




WHO Prequalification:

Impact on Global access

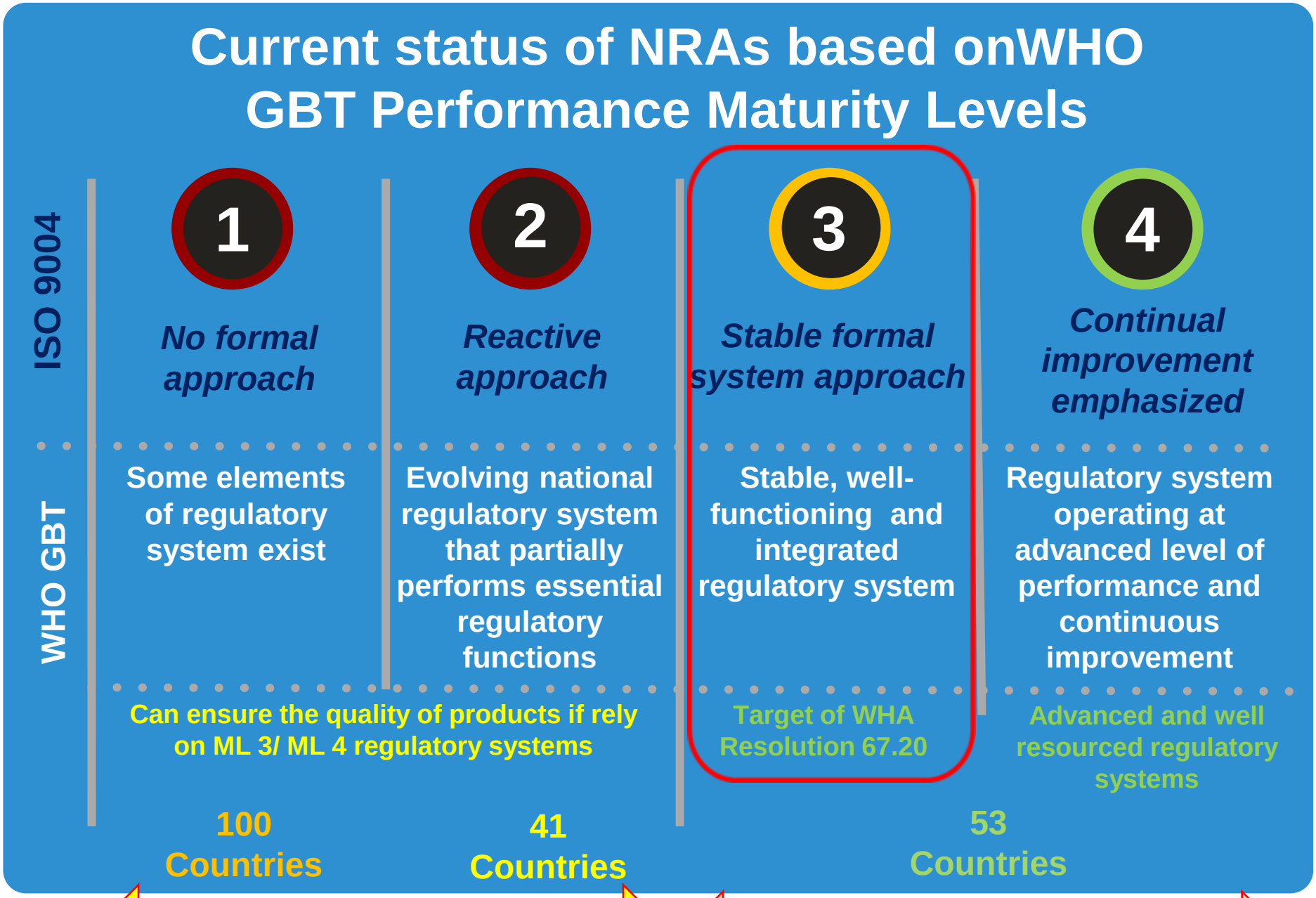
16 August 2022

Deus Mubangizi
Unit Head
Prequalification Unit(PQ)
Regulation and Prequalification (RPQ)

Outline of the presentation

- What is and Why Prequalification (PQ)?
- PQ process, requirements and standards
- Benefits and impact of WHO-PQ
- Summary and take-home messages

Current status of NRAs based onWHO GBT Performance Maturity Levels



What is WHO Prequalification?

- 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.
- Today, there are almost 1,500 WHO prequalified products — in vitro diagnostics (IVDs), male circumcision devices, medicines, vaccines, immunization devices and cold chain equipment, and vector control products — that have assisted in improving public health in low- and middle-income countries (LMIC).
- WHO prequalification has become a trusted and reputed symbol for *safety, quality and efficacy* across stakeholders.

→ *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

- *Origin*: **Request by UNICEF and PAHO** to evaluate quality, safety and efficacy of vaccines in the context of **national immunization programmes**
- *PQ beginning*: 1987

Medicines

- *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

Diagnostics

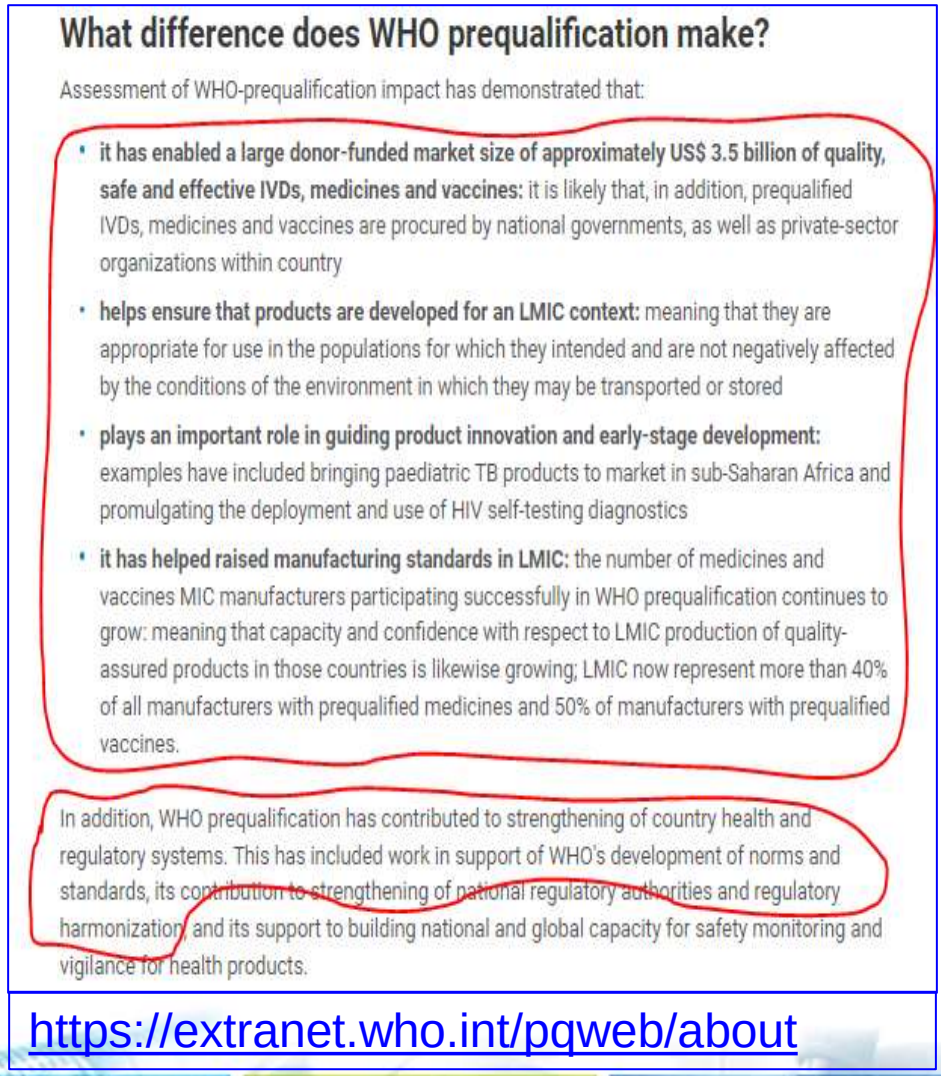
- *Origin*: Substandard **performance of HIV assays in sub-Saharan Africa**
  - *Response*: HIV Test Kit Evaluation Programme (1988)
  - ***For initiation & monitoring Tx***
- *PQ beginning*: 2010

Vector Control

- *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

Placing countries at the centre

- **"*PQTm's mission is to work in close cooperation with national regulatory agencies and partner organizations to make quality priority medicines available for those who urgently need them. This is achieved through assessment and inspection activities, building national capacity for manufacture, regulation and monitoring of medicines, and working with regulators to register those medicines quickly*."**
  https://extranet.who.int/prequal/content/overview-history-mission
  - Each bimonthly assessment session in CPH attracts ≥50 experts from across the globe, ≥35 from LMICs and ≥15 from well resourced NRMAs – best impact on capacity building and promoting convergence



What difference does WHO prequalification make?

Assessment of WHO-prequalification impact has demonstrated that:

- **it has enabled a large donor-funded market size of approximately US$ 3.5 billion of quality, safe and effective IVDs, medicines and vaccines:** it is likely that, in addition, prequalified IVDs, medicines and vaccines are procured by national governments, as well as private-sector organizations within country
- **helps ensure that products are developed for an LMIC context:** meaning that they are appropriate for use in the populations for which they intended and are not negatively affected by the conditions of the environment in which they may be transported or stored
- **plays an important role in guiding product innovation and early-stage development:** examples have included bringing paediatric TB products to market in sub-Saharan Africa and promulgating the deployment and use of HIV self-testing diagnostics
- **it has helped raised manufacturing standards in LMIC:** the number of medicines and vaccines MIC manufacturers participating successfully in WHO prequalification continues to grow: meaning that capacity and confidence with respect to LMIC production of quality-assured products in those countries is likewise growing; LMIC now represent more than 40% of all manufacturers with prequalified medicines and 50% of manufacturers with prequalified vaccines.

In addition, WHO prequalification has contributed to strengthening of country health and regulatory systems. This has included work in support of WHO's development of norms and standards, its contribution to strengthening of national regulatory authorities and regulatory harmonization, and its support to building national and global capacity for safety monitoring and vigilance for health products.

https://extranet.who.int/pqweb/about

Original Article | Published: 16 January 2014

A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme

Ellen F M 't Hoen, Hans V Hogerzeil, Jonathan D Quick & Hiiti B Sillo

Journal of Public Health Policy 35, 137–161 (2014) | Cite this article

WHO Prequalification and National Regulators

The programme promotes interaction and close collaboration with and between national drug regulatory agencies, in both developing and wealthy countries. The legitimacy of the WHO PQP's decisions derives in part from this collaboration, and from its solid and transparent procedures and standards. The standards come out of an international consensus process conducted with Member States. The process concludes with review and adoption by the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Transparency builds confidence. The WHO PQP goes beyond the current information-sharing practices of national drug regulators.

Saving Lives and Saving Money

From a public health perspective, WHO PQP's greatest achievement is improved quality of key medicines used by millions of people in developing countries. In a study of 12 958 ARV purchase transactions between 2002 and 2008, Brenda Waning concluded that five ARVs recommended by WHO in 2003 constituted 98 per cent of the ARVs purchased in 2004–2006. The price of the major FDCs decreased from $484 per person in 2002 to $88 in 2008. Purchases of new ARVs recommended by WHO in 2006 increased 16–20 times in the 2 following years. By 2008, 85–88 per cent of the ARVs procured by PEPFAR, the Global Fund, and UNITAID were prequalified.[29]

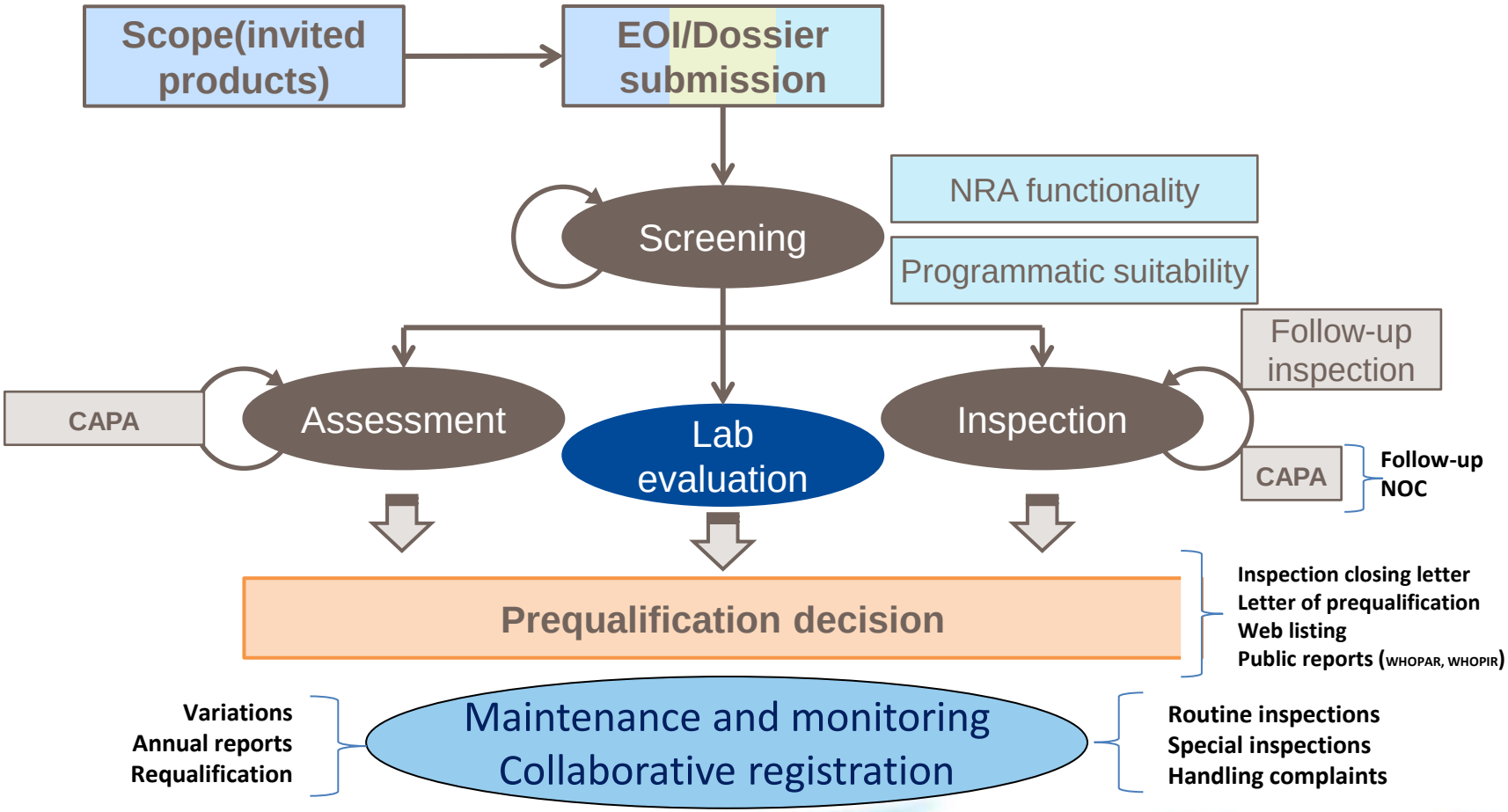
References: https://link.springer.com/article/10.1057/jphp.2013.53#article-info

PQT as a tool for capacity building for NRAs

- ✓ **PQ has been instrumental in building national capacity for the manufacture, regulation and monitoring of medicines – promoting harmonization and convergence**
  - Hands-on training through participation in WHO assessments and inspections – peer training.
  - Rotational fellows spending time (3 – 4 months) embedded in PQ working along with PQT experts:
    - **43 so far – funded by PQ budget**
  - Participation in PQ organised workshops:
    - **Annual PQ training for dossier assessors:**
      - **14th Annual PQT Medicines Quality Assessment Training took place between 14 – 17 June 2022**
      - **1st Biotherapeutic Product and Similar Biotherapeutic Product assessment training 18 June 2022**
    - **Annual Quality Workshop for manufacturers:**
      - **5th Medicines Quality Workshop to take place 26-29 September 2022**
      - **2nd on Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) - 30 September 2022**
    - **Many workshops on technical requirements and procedures.**
  - Supporting regional joint assessment activities, e.g. EAC, ZaZiBoNa,
  - Facilitating harmonisation:
    - **Experience of working together beyond legal regulators jurisdiction**
    - **Interpreting requirements at an international level.**
    - **PQ tools facilitating harmonisation – international comparator, QIS now being used for verification of sameness under SRA CRP.**
    - **Model for harmonisation**

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*



→ *FPPs & APIs Eligible for Prequalification ("EOIs")*

Eligible FPPs

Invitations to manufacturers to submit an expression of interest (EOI) for product evaluation are currently open in the following therapeutic areas with respect to FPPs:

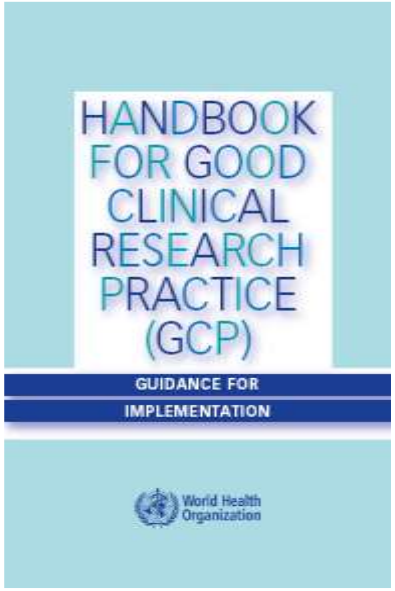
- COVID-19
- diarrhoeal disease
- ebola virus disease
- hepatitis B and C
- HIV/AIDS
- infections in newborn and young infants and childhood pneumonia
- influenza
- malaria
- neglected tropical diseases
- reproductive health
- tuberculosis

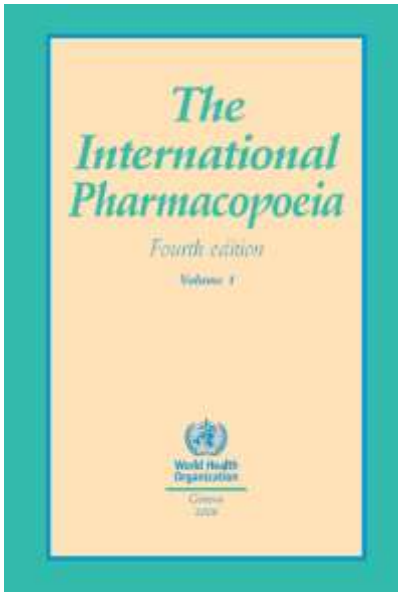
Eligible APIs

APIs used in the production of the FPPs included in the EOIs to FPP manufacturers are all eligible for prequalification, that is, selected APIs relating to the following therapeutic areas:

- COVID-19
- diarrhoeal disease
- hepatitis B and C
- HIV/AIDS
- infections in newborn and young infants and childhood pneumonia
- influenza
- malaria
- neglected tropical diseases
- reproductive health
- tuberculosis

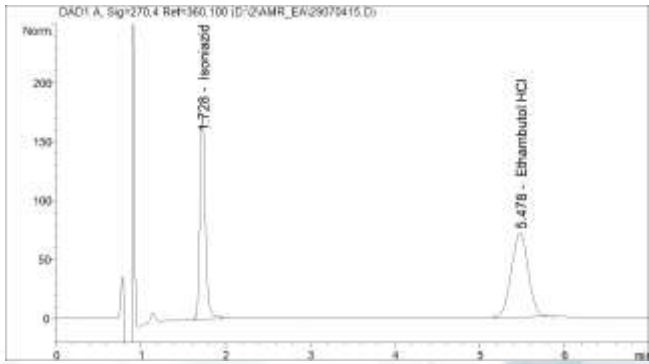
Prequalification Programme: International norms, standards and guidelines used to ensure wide applicability





USP
BP
Ph. Eur.
Ph. Int.

Other guidelines
e.g. ICH, ISO



MED: Paths for inclusion of products in the list of prequalified FPPs

- **Prequalification of generic products (full assessment pathway)**
  - Full review/assessment of dossier and inspection of sites by WHO PQT
  - Such products are eligible for CRP once prequalified
- **Prequalification of SRA*-approved generics and innovator products – a recognition procedure (abridged pathway)**
  - Approval based on marketing authorization issued by Stringent Regulatory authority (SRA*)
- **Alternative listing**
  - USFDA PEPFAR or EMA Art 58 approval/tentative approval

*Term changed to WLA (WHO Listed Authority)

MED: Dossier Format – full assessment pathway

- **Dossier format:** follows the modular format of the ICH Common technical document (CTD) M4, with certain PQ specific requirements:

  - QOS -PD (quality overall summary): - QOS template as modified for purposes of prequalification

  - Quality information summary (QIS) – an additional PQ specific template - to provide a condensed summary of the key quality information

Guideline: *TRS 961, Annex 15: Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format*

https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesSubmissionDocumentationMultisourceGenericGeneralFormatTRS961Annex15.pdf

MED PQ – full assessment: main requirements

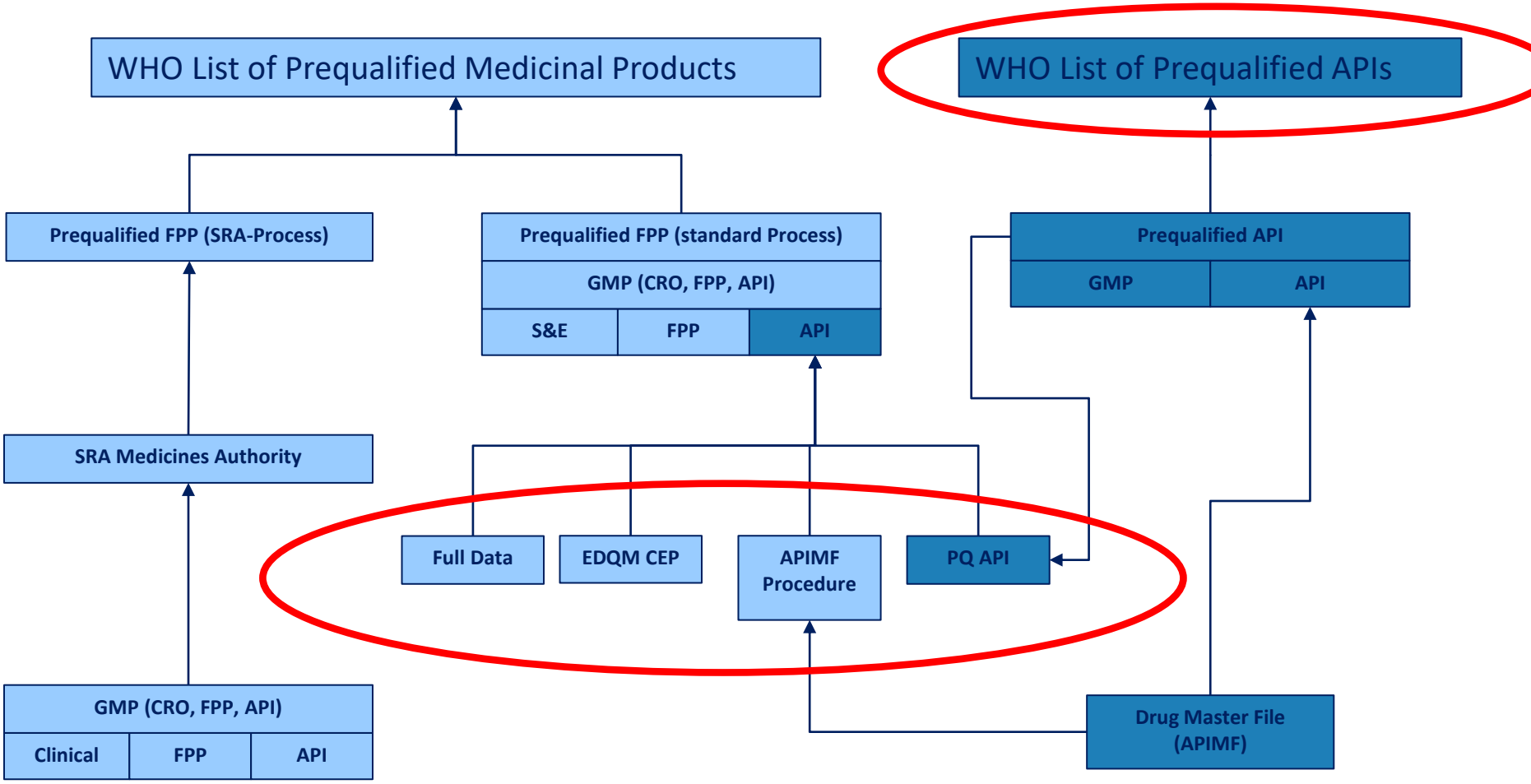
- ✓ CTD dossier and associated summary forms required:
  - Quality of API and FPPs – should be demonstrated according to the generic guide (Annex 4, TRS 970)
  - Safety/efficacy: usually based on bioequivalence study data or where applicable BCS based biowaivers (Annex 6, TRS1003)
    - ✓ Clinical data, if the COVID-19 indication is yet to be approved by an SRA (for repurposed products only)
- ✓ Acceptable GMP status for API and FPP manufacturing sites
- ✓ Acceptable GCP status for bioequivalence studies/GLP(QC)/GMP for invitro dissolution studies
- ✓ Undertaking to maintain the prequalification status of the Product:
  - Variations (Annex 3, TRS981); Requalification; Complaint handling and out of specification results reporting

MED PQ – full assessment: quality/CMC requirements

Complete CTD module 3.2 required – PQ specific aspects to mention:

- ✓ API information – prequalified API, CEP, APIMF or full data in the FPP dossier
- ✓ Only established excipients should be used (novel excipients are not acceptable).
- ✓ Stability data on minimum of 2 batches of at least pilot scale
- ✓ Required storage conditions for stability studies are 40ºC/75%RH for accelerated study and 30°C / 75% RH for long term study ; 6 months accelerated, and 6 months long-term stability data required at the time of submission.
  - **For COVID-19 therapies less than six months stability acceptable at the time of submission – updated data to be submitted on a rolling basis**

Prequalification of APIs and FPPs



MED: Guidance for designing BE studies

- **General WHO guidelines published in Technical Report Series (TRS)**
  - WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)

- **PQT/MED-specific guidance found on PQ website**

https://extranet.who.int/pqweb/medicines

MED: Notes on the Design of Bioequivalence Study (NDBS)

- **Product specific guidance individualized for each API or combination of APIs included in the Expressions of Interest (EoI)**
- **Based on best information available to PQT/MED**
  - Updated as more information becomes available to PQT/MED
- **71 guidances + RH guidance currently posted**
- **Always check for most up-to-date version on NDBS when planning a BE study**

MED: Types of biowaivers

- **'Type of product'-related biowaivers**
  - Refer to TRS 1003, Annex 7
- **Biopharmaceutics Classification System (BCS)-based biowaivers**
  - Refer to ICH Harmonised Guideline M9: Biopharmaceutics Classification System-Based Biowaivers
  - PQT/MED-specific annotations for ICH M9 Guideline for Biopharmaceutics Classification System (BCS)-based Biowaiver Applications
  - Biowaiver Application Form: Biopharmaceutics Classification System (BCS
- **Additional strength biowaivers**
  - Refer to TRS 1003, Annex 7
  - PQT/MED-specific annotations for Additional Strength Biowaiver Applications
  - PQT/MED Additional Strength Biowaiver application form

WHOPAR and WHOPIR

- Following prequalification of a product, WHO publishes its public assessment report **(WHOPAR)**
  - Provides summary of the assessment of the product data and accepted product information (excluding confidential/ proprietary information).

- Following completion of API/FPP manufacturing sites or CRO inspections, WHO publishes its public inspection report **(WHOPIR)**
  - Provides summary of the inspected site, scope of inspection, findings and conclusions (excluding confidential/ proprietary information).

GMP Inspections

GMP

What?

- proper design, monitoring and control of manufacturing processes and facilities
- identity, quality and purity of products by requiring adequate control of manufacturing operations
- prevention of contamination, mix-ups, deviations, failures and errors

How?

- strong QMS
- appropriate quality raw materials
- robust operating procedures
- detecting and investigating product quality deviations
- maintaining reliable testing laboratories

Inspection of manufacturing sites and CROs

- PQT inspection team conducts risk based inspections of
  - API/DS manufacturing sites
  - FPP/FP manufacturing sites
  - Clinical Research Organizations (Clinical trials, usually BE studies)

- PQT inspection team also performs desk review of available inspection reports issued by SRAs/WLAs.
  - waive onsite inspection depending on the scope and how recent

- **For the abridged pathway**, the current GMP status of the API/DS and FPP/FP sites (as inspected by the SRA/WLA) is verified

Fast track to prequalification

=

Good quality dossier at submission

+

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

Maintenance of prequalification status of products

- **Variations**
  - Changes to prequalified products should be reported to WHO
  - Changes to products prequalified via the abridged pathway should first be reviewed and accepted by the SRA and later notified to WHO (only certain changes to be reported to WHO)
- **Requalification**
  - Requalification of products every 5 years based on selected documentation
  - To verify the continued compliance of the product to WHO requirements
- Risk based **periodic inspection** of API and FPP manufacturing sites
- Product **quality surveys**

Support to applicants

- Detailed guidelines and model CTD dossier
- Additional product or therapeutic area specific guidance documents
- BE design advice for most of the invited medicines and review of study protocols
- Prompt response to questions or request for clarifications
- Face to face or virtual meetings when requested at any stage
- Pre-submission meetings - required by PQTm for all new applicants submitting via the full assessment route - to help the applicant resolve critical issues before submission
- Technical assistance - administered by a separate unit within WHO
- Certain market related information on our website

Specific aspects considered during PQ review

- General understanding of production process and quality control methods Quality
- Production consistency at commercial scale (assessed by testing of samples of final product) Quality
- Compliance with GMP Quality
- Compliance with WHO recommendations and UN tender specifications including labels and inserts Quality
- Programmatically suitable presentation Quality
- Clinical data relevant for the target population in the recommended schedules Safety & Efficacy/performance

→ *The collaborative procedure enables NRAs to accelerate the registration of prequalified products so that they can enter local markets more quickly*

Process

- WHO PQ shares the reports that served as the basis for the prequalification decision, so that NRAs do not conduct assessment and inspections
- National registration based on PQT evaluation

Principles of CRP

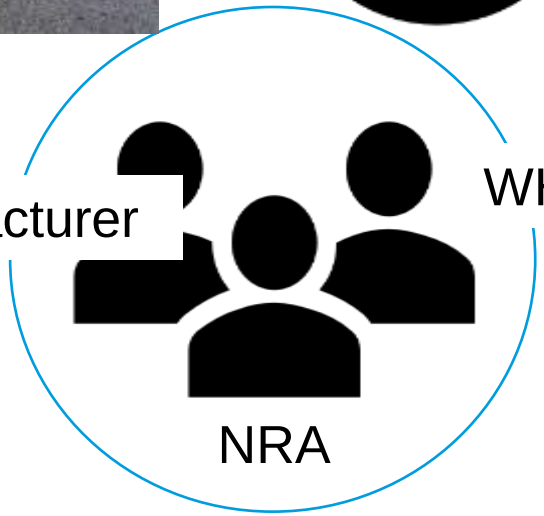
- **Voluntary** for both applicant and NRA
- Product and registration dossier in countries are **'the same'** as **prequalified by WHO.**
- Shared confidential information to support NRA decision making in **exchange for accelerated registration process**
- **'Harmonized product status'** is monitored and **maintained**

Days

WHO PQ Collaborative procedure (CRP) as at 29 September 2021

Median = 85 days

Before CRP – 2 months to 10 years



704 registrations

44 countries
+ 1 REC(CARICOM)

Collaborative Registration Procedure: 45 Participating NRAs, plus 1 Regional Economic Community

As at 29 Sept 2021

Armenia
Azerbaijan
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
*Caribbean Community (CARICOM)
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malaysia
Malawi
Mali
Mauritania
Mozambique
Namibia
Nigeria
Pakistan
Philippines
Rwanda
Senegal
Sierra Leone
South Africa
Sri Lanka
Sudan
Tanzania
Thailand
The Gambia
Togo
Uganda
Ukraine
Uzbekistan
Zambia
Zanzibar
Zimbabwe

* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

World Health Organization

Strategic Priority 3: Prequalification programme mechanisms for expanding product scope

- **Gradually expand the mechanisms for PQ through:**
  - Expand the abridged assessment of products approved by WHO Listed Authorities assessed using the GBT + evaluation of performance.
  - Consideration of quality assured regional-network-joint-assessments.
- **Expand mechanisms to evaluate new products developed with special focus on LMICs and emergencies (**PQT CRP Lite Pilot with USFDA, EU Art.58, Swiss MAGHP**)**
- **Expand risk based approaches for products not yet stringently assess including for emergencies: ERP, ERPD, EUL (*Ebola, Zika, nOPV2 & now COVID-19*) and other mechanisms - Snake anti-venoms, small pox, laser fever, etc.**

Why expand the scope of Prequalification?

→

- **The regulatory systems of 73% of the member states are below maturity level 3 – unable to assure their population of quality assured medical products**

- **THEREFORE:**
  - **GPW13 (2019-2023) recognizes the role of PQ** in contributing to access to quality assured health products.
    - "The Organization will **continue to support the availability of quality-assured generic products** for procurement by global agencies and countries **through the WHO prequalification Programme**, which will evolve to meet the changing health needs of countries."
  - **The WHO's five-year plan 'Delivering Quality-assured Medical Products for All 2019–2023':**
    - Strengthen and expand WHO prequalification

(https://www.who.int/medicines/news/2019/WHO_ActionPlanWeb.pdf?ua=1)

→ *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

To summarise, WHO Prequalification:

- **Current scope:** IVDs, MCDs, FPPs, APIs, QCLs, vaccines, immunization devices, VCPs and VCIs
- **Contributes to achieving SDGs and UHC**
  - ✓ facilitates access to quality assured priority health products
- **Role recognized by WHO 13th General Programme of Work (2019 – 2013):**
  - ✓ *The Organization will continue to support the availability of quality-assured generic products for procurement by global agencies and countries through the WHO prequalification programme, which will evolve to meet the changing health needs of countries.*
- **Already designed to fit in the WHO 13th GPW strategic shifts:**
  - ✓ Step up global leadership - *recognized as a stamp of quality*
  - ✓ Drive impact in every country and placing countries at the centre:
    - ➢ Doing it with NMRAs – best impact on capacity building, promoting convergence and facilitating reliance.
    - ➢ Programmatic suitability of vaccines
    - ➢ Focus on products for use in resource limited settings

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

END

BACK UP SLIDES

PQT: Procedures and websites (1/3)

- **PQ medicines:**
  - *Procedure:* https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2
  - *Website:* https://extranet.who.int/pqweb/medicines
  - *Products under assessment:* https://extranet.who.int/pqweb/medicines/prequalification-pipeline
  - *PQ list FPP:* https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products
  - *PQ list API:* https://extranet.who.int/pqweb/medicines/active-pharmaceutical-ingredients
- **PQ BTPs/SBPs Pilot:**
  - *Procedure:* https://extranet.who.int/pqweb/sites/default/files/documents/01_Prequalification_procedure_General_0.pdf
  - *Website:* https://extranet.who.int/pqweb/medicines/pilot-prequalification-biotherapeutic-products
  - *PQ list:* https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products
- **PQ Vaccines:**
  - *Procedure:* http://apps.who.int/iris/bitstream/handle/10665/89148/9789241209786_eng.pdf?sequence=1&isAllowed=y#page=329
  - *Website:* https://extranet.who.int/pqweb/vaccines
  - *PQ list:* https://extranet.who.int/pqweb/vaccines/prequalified-vaccines
- **PQ Diagnostics:**
  - *Procedure:* http://apps.who.int/iris/bitstream/handle/10665/259403/WHO-EMP-RHT-PQT-2017.02-eng.pdf;jsessionid=387D24F53BDCAA88F4DBA8BFD1B8DBF1?sequence=1
  - *Website:* https://extranet.who.int/pqweb/in-vitro-diagnostics
  - *IVDs under assessment:* https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment
  - *PQ list:* https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

PQT: Procedures and websites (2/3)

- **PQ Vector control products:**
  - *Procedure:* https://extranet.who.int/pqweb/sites/default/files/documents/WHO_PQT_VectorControlProducts_June2021.pdf
  - *Website:* https://extranet.who.int/pqweb/vector-control-products
  - *Products under assessment:* https://extranet.who.int/pqweb/vector-control-products/prequalification-pipeline
  - *PQ list:* https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list
- **PQ Immunization devices:**
  - *Procedure:* https://extranet.who.int/pqweb/immunization-devices/who-catalogue-prequalified-immunization-devices
  - *Website:* https://extranet.who.int/pqweb/immunization-devices
  - *PQ list:* https://extranet.who.int/pqweb/immunization-devices/category-information
- **PQ Quality Control Laboratories**
  - *Procedure:* https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs1003-annex3-quality-control-laboratories.pdf?sfvrsn=c07d6468_2
  - *Website:* https://extranet.who.int/pqweb/medicines/information/quality-control-laboratories
  - *PQ list:* https://extranet.who.int/prequal/content/medicines-quality-control-laboratories-list
- **PQ Inspections:**
  - *Procedures and website:* https://extranet.who.int/pqweb/inspection-services
- **PQ Human Insulin Pilot**
  - *Procedure:* https://extranet.who.int/pqweb/medicines/pilot-prequalification-procedure
  - *Website:* https://extranet.who.int/pqweb/medicines/human-insulin

PQT: Procedures and websites (3/3)

PQT/MED

- Medicines Pipeline (FPPs): https://extranet.who.int/pqweb/medicines/dossier-status
- Full Assessment – Multisource (Generic) FPPs: https://extranet.who.int/pqweb/medicines/full-assessment-multisource-generic-fpps-0
- SRA-approved Multisource (Generic) or Innovator FPPs: https://extranet.who.int/pqweb/medicines/abbreviated-assessment-multisource-generic-or-innovator-product
- Full API Assessment – APIMF Not Previously Assessed: https://extranet.who.int/pqweb/medicines/full-api-assessment-%E2%80%95-apimf-not-previously-assessed
- Abridged Assessment – APIMF Assessed Previously Using APIMF Procedure: https://extranet.who.int/pqweb/medicines/abbreviated-assessment-%E2%80%95-api-master-file-assessed-previously-under-fpp-assessment
- Abridged Assessment – API Accepted Previously by an Authority Applying Stringent Standards: https://extranet.who.int/pqweb/medicines/abbreviated-assessment-api-already-accepted-stringent-regulatory-authority

PQT/IVD

- In Vitro Diagnostics Under Assessment: https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment
- In Vitro Diagnostics Eligible for WHO Prequalification: https://extranet.who.int/pqweb/vitro-diagnostics/eligibility
- Full Assessment of an IVD: https://extranet.who.int/pqweb/vitro-diagnostics/full-assessment
- Abridged Assessment of an IVD: https://extranet.who.int/pqweb/vitro-diagnostics/abridged-assessment-ivd

Emergency Use Listing (EUL)

PQT/MED

- EUL procedure (Therapeutics): https://extranet.who.int/pqweb/medicines/emergency-use-listing
- EOI COVID-19: https://extranet.who.int/pqweb/key-resources/documents/eoi-therapeutics-against-covid-19
- Status of COVID-19 Medicines and Active Pharmaceutical Ingredients (APIs): https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-medicines-and-apis

PQT/VAX

- EUL procedure (Vaccines): https://extranet.who.int/pqweb/vaccines/emergency-use-listing-procedure
- COVID-19 (Guidance documents & EUL Submissions): https://extranet.who.int/pqweb/vaccines/covid-19-vaccines
- EOI COVID-19: https://extranet.who.int/pqweb/key-resources/documents/first-invitation-manufacturers-vaccines-against-covid-19-submit-expression
- Status of COVID-19 vaccines within WHO EUL/prequalification evaluation process: https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process
- COVID-19 vaccines WHO EUL issued: https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued

PQT/IVD

- EUL procedure (IVDs): https://extranet.who.int/pqweb/vitro-diagnostics/emergency-use-listing-procedure & https://extranet.who.int/pqweb/sites/default/files/documents/EUL-FINAL-13_12_2020.pdf
- Coronavirus disease (COVID-19) Pandemic — Emergency Use Listing Procedure (EUL) open for IVDs (Guidance & Reports): https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open
- EOI COVID-19: https://extranet.who.int/pqweb/key-resources/documents/invitation-manufacturers-vitro-diagnostics-sars-cov-2-submit-application
- Status of IVDs under EUL: https://extranet.who.int/pqweb/key-resources/documents/sars-cov2-nucleic-acid-tests-applications-under-assessment-emergency-use