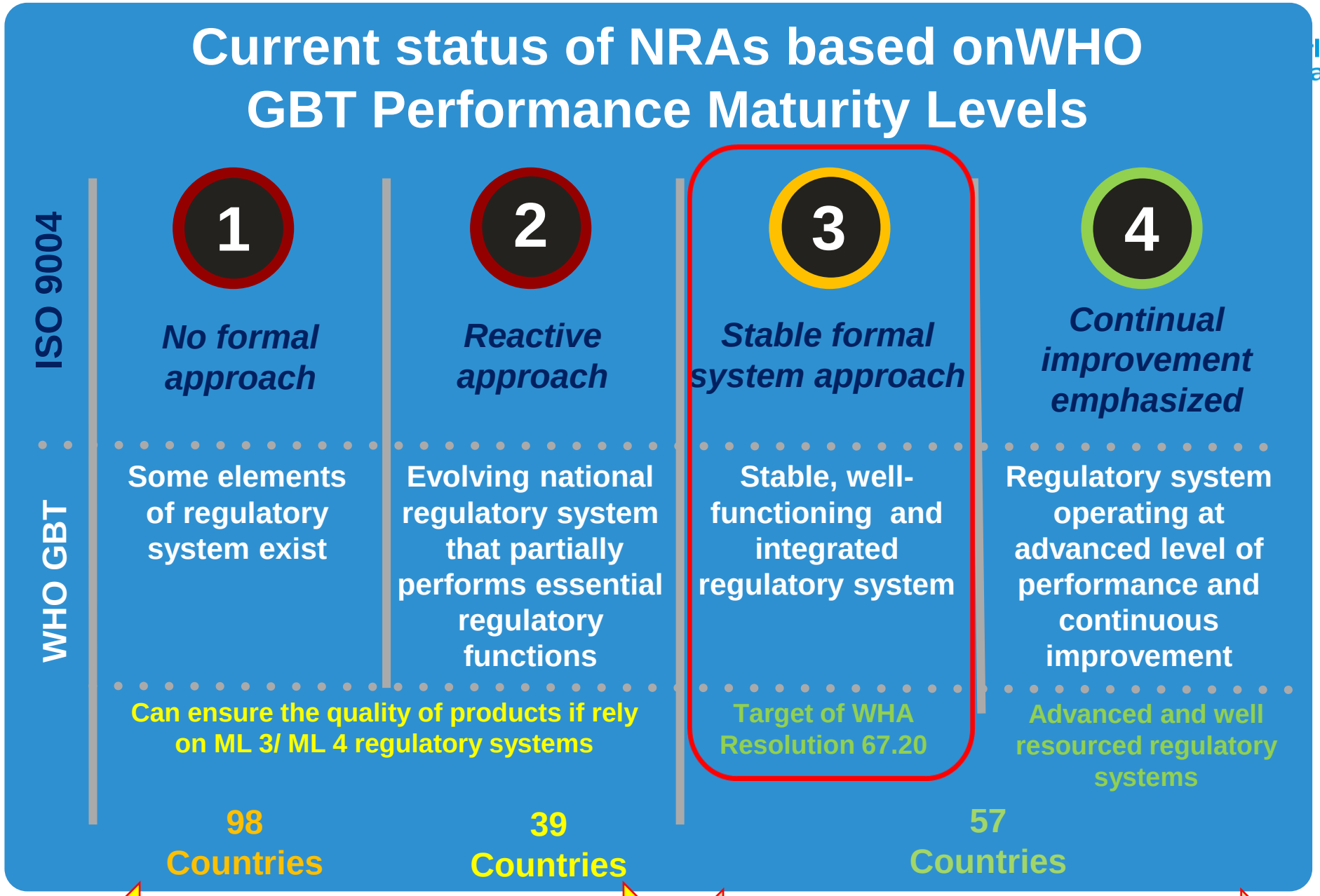
Vector control

Mandate, activities, achievements

Mission

World Health Organization

Current status of NRAs based onWHO GBT Performance Maturity Levels



PQT Unit's Mandate

- Response to MDGs (4.5,6) and SDGs (3.8)
- Facilitating global and national procurement of Quality assured medical products (WHA67.20 of 24 May 2014)
- Improved access to essential medicines, vaccines, diagnostics and devices for primary health care GPW 13; Outputs 1.3.1 and 1.3.3
- *The WHO's five-year plan 'Delivering Quality-assured Medical Products for All 2019–2023': SP3 - Strengthen and expand WHO prequalificationEUL & ERPD*

- MDGs (4, 5 & 6) 2000 – 2015
- SDGs (3.8) 2016 - 2030
- WHA67.20 of 24 May 2014
- WHA53.14 of 20 May 2000; WHA57.14 of 22 May 2004; WHA67.21 of 24 May 2014 (BTPs)
- WHA70.20, WHA69.25, WHA69.20, WHA65.19, WHA63.12, WHA59.24, WHA54.11, WHA52.19, WHA47.17, WHA45.17

Why PQ: PQT Mission

WHO prequalification aims to ensure access to key health products that meet global standards of quality, safety, and efficacy/performance, in order to optimize use of health resources and improve health outcomes. PQ is designed based on best international practice combined with assessing aspects of particular relevance for LMIC.

- WHO responded to the need of procurement agencies and WHO Member States for quality-assured health products, by creating and applying quality-assurance mechanisms.
- WHO prequalification has become a trusted and reputed symbol for safety, quality and efficacy across stakeholders. WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise.
- PQ has been instrumental in building national capacity for the manufacture, regulation and monitoring of health products – promoting harmonization, convergence, and reliance.

→ *WHO responded to the need of procurement agencies and WHO Member States for quality-assured health products, by creating and applying quality-assurance mechanisms*

Vaccines	Medicines	Diagnostics	Vector Control
❑ *Origin*: **Request by UNICEF and PAHO** to evaluate quality, safety and efficacy of vaccines in the context of **national immunization programmes** ❑ *PQ beginning*: 1987	❑ *Origin*: **Request by WHO MS** to assess the quality, safety and efficacy of low-cost and **new FDCs HIV/AIDS generic medicines in response to MDG 4, 5 & 6** ❑ *PQ beginning*: 2001	❑ *Origin*: Substandard **performance of HIV assays in sub-Saharan Africa** ➢ *Response*: HIV Test Kit Evaluation Programme (1988) ➢ ***For initiation & monitoring Tx*** ❑ *PQ beginning*: 2010	❑ *Origin*: WHOPES set up in 1960 for **evaluation of pesticides for public health**. In 2015, WHO initiated reforms to foster innovation, improve efficiency, assure quality and **align with other PQ programmes** ❑ *PQ beginning*: 2017

PQT Functions

- Prequalification
  - Dossier assessment
  - Inspection of manufacturing and testing sites/facilities
  - Sample testing/Independent performance evaluation
- Maintain and monitor prequalified products
- Health products evaluation and/or risk assessment to support health emergencies, shortages and other needs outside scope of PQ
- Provide scientific advice to manufacturers and other stakeholders
- Capacity building for regulators and harmonization.
- Support product evaluation activities at international, regional, and national levels, including reliance
- Provide technical advice to other WHO programmes

SCOPE AND NUMBER OF PREQUALIFIED PRODUCTS*

Diagnostics

In vitro diagnostics (IVD) & male circumcision device (MCD)

- ✓ HIV/AIDS
- ✓ Hep B
- ✓ Hep C
- ✓ HPV
- ✓ Malaria
- ✓ G6PD
- ✓ Cholera
- ✓ Syphilis
- ✓ TB NAT
- ✓ Haemoglobin POC
- ✓ Glucose meter & Test strips

105 IVDs | **1 MCDs**

EUL:
- ✓ **Covid-19: 33**
- ✓ **Ebola: 6**
- ✓ **Zika: 4**

Medicines

Finished pharmaceutical product (FPP), active pharm ingredient (API), quality control lab (QCL)

- ✓ Child health
- ✓ Covid-19
- ✓ HIV/AIDS
- ✓ Malaria
- ✓ Tuberculosis
- ✓ Diarrhoea
- ✓ Influenza
- ✓ Reproductive Health
- ✓ Neglected tropical diseases (NTDs)
- ✓ MDR bacterial infections
- ✓ BTP/SBPs (Cancer, Insulin)
- ✓ Hep B
- ✓ Hep C
- ✓ Ebola

643 FPPs | **161 APIs**

57 QCLs

Vaccines

Vaccines (Vx), Immunization device (ImD) & cold chain equipment (CCE)

- ✓ 24 priority diseases, covering all vaccines required for routine immunization
- ✓ Eligibility criteria for evaluation includes NRA functionality & programmatic suitability

170 Vx | **EUL: 12 Vx**

421 ImDs/CCEs

Vector Control

VC Products: FPPs & APIs

- ✓ Larvicides
- ✓ Long-lasting insecticidal nets
- ✓ Indoor residual spraying products
- ✓ Space spraying products

88 VCPs

(*Current numbers of Pqed/EULed products: March 2023)

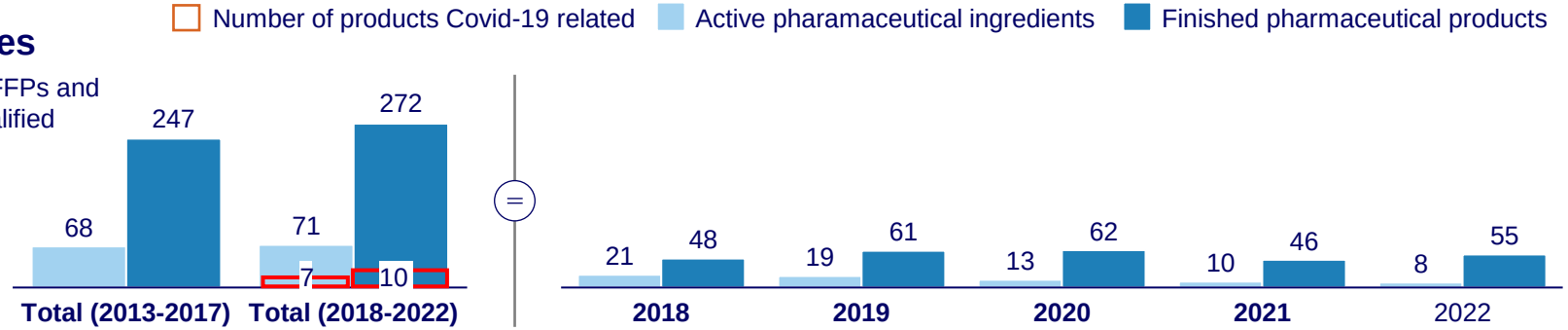
A. Prequalification and EUL: key findings (1 of 3)

Summary of assessment

- **PQ: 13% more products were prequalified in the last 5-year period** (2018-2022) compared to the previous 5-year period
  - If adjusted by removing COVID-19 products – the numbers are the same
- **EUL: 3x more products EUL-listed in the last 5-year period** (2018-2022) compared to the previous 5-year period, almost 100% of them are COVID-19 products
- For medicines, COVID-19 products were eligible for PQ - team was able to **establish a fast-track process to process them achieving median times far lesser than target**
- **Increase in the therapeutic areas within PQ scope** - five added for medicines[1], three for vaccines[2] and three for diagnostics[3]

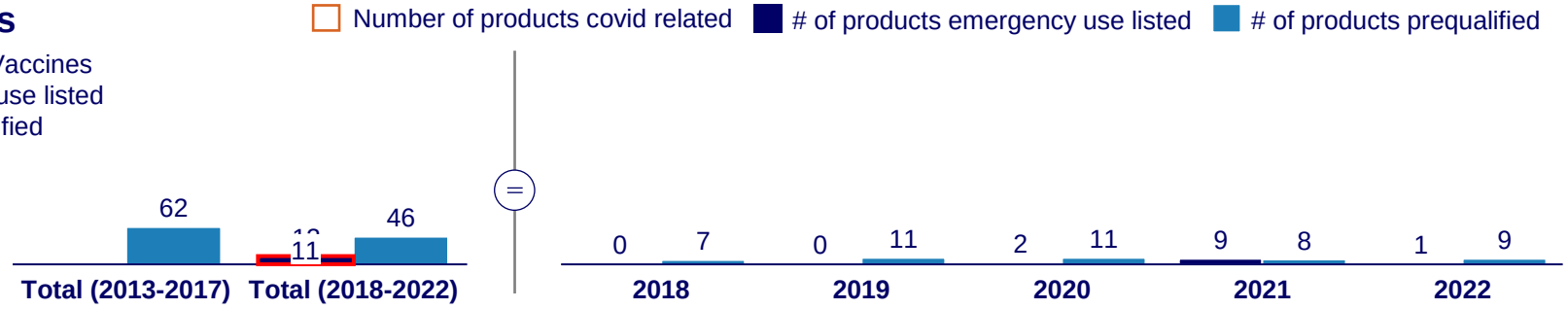
Medicines

Number of FFPs and APIs prequalified



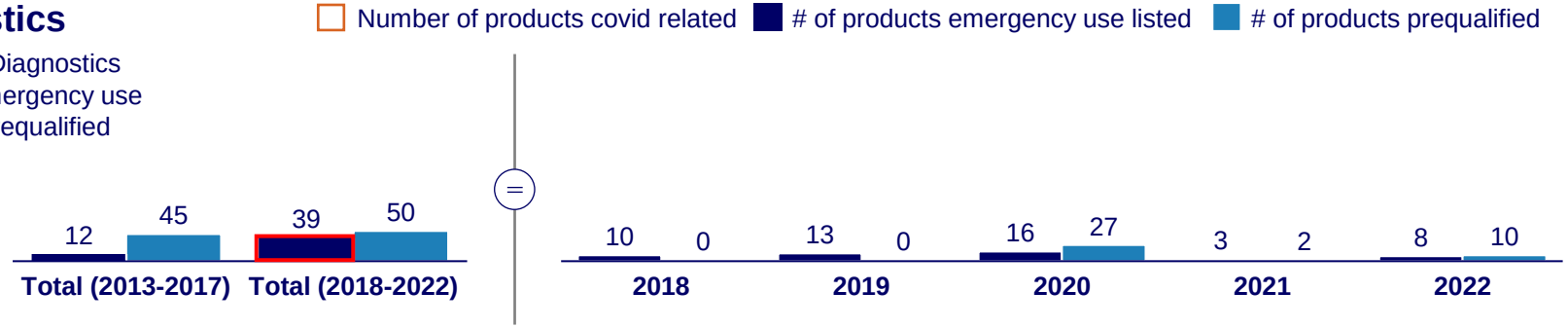
Vaccines

Number of Vaccines emergency use listed and prequalified



Diagnostics

Number of Diagnostics products emergency use listed and prequalified



1. Infections in new-born and young infants and childhood pneumonia; Insulins and insulin analogues (BTPs); Certain cancers (BTPs); COVID-19 (BTPs and small molecules); Ebola Virus Disease (BTPs); 2. Ebola, Pneumonia, Malaria; 3. G6PD, Cholera, Syphilis, TB

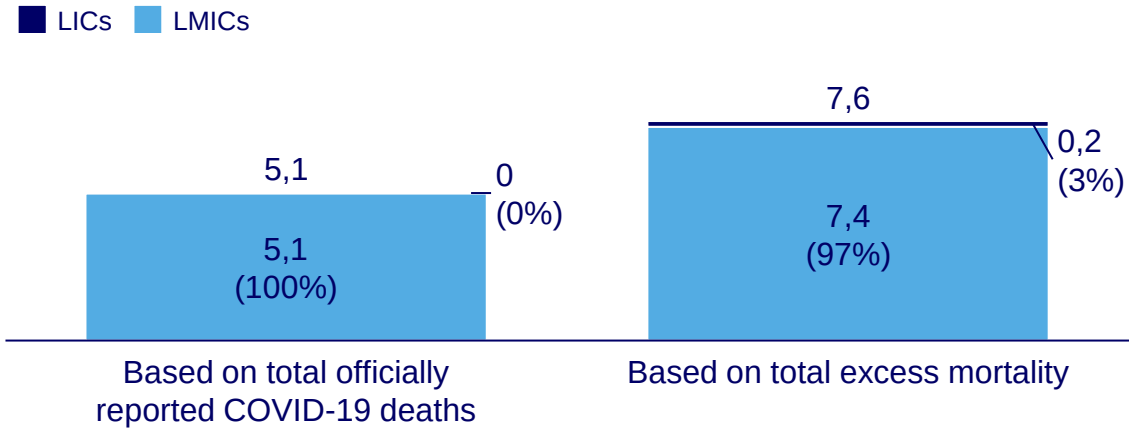
Source: WHO data

A. Prequalification and EUL: key findings (2 of 3)

Deep dive: Impact of COVID-19 vaccine EUL

Between 5.1 million and 7.6 million deaths have been averted in LMICs in 2021 thanks to COVID-19 vaccinations. WHO RPQ contributed to this positive impact as it has listed most COVID-19 vaccines for emergency use that have been used in LMICs and as most LMICs have relied on WHO EUL to start their vaccination campaigns.

Estimated total deaths averted in LICs and LMICs in 2021 thanks to COVID-19 vaccines
Millions of deaths averted (% of total deaths averted in LMICs and LICs)

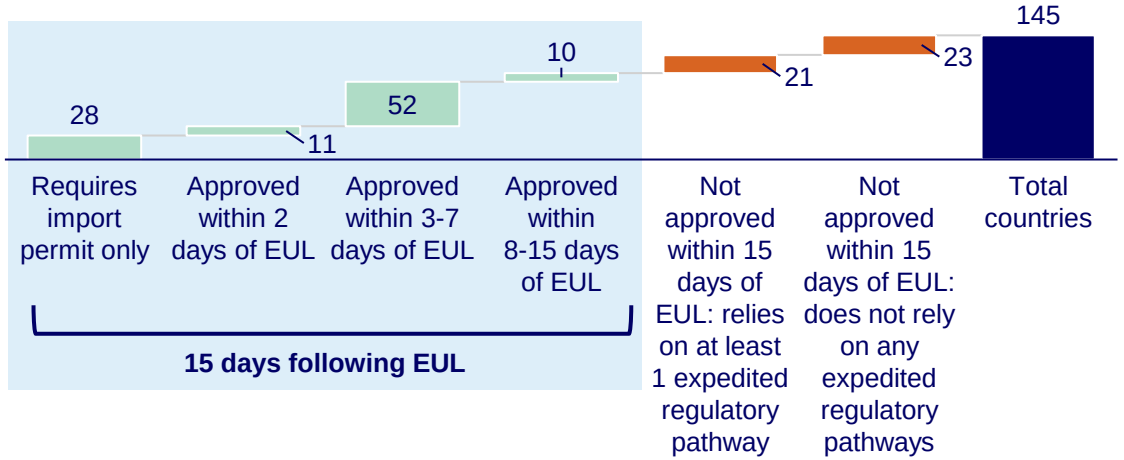


Source: Global impact of the first year of COVID-19 vaccination: a mathematical modelling study, The Lancet (2022)

WHO EUL approvals for medical products were relied on by more than 170+ Member States and Territories to approve COVID-19 medical products for entry into their markets

As an example: 101 countries (out of 145) approved AstraZeneca or Serum Institute of India vaccines within 15 days after WHO EUL and were allocated doses in the first COVAX allocation round

Overview of approval of AstraZeneca and Serum Institute of India doses within 15 days following WHO EUL
Number of countries



Source: WHO data

A. Prequalification and EUL: key findings (3 of 3)

Deep dive: NRA and procurer/donor scoring and perception of PQ and EUL process

While there was no specific perception question on PQ, many interviewers raised the topic themselves.

1. **Procurers/donors continue to rely heavily on PQ assessments** for guiding their procurement decisions; **Manufacturers appreciate the team's responsiveness**

> *PQ is absolutely fundamental for our activities. (Procurer)*
> *WHO RPQ department has been very fast, dedicated, and quick to respond to questions. It feels like they have gone through the approval process faster than the timelines they have set. (Rx Manufacturer).*

2. **Opportunity for a broader coalition building and collaboration** between the WHO RPQ department, other WHO departments, donors, procurers, and manufacturers to set global health priorities

> *A pattern I have noted over the years is that the PQ department tries to set world priorities, and that can be frustrating for manufacturers or procurers who see other priorities. (Procurer/Donor)*

3. **Opportunity to improve post-approval change notifications process** (for Vx and Dx)

> *During the whole process, the batches of the new medicine are sitting on the shelves, losing shelf life. Therefore, batches are often wasted, or we lose tenders as they need to have a minimum shelf life left to be sold. (Vx Manufacturer)*

4. **Concern about the team's resourcing capacity** and the need to consider what can be some alternate ways to combat this constraint

> *If this [delays due to resource constraints] remains, then it will actually become a barrier rather than a facilitator.*
> *(Vx Manufacturer)*

5. **Opportunity to improve overall operational efficiency in the PQ process** (more automation, digitization of processes, live/real time availability of data). Similar feedback was raised in the 2018 Assessment as well.

> Note: As of December 2022, the RPQ department is in the process of migrating to a new IT system (ePQS) that is expected to begin roll out in May 2023. Ensuring that the new ePQS system planned for roll out has the appropriate features and data migration to action stakeholder feedback received in the previous assessment (and this assessment) will be critical

Source: Interviews conducted as a part of the 2018-2022 Impact assessment

Exhibit 31: Overview of major donors requiring PQ for the procurement of medicines

Organization	Donor/ procurer perspective on PQ: HIV/AIDS	TB[2]	MALARIA	RH	Contingency approval process
PEPFAR	FDA (NDA or ANDA or tFDA [1])	-	-	-	-
PMI	-	-	PQ or SRA approval	-	Test prior or concurrent to shipment
USAID	FDA (NDA or ANDA or tFDA	-	PQ and SRA approval and preapproved by a USAID wholesaler	FDA NDA or ANDA or PQ or SRA approval	UNFPA ERP[2] (for RH only)
UNFPA	-	-	-	WHO/UNFPA PQ or SRA approval	UNFPA ERP or pre-shipment inspection of pharmaceuticals
Unitaid	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-	ERP
unicef	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	ERP
The Global Fund	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-	ERP or meet various ISO standards and GHTF authorization[3]
Stop TB Partnership GLOBAL DRUG FACILITY	-	PQ or SRA approval	-	-	ERP
MEDECINS SANS FRONTIERES	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	ERP[3] or MSF qualification process[2]
UNDP	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	ERP
Pan American Health Organization	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	Internal PAHO mechanisms for quality assurance with NRAs
ICRC 6	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-
IPPF	-	-	-	WHO/UNFPA PQ or SRA approval	ERP

New compared to 2018

1. Tentative FDA; 2. Includes a preassessment based on product and manufacturer questionnaires, a Good Manufacturing Practices (GMP) of the manufacturing site, a product evaluation based on product and/or manufacturer questionnaire(s) according to standards set by WHO, and based on a standard Product Questionnaire common to the Interagency Pharmacist Group (UNICEF, ICRC, The Global Fund, WHO procurement center, UNFPA, GDF and MSF) and active monitoring and follow up; 3. Expert Review Panel; 4. Specifically, the "WHO certification scheme on pharmaceuticals moving in International Commerce"; 5. Good Manufacturing Practice; 6. Details provided based on interviews with WHO colleagues / could not be validated with publicly available information

Source: Donor/procurer publications; web search; expert interviews

Exhibit 32: Overview of major donors requiring PQ for procurement of vaccines

New compared to 2018

	Donor/ procurer perspective on PQ	Contingency approval process
Gavi The Vaccine Alliance	Only PQ accepted	Specific exemption to procure non-prequalified products possible under defined criteria
unicef supply	Only PQ accepted	-
Pan American Health Organization	PQ or SRA approval (PQ preferred)	Internal PAHO processes for the assurance of quality
MEDECINS SANS FRONTIERES	PQ or SRA approval or tFDA[1]	ERP[2] or MSF qualification process[3]
ICRC[4]	PQ or SRA approval	
International Coordinating Group (ICG) on Vaccine Provision[4]	PQ or SRA approval (PQ preferred)	Products listed under EUAL[5] or final written acceptance of product and manufacturer by the recipient country and WHO final procurement procedures

1. Tentative FDA 2 Expert Review Panel 3 Includes a preassessment based on product and manufacturer questionnaires, a Good Manufacturing Practices (GMP) of the manufacturing site, a product evaluation based on product and/or manufacturer questionnaire(s) according to standards set by WHO, and based on a standard Product Questionnaire common to the Interagency Pharmacist Group (UNICEF, ICRC, The Global Fund, WHO procurement center, UNFPA, GDF and MSF) and active monitoring and follow up 4 Details provided based on interviews with WHO colleagues / could not be validated with publicly available information 5 Emergency Use Assessment and Listing

Source: Donor/procurer publications; web search; expert interviews

Definition of a WHO Listed Authority

Adopted by the ECSPP in October 2020, TRS 1033

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an

established benchmarking (GBT) **AND** a **Performance Evaluation process**

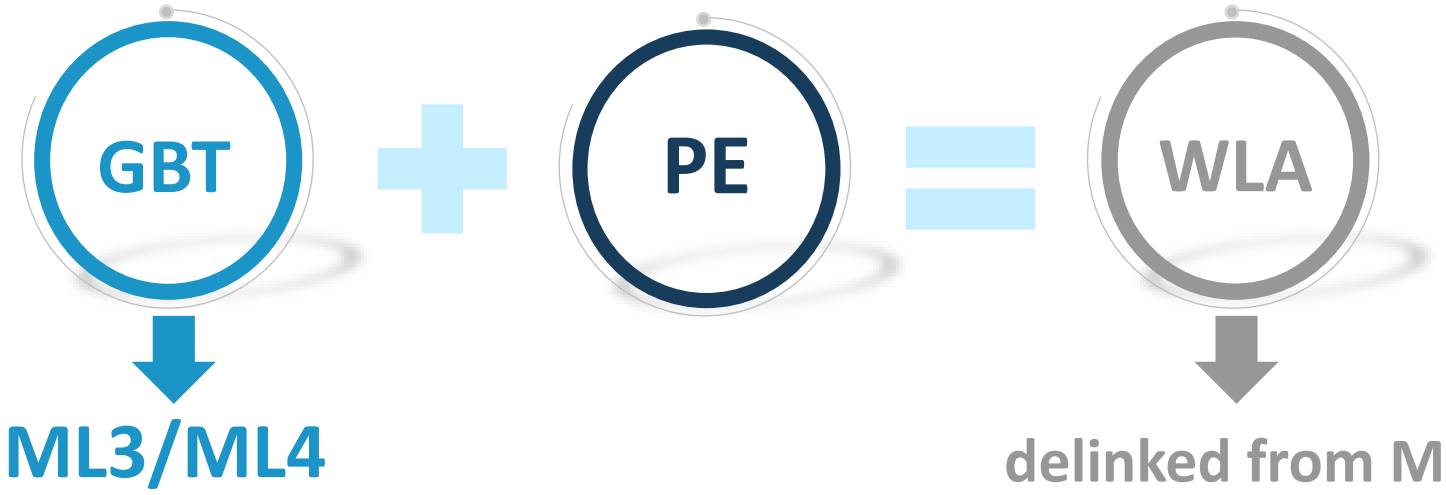
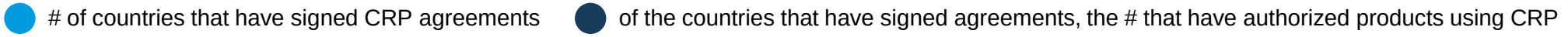
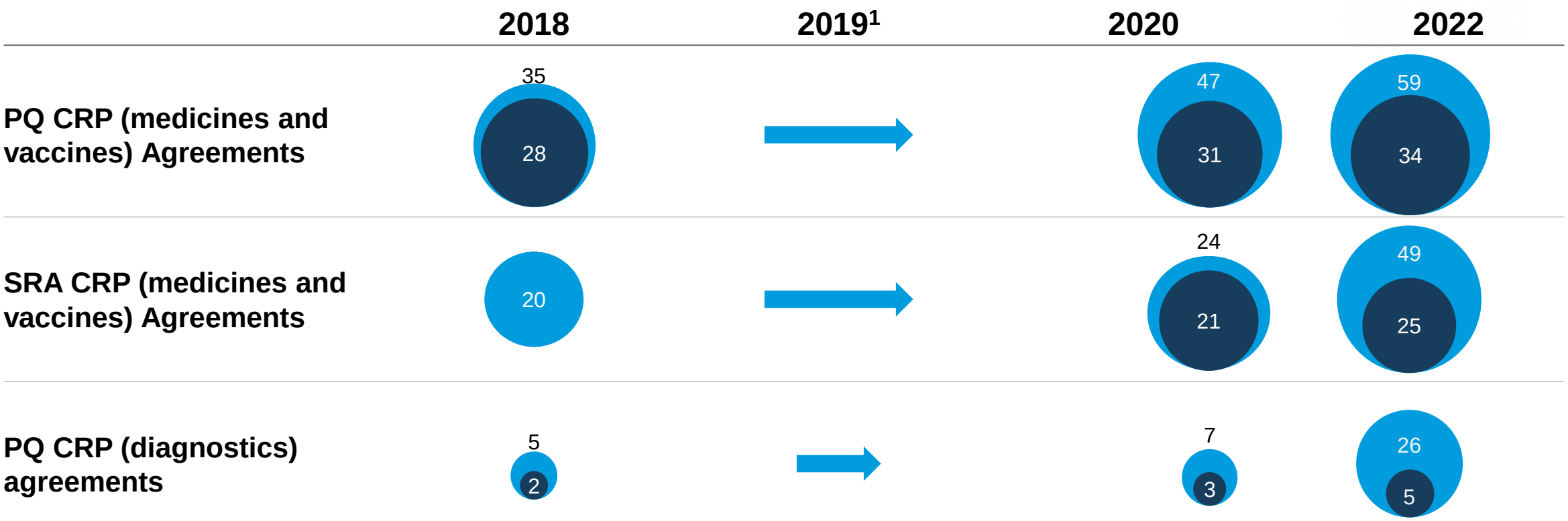


Exhibit 34: Number of countries that have signed PQ CRP agreements for vaccines and medicines and diagnostics, and SRA CRP agreements for vaccines and medicines between 2018 and 2022



Cumulative number of countries signing CRP agreements and subsequently registering products using them, 2018-2022



1. PQ CRP for diagnostics started in 2019

Source: Data from WHO FPI team

Priorities, Challenges and Opportunities

PQT Unit Summary

World Health Organization

2023 Priorities - PQT (1)

- Maintaining and continuous improvement of current PQ activities (QMS and streamlining processes).
- Consolidation of activities to support response to emergences – EUL and facilitation of access health products at international, regional and national level.
- Expansion of resources for PQ under realities of cap on FTEs at HQ:
  - Use of full-time consultants
  - Expand the pool of external experts – measures to develops experts including from non-traditional sources (Annual training workshops).
  - Explore placing PQ staff in certain WHO Regional and Country offices or other offshore stations.
- Complete and fully implement new IT solution (ePQS).
- Expansion of the scope of PQ:
  - Establish the PQ Team for priority medical devices (MD) and personnel protection equipment (PPE)
  - Expand therapeutic and/or product types covered by PQ assessments.
- Review approaches and criteria for defining eligibility:
  - Procedure for defining PPCs/TPPs and parallel progress to WHO guideline recommendation and eligibility for PQ/EUL.
  - Co-ordinated scientific advice (CSA) with Clinical/Disease programmes – initiated by the Science Division
- Adjusting to new realities and defining the role of PQ:
  - Strengthened NRAs – increasing number of ML3 NRAs.
  - Roll out of WLAs and replacement of SRAs.
  - Establishment of new regional regulatory systems – e.g., AMA, other regulatory networks
- Strengthening international collaboration:
  - ICMRA, ICH, IMDRF, RAG, Vaccine Cluster.
  - Expand list of SRAs/WLAs with confidentiality agreements with WHO/MHP/RPQ/PQT.
  - Expand collaboration with regional assessment arrangements: EMA, AMA, ASEAN, GCC, AVRAREF, etc.

2023 Priorities - PQT (2)

- Continuous staff improvement and motivation.
- Strengthen PQ communication, transparency and advocacy activities:
  - Improvement and maintenance of PQT website.
  - Develop and publish annual report and website dashboards.
  - Continue to develop and maintain the PQT QMS.
  - Continue arranging the annual Joint UNICEF/UNFPA/WHO meeting with manufacturers and suppliers.

Challenges - PQT

- Limited human resources – staff and external experts.
- Ever increasing workload without corresponding increase in resources.
- Competition for capacity of laboratories for PQ Performance Evaluation.
- Backlog as the result of the impact of the pandemic on PQ internal and external resources and on timely response of the applicants.
- Immature regulation, harmonisation and diverse stakeholders plus legacy of old programmes in certain product areas.
- Travel restrictions and tough quarantine requirements impacting on inspections and other travel missions.

Opportunities - PQT

- ✓ Continued support and recognition of the work of PQT by stakeholders, including member states, development partners, procurers and clinical departments, as a trusted symbol for safety, quality and efficacy.
- ✓ Increasing number of WLAs – may help PQT extend its reliance on the work of others and pool for experts.
- ✓ New procedures (TPPs/PPCs, CSA, Guideline/PQ EOIs parallel procedures) and strengthened QMS – better pipeline scanning, streamlining procedures, etc
- ✓ RPQ impact assessment – tool for advocacy and continuous improvement
- ✓ Implementation of the new IT system will facilitate streamlining of workflow, transparency and reporting.

BACK UP SLIDES

Objectives/prerequisites of local production

- Local production of heath products should aim and be trusted to meet the following objectives/prerequisites:

1) Ensure quality/safety/efficacy.

2) Facilitate access.

3) Ensure sustainability.

Objective 1: Ensure quality/safety/efficacy:

- Robust development:
  - R&D capacity (*Pharmaceutical development and clinical studies*)
  - Technology transfer: C-TAP, mRNA Hub, bilateral.
- Robust production:
  - Appropriate investment in sustainable GMP compliance
- Robust evaluation:
  - Regulatory system strengthening: GBT, IDP, WLA
  - PQ available to facilitate robust evaluation of these health products.
    - ✓ Involvement of African regulators in WHO evaluations.
    - ✓ Participating and facilitating AMA/AVAREF assessments.

Objective 2: Facilitate access

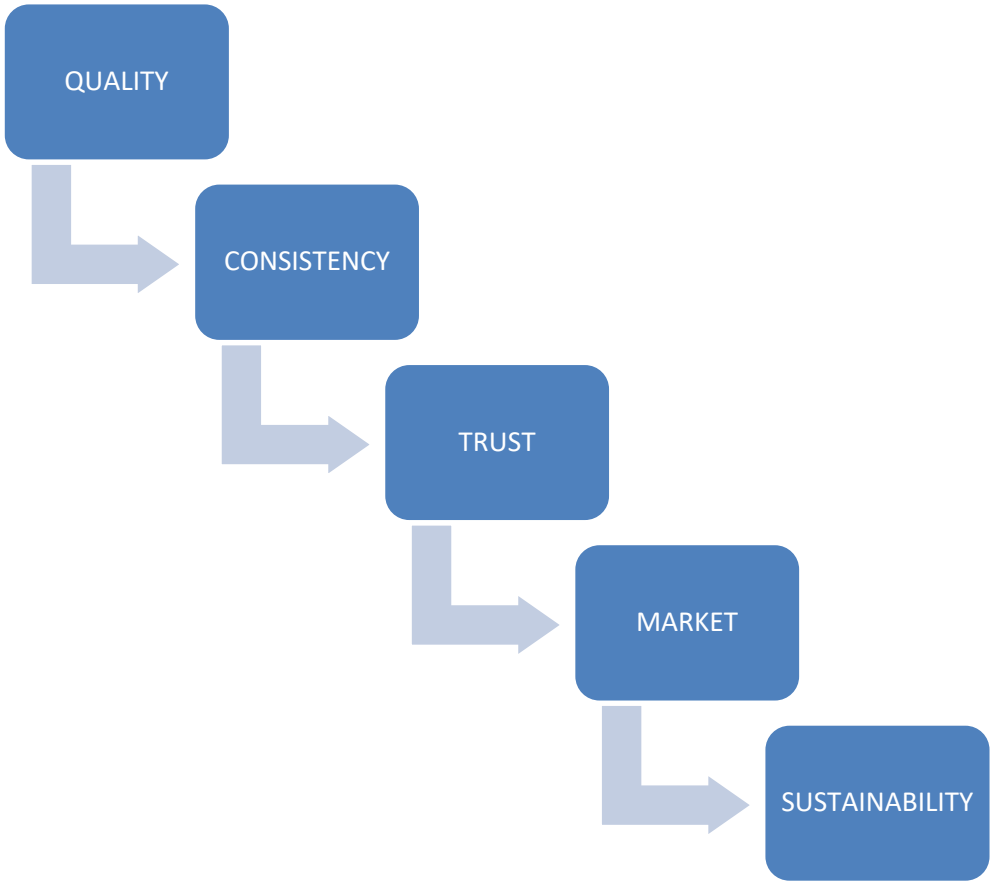
- Adequate production capacity:
  - access to sustainable financing
  - secure supply of raw materials
  - human resources of appropriate quality and numbers

- Timely national authorization:
  - efficient process – GBT, WLA
  - applying reliance – PQ, SRA,
    - ✓ PQ commits to share reports to facilitate local authorizations to facilitate timely local access.

- Procurement and effective supply:
  - Joint tenders and pooled procurement
  - Common QA policy for market shaping and aggregation of demand.

Objective 3: Ensure sustainability.

- Targeting a wider market – domestic and foreign:
  - using international requirements, robust assessments and building trust:
    - ✓ PQ in collaboration with AMA/AVAREF will facilitate this.
- Ensure a health product pipeline:
  - Wide product pipeline and adaptive technology important for resilience and sustainability: - variants of concern, AMR and change in policy/guidelines impact of product lifecycle.


QUALITY
CONSISTENCY
TRUST
MARKET
SUSTAINABILITY

Activities and achievements

	2019	2020		2021		2022		2023		2024		2025	
Product type		# PQed	EUL	# PQed	EUL	# PQed	EUL	# PQed	EUL	# PQed	EUL	# PQed	EUL
APIs	19	13		10		8	NA	10	?	10	?	10	?
FPPs	61	62		46		55	NA	40	?	40	?	40	?
IVDs	13	16	26	3	2	8	10	10	10	12	?	14	?
Immu. devices	37	23		27		31	NA	50	NA	50	NA	50	NA
Vx	11	11	2	8	9	8	1	8	5	10	?	10	?
VCPs*	3	4		3		0	NA	10	NA	10	NA	10	NA
Total for year	**144**	**129**	**28**	**97**	**11**	**110**	**11**	128	15	132	0	134	0

Combine Total	144	157	108	121	143	132	134

Inspections		166	150	163	90	150	150

Human resources

PQT STAFFING	FULL TIME HUMAN RESOURCE TYPE								TOTAL
	G-STAFF				P-STAFF				
OFIICE	LT	ST	60 Days	FT CONS	LT	ST	60 Days	FT CONS	
UNIT HEAD's Office (PQT	2	1			1	2		1	7
DIAGNOSTICS (PQT/IVD)	1	2			3	5		4	15
MEDICINES (PQT/MED)	1	3			9	4			17
VACCINES (PQT/VAX)	2			1	3	10	2	1	19
VECTOR CONTROL (PQT/VCP)*		1			2	3			6
INSPECTIONS (PQT/INS)**	2	3			6	6			17
MEDICAL DEVICES (PQT/MDV)									0
TOTAL	8	10	0	1	24	30	2	6	81

KEY:

ST= short term/Temporary

LT= Long term (fixed term+ continuous)

FT Cons = Full time consultant

60 Days = 60 days contract

*2 of these (2P) are under recruitment

**4 of these (3 P & 1G) are vacant under recruitment

LT	32	39.5%
ST	40	49.4%
60 Days	2	2.5%
FT Cons	7	8.6%
	81	100.0%

→ *PQ has been proven as an effective mechanism for facilitating access to quality assure health products*

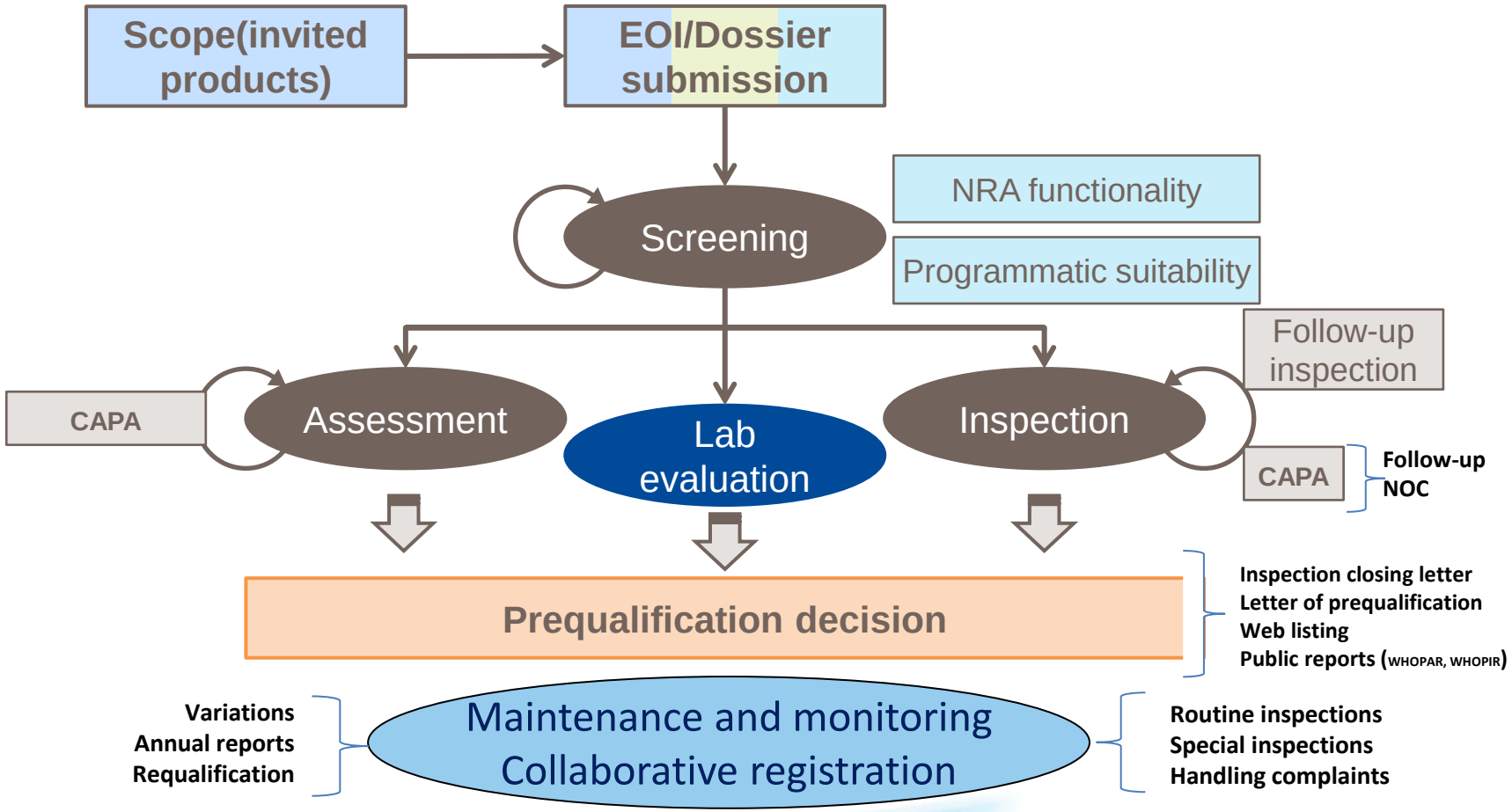
❑ **Key findings of the independent external impact assessment:**

(https://www.who.int/medicines/news/2019/report_Impact-assessment_WHO-PQ-Reg-systems.pdf?ua=1)

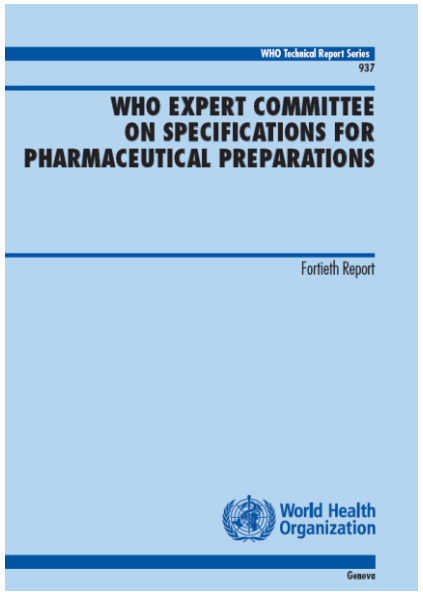
- ✓ WHO Prequalification (PQ) programme **enables a core market of approximately US$3.5 billion** with the majority coming from vaccines
- ✓ WHO PQ has a **Return on Investment of 30-40 to 1** for the PQ-enabled donor-funded market (US$ million)
- ✓ Most donors and procurers and implementing partners view **PQ approval as equivalent to approvals by stringent regulatory authorities**
- ✓ **340-400 million more patients have access** thanks to resources freed up by PQ
- ✓ National regulatory authorities (NRAs) relying on Collaborative Registration Procedure (CRP) have **achieved significant acceleration of approval timelines** vs pre-CRP registrations

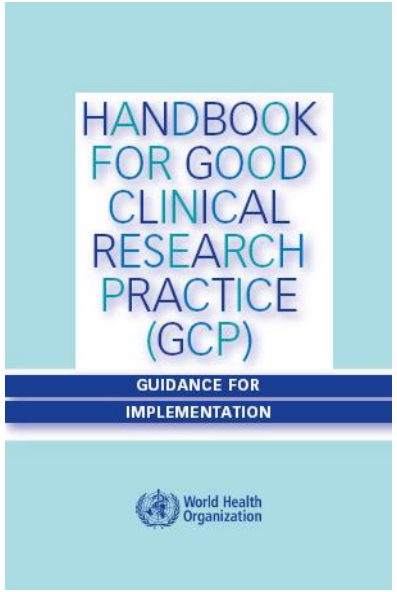
Prequalification workflow

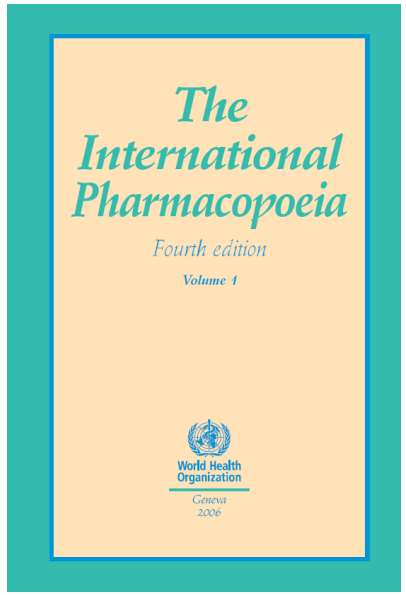
For each type of product, prequalification includes a comprehensive dossier assessment and a manufacturing site inspection, as well as other product-specific elements of evaluation



Prequalification Programme: International norms, standards and guidelines used to ensure wide applicability

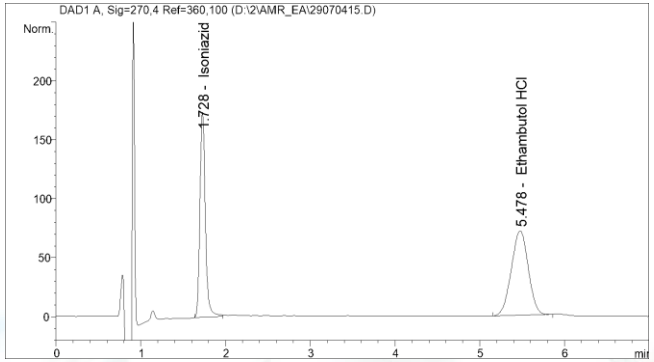






USP
BP
Ph. Eur.
Ph. Int.

Other guidelines
e.g. ICH, ISO



Fast track to prequalification

=

Good quality dossier at submission

+

prompt, complete, good-quality responses to PQ's questions, throughout the process.

Benefits for stakeholders

→ *WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise*

Patients

- ✓ Access to quality-assured products, adapted to their specific needs
- ✓ Accurate prevention, diagnosis, and treatment

WHO Member States & NRAs

- ✓ Reduced burden for regulatory approval
- ✓ Increased regulatory capacity & harmonization of regulatory practices in WHO MS
- ✓ Implementation of specifically developed and road-tested international guidelines
- ✓ Access to quality-assured products

Donors, procurers and UN agencies

- ✓ List of prequalified products
- ✓ Increased availability of quality-assured products
- ✓ Monitoring quality of prequalified products
- ✓ Healthy market: diversity and affordability of products

Benefits for stakeholders

→ *WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise*

Manufacturers

- ✓ Access to donor-sponsored tenders
- ✓ Faster regulatory approval
- ✓ Timely assessment of variations and changes
- ✓ International quality-assured product status (improved image)
- ✓ Recognition of GMP status, beyond prequalified products
- ✓ Increased capacity in quality management systems
- ✓ Target Product Profiles
- ✓ Harmonization of regulatory practices within WHO Member States
- ✓ Reduced operating and manufacturing costs

QC labs

- ✓ International recognition of prequalified QCLs
- ✓ Technical assistance and scientific advice

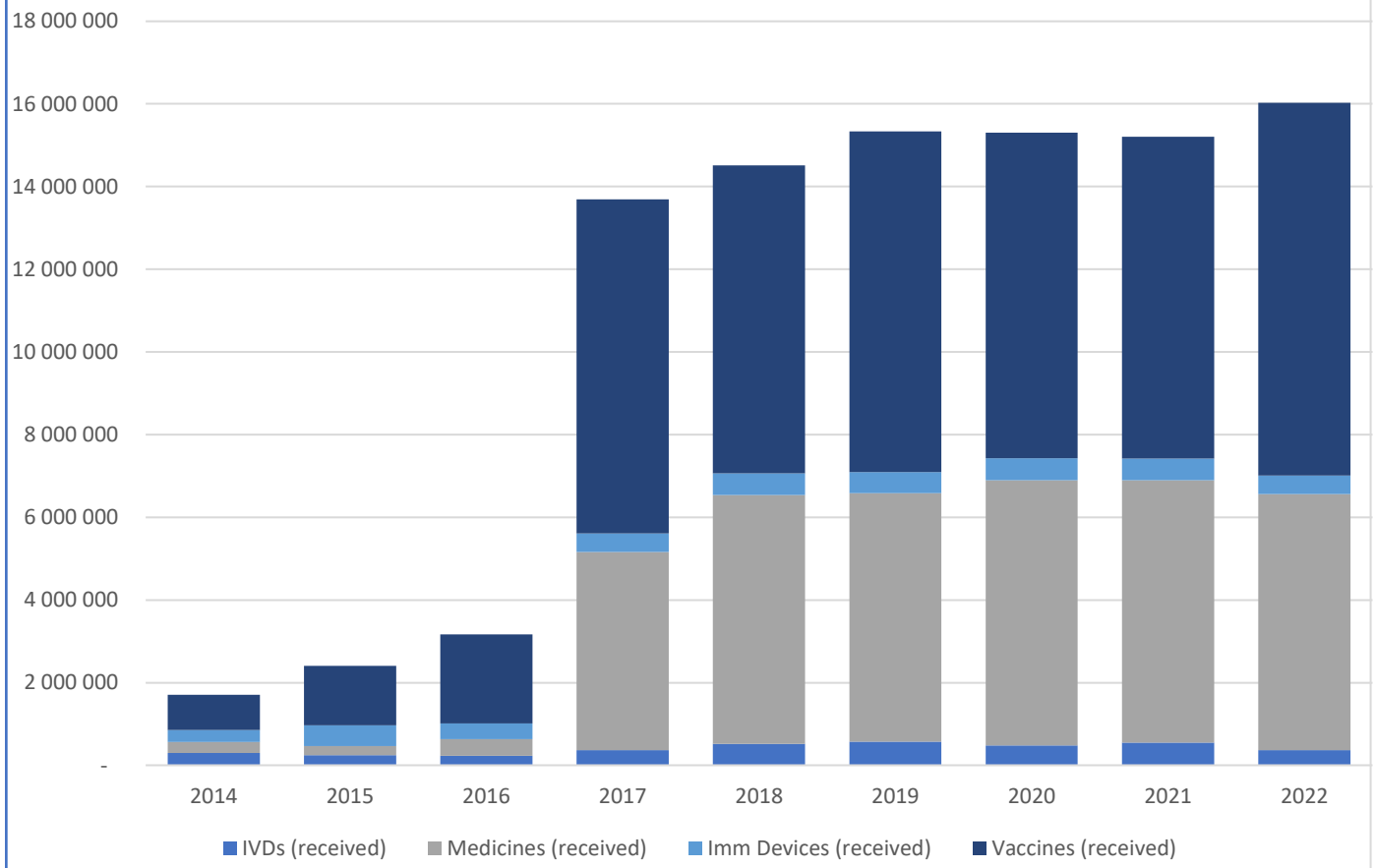
Take home messages

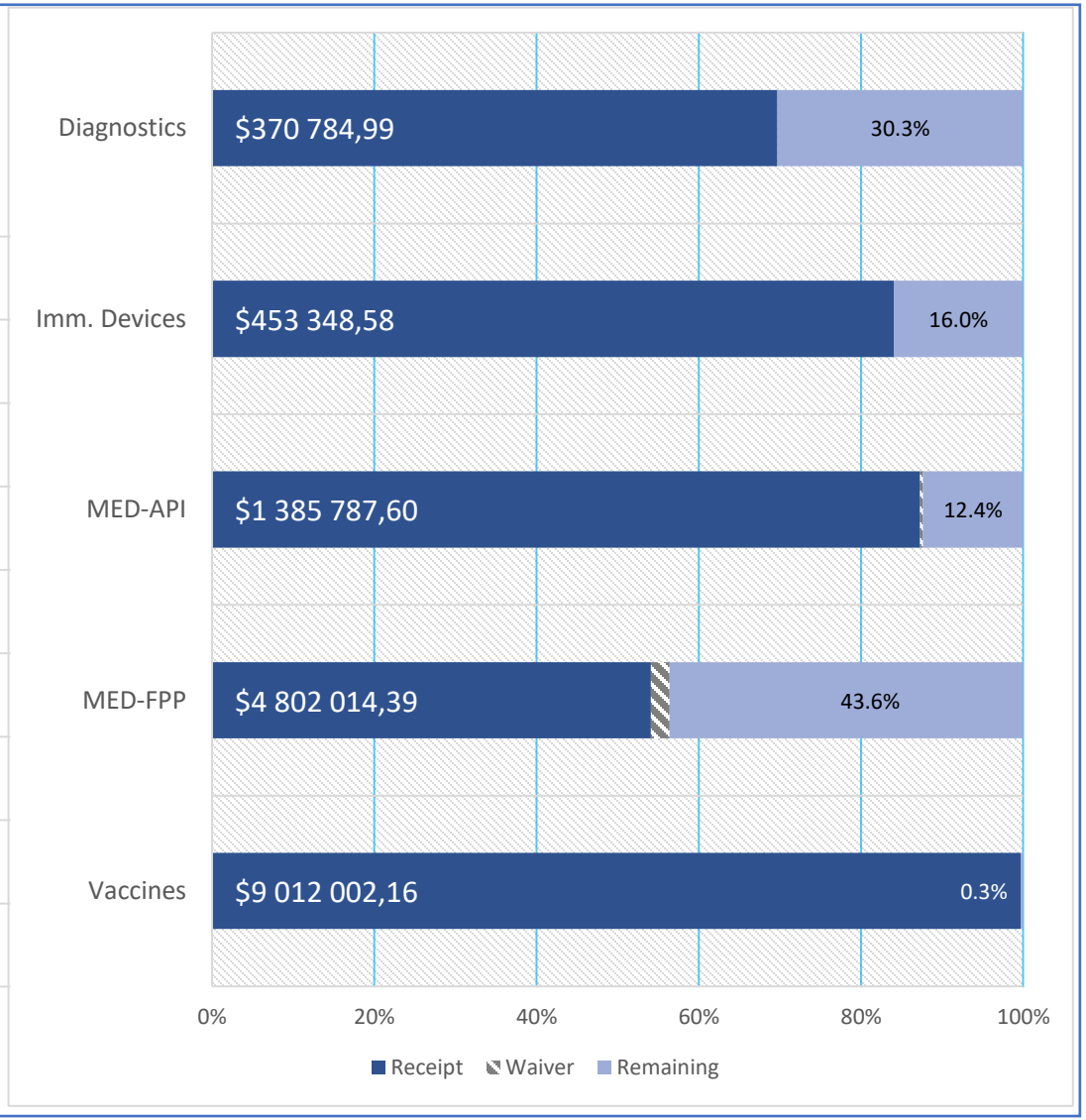
- ✓ PQ responded to needs of members states and contributed to objectives and targets of MDGs and SDGs
- ✓ The WHO 13th GPW (2019 – 2013) recognises continued need for PQ which will evolve
- ✓ PQ has been recognized as a stamp of quality and a point of reference for QA for UN, International, regional and national procurement
- ✓ PQ has been instrumental in building national capacity for the manufacture, regulation and monitoring of medicines – promoting harmonization and convergence
- ✓ PQ has put in place measures to improve sustainability and transparency
- ✓ PQ is evolving and adapting to the needs of the time and future

SP3: Analysis of PQ fees

Based on data collected up to 17th January 2023

Introduction of new fee models
Medicines & vaccines : Jan 2017
IVDs : Aug 2018





SP3: Analysis of PQ fees – key messages

	2017	2018	2019	2020	2021	2022
Fee invoiced/receivable as % of target	84%	89%	88%	92%	88%	103%
Actual fee received as % of target	68%	72%	71%	77%	76%	80%
%↑se fee received with respect to 2016 baseline	432%	459%	484%	483%	480%	506%
Fee received as % of RHT expenditure	30%	33%	31%	38%	38%	40%
Waived/reduced/loss as % of invoiced/receivable	19%	19%	19%	17%	11%	1%

*as of Jan 2023

- ✓ New funding model **substantially increased revenue from fees**, thus contributing to sustainability
- ✓ New funding model still **falls short of the target ($20m)**, both in Invoiced/receivables and/or actually received
- ✓ Received fees are at a level of 30% - 40% of RHT/RPQ expenditure 2017 to 2022, which is more than USD 40m used in the model.
- ✓ **No significant negative impact** on the prequalification product pipeline:
  - Medicines noted product withdrawal higher than others, but no vulnerable products were withdrawn, except no longer included in the relevant treatment guidelines or those over-represented on the PQ list
- ✓ **Revenue loss** was due to:
  - ➢ fee waivers and reductions (automatic or at request with justification)
  - ➢ Withdrawal or delisting (voluntary or due to lack of payment)
  - ➢ Waivers for vaccines and other health products used in emergencies/pandemic including COVID-19

Objectives/prerequisites of local production

- Local production of heath products should aim and be trusted to meet the following objectives/prerequisites:

1) Ensure quality/safety/efficacy.

2) Facilitate access.

3) Ensure sustainability.