Leveraging the WHO PQ Decision: Evidence to Support the Regulatory Decision

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Prequalification Team – Diagnostics Assessment

World Health Organization

WHO Prequalification

- promoting and facilitating access to safe, appropriate and affordable IVDs or Medical Devices of good quality in an equitable manner

Overview

- What is the PQ decision?
- How is the PQ decision made?
- Why utilise the PQ decision?
- Why can the PQ decision be leveraged?
- How can the PQ decision be leveraged?

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What is the PQ decision?

- The PQ decision is a conclusion made by WHO regarding the quality, safety, performance and suitability of an IVD/MD when it is used in WHO Member States
- The PQ decision is used by UN bodies and procurement agencies as a means for quality assuring IVDs/MD and other health products
- The PQ decision can be used by Member States without strong regulatory systems or with limited resources to provide assurance of quality, safety and performance
- The PQ decision is used by health implementing programmes to guide product selection

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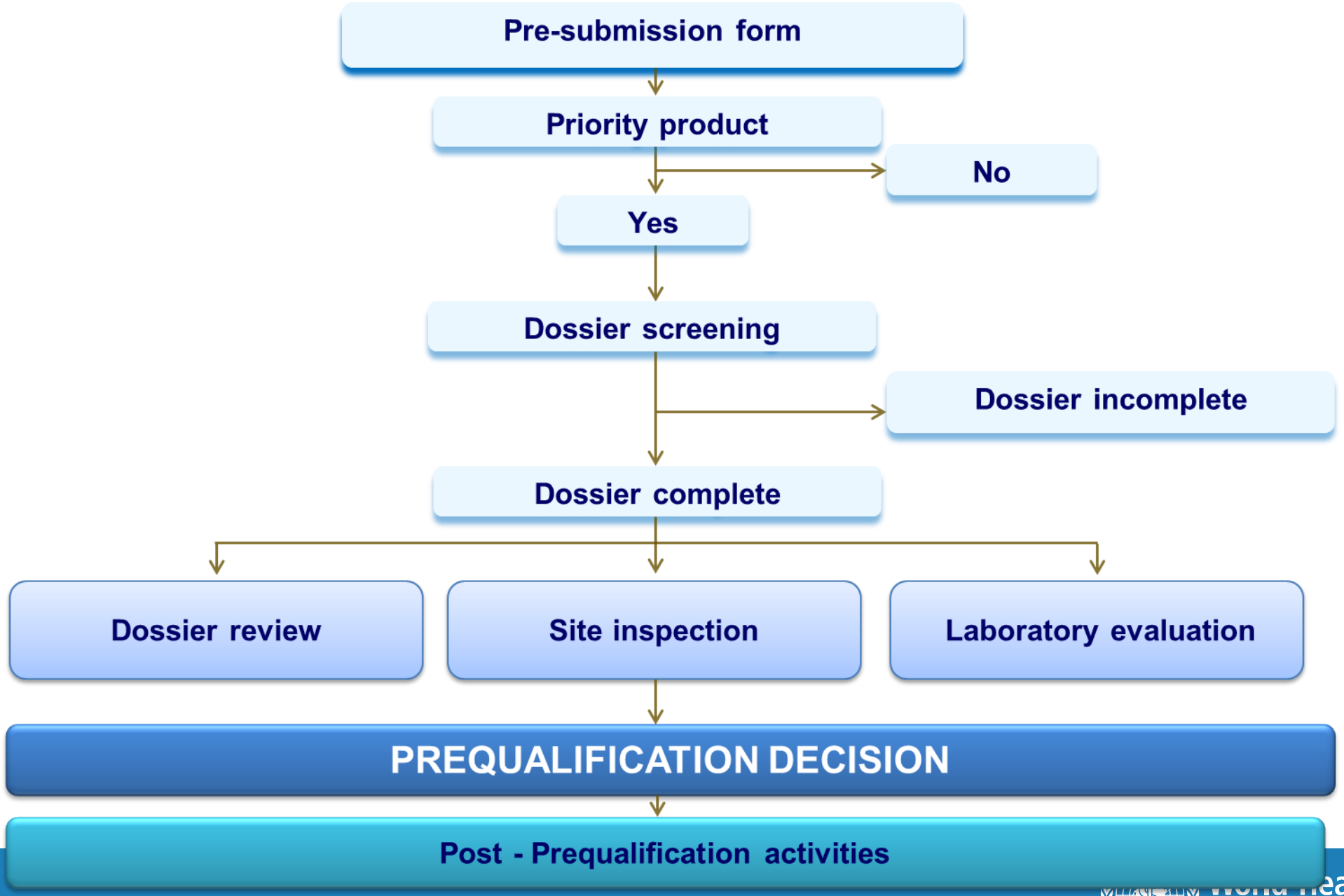
How is the PQ decision made?

- WHO prequalification is a risk-based procedure founded on best regulatory practice
- WHO undertakes a comprehensive assessment of individual IVDs/MDs through a standardized procedure aimed at determining if the product meets PQ requirements.
- Focus is placed on IVDs/MDs for priority diseases:
  - HIV, malaria, hepatitis C, HPV, HBV

How is the PQ decision made?



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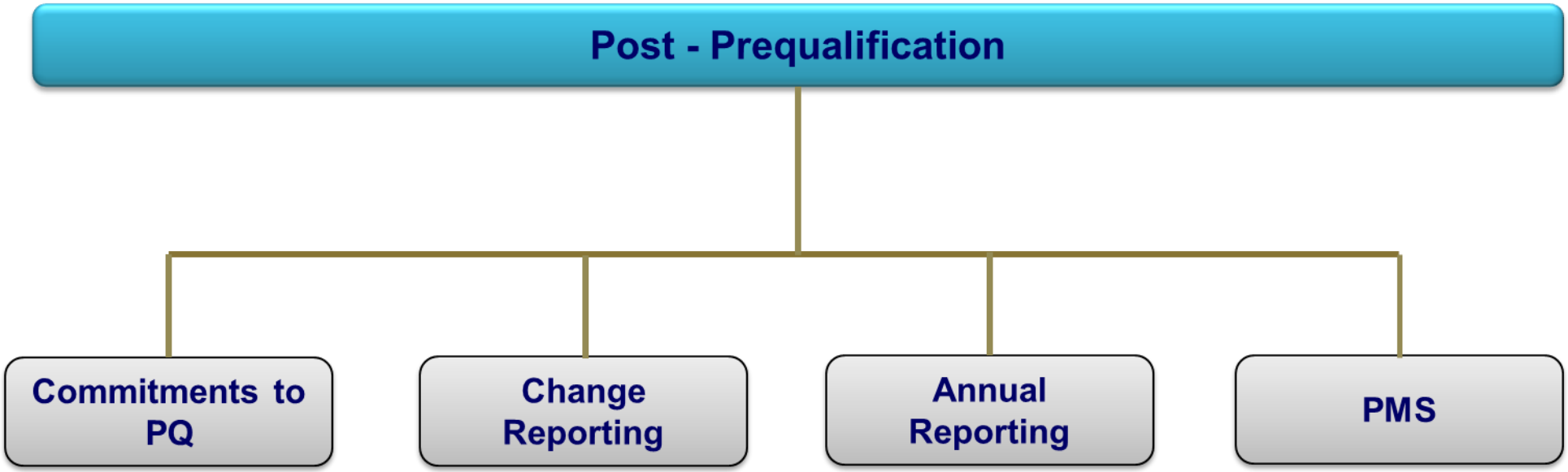
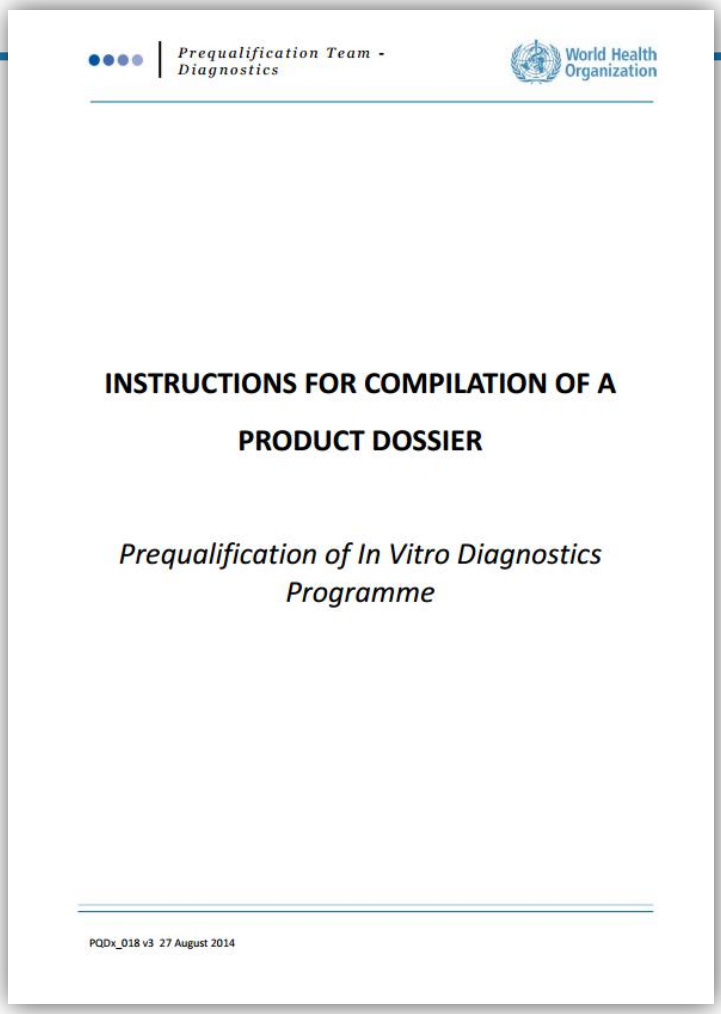


How is the PQ decision made?

Dossier Assessment

- The dossier contains a subset of the technical documentation held by the manufacturer
  - to demonstrate that the IVD/MD to which it applies conforms to the “Essential Principles of Safety and Performance of Medical Devices” as defined by GHTF
- The dossier reflects the status of the IVD/MD at a particular moment in time
- The contents of the dossier are aligned with IMDRF Table of Contents



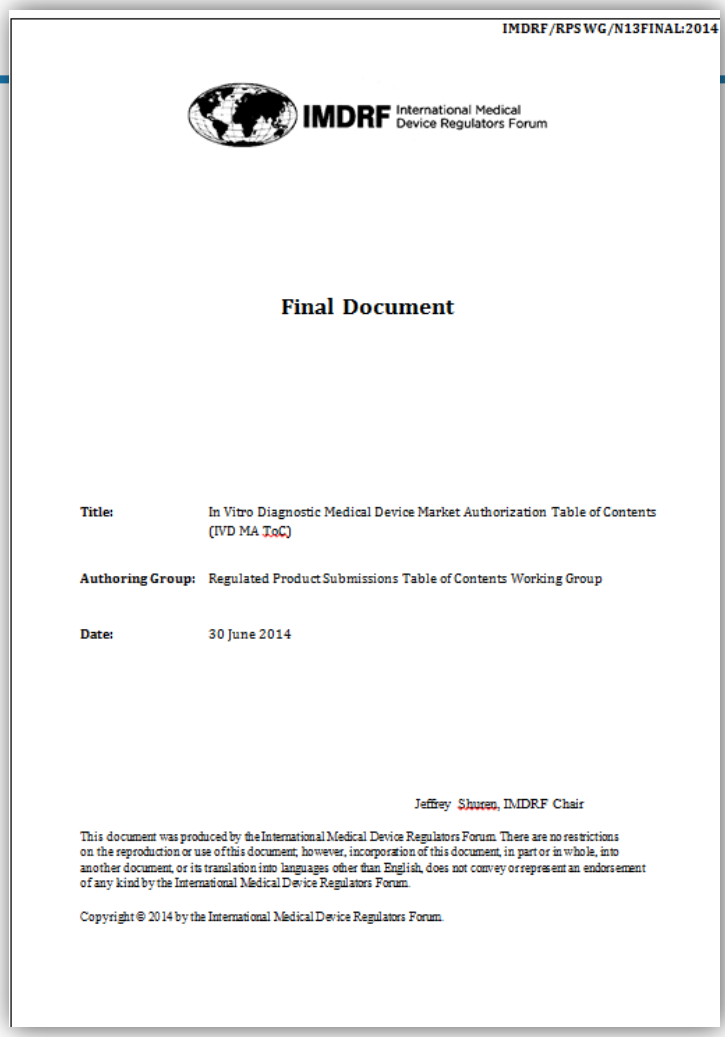
Prequalification Team - Diagnostics

World Health Organization

INSTRUCTIONS FOR COMPILATION OF A PRODUCT DOSSIER

Prequalification of In Vitro Diagnostics Programme

PQDx_018 v3 27 August 2014



IMDRF/RPS WG/N13FINAL:2014

IMDRF International Medical Device Regulators Forum

Final Document

Title: In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 30 June 2014

Jeffrey Shuren, IMDRF Chair

How is the PQ decision made?

- Dossier should also provide sufficient information to inform the PQ Inspection team regarding:
  - Sites responsible for design and manufacture to enable planning of inspection/s
  - Information demonstrating the maturity of the manufacturer's QMS
- It should demonstrate that the Mx has considered the safety and performance in WHO Member States.
- It should provide sufficient information to determine the **regulatory version** submitted to PQ

How is the PQ decision made?

Regulatory Version

- Relates to the information associated with a submission for approval by a regulatory authority.
- The submitted version is defined by all of the documentation related to development, manufacture, and intended use, labelling and post market surveillance of the product and all the documented evidence supporting the safety and performance claims associated with that submission.

How is the PQ decision made?

Technical Requirements

- Based on international requirements
  - CTS, FDA, HC, ISO, CLSI
- WHO Technical Specification Series
  - Guidance specific to each type of IVD accepted to PQ to address the question “how much and what type of evidence do you consider to be ‘sufficient’ for prequalification?”
  - Will not only inform manufacturers but will to provide greater review/assessment consistency

How is the PQ decision made?

Technical Requirements

- WHO Technical Specification Series
  - HIV RDTs
  - Malaria RDTs
  - G6PD IVDs
  - HIV NAT
  - HBV RDTs and EIAs
  - HCV RDTs and EIAs
  - CD4 POC
  - HPV POC NATs
  - HIV/Syph RDTs

How is the PQ decision made?

Inspection

- Requirements based on compliance with ISO 13485
- WHO is an observer of MDSAP, and has adopted practices to be aligned
- Special emphasis on post-market support and investigations, change control, risk management

How is the PQ decision made?

Laboratory Evaluation

- Acceptance criteria set on programmatic needs
- The evaluations focus on operational characteristics including
  - sensitivity,
  - specificity on a WHO serum/plasma evaluation panel,
  - ease of use, and
  - suitability for use in small laboratories with limited facilities.

How is the PQ decision made?

Laboratory Evaluation

- Comprehensive summaries are available in the form of Reports (on PQ website)
- The information is intended for use by those responsible for deciding which tests to use, e.g. programme managers and potential users of tests, to enable them apply their own criteria and choose the best test for their particular situation.

http://www.who.int/diagnostics_laboratory/publications/evaluations/en/

How is the PQ decision made?

- WHO assessment supported by a network of subject matter experts (regulation, industry, QMS, lab, academia) and WHO CCs
- Final prequalification outcome depends on:
  - Results of dossier assessment and acceptance of action plan
  - Results of inspection(s) and acceptance of action plan
  - No level 5 nonconformities outstanding for either dossier or for inspection
  - Meeting the acceptance criteria for the laboratory evaluation

How is the PQ decision made?

PQ Decision

- WHO PQDx Public Report is posted on WHO website and product is added to the list of WHO prequalified products
- A public report is available for each prequalified product which notes:
  - Catalogue numbers
  - Regulatory version
  - Important usage aspects eg storage specimen type
  - Summaries of outcomes of dossier, inspection, and laboratory assessments
  - A copy of the approved IFU
  - Any commitments to PQ

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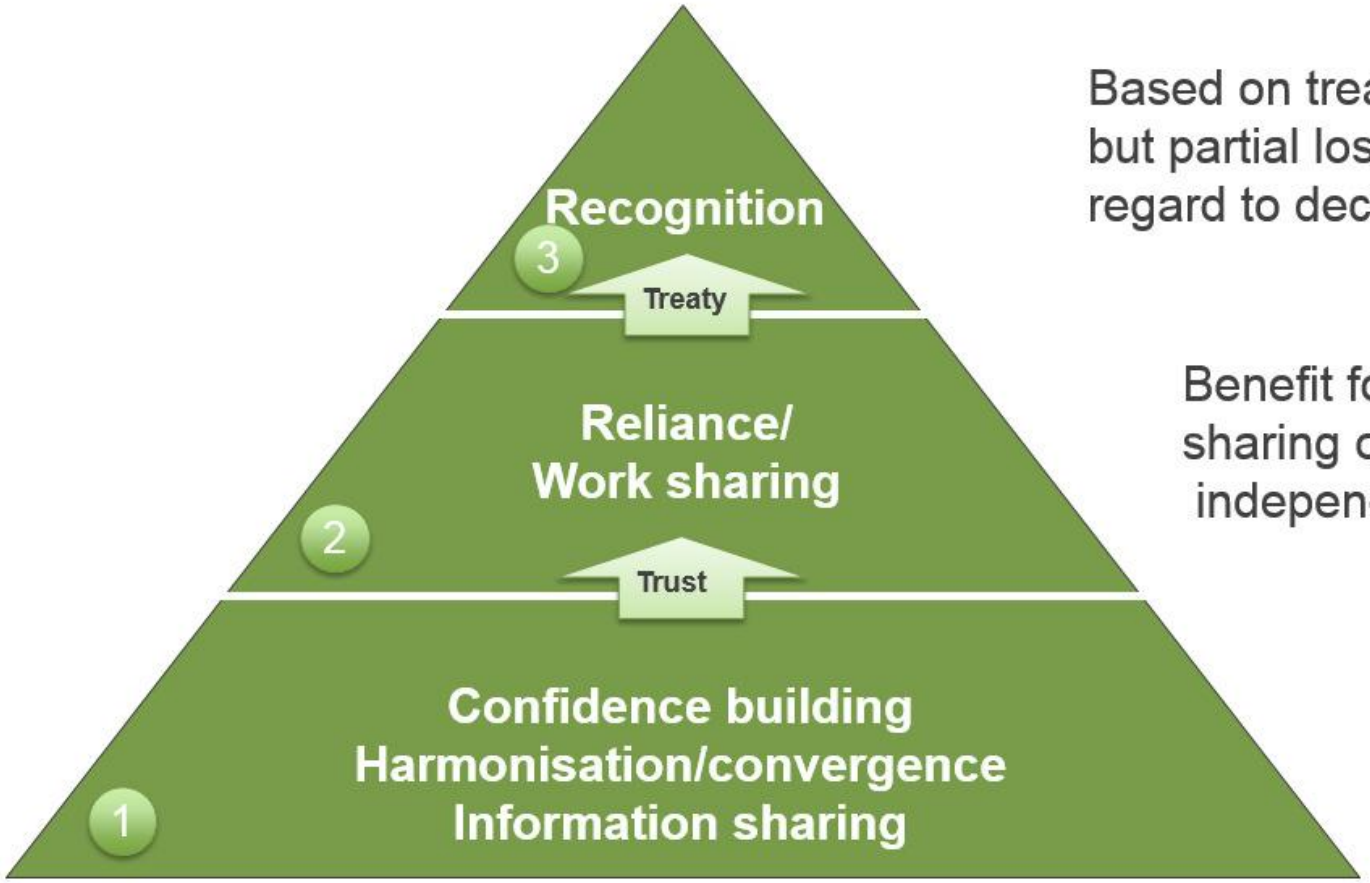
Why utilise the PQ decision?



Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

Source: Swissmedic

Good regulatory practice

Harmonisation, convergence, reliance and recognition

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Why can it be leveraged?

- Comprehensive assessment of quality, safety, performance and usability
- Based on regulatory best practice and harmonised requirements
- Using international experts for assessment
- Assuredness of the regulatory version
- PQ emphasis on aspects for countries with limited regulatory capacity

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How can it be leveraged?

- Full reliance
- Collaborative registration
- Joint assessments
- For performance studies, use the information in the reports to assist in
  - Design of studies
    - Clinical utility, HTA, geographical specific issues
- ……

Leveraging the WHO PQ Decision

- Optimising scarce resources for public health
- Accelerating access to quality assured IVDs for public health programs

World Health Organization