Expert Review Panel for Diagnostics (ERPD)

World Health Organization

PQT-IVD

GRUSZKA, Fatima - Technical Officer - HQ/MHP/RPQ/PQT/IVD

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Outline of presentation

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Background

Procurement Agencies (PA) and WHO Technical Programs (TP) can only procure **quality assured** IVD, compliant with applicable **stringent regulations** or **WHO policies and guidance** and appropriate for the **intended use settings**.

ERPD Mechanism based on previous experience with ERP for medicines was integrated for **product not approved** by stringent authority or WHO prequalification programs

Since 2014 The Global FUND/UNITAID requested WHO to organize a ERPD rounds for selected IVD devices

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Purpose

To assess the potential risks/benefits associated with the procurement of diagnostic products that may have a high public health impact, but have not yet undergone a stringent assessment, either by WHO Prequalification or by a SRA.

To advise the PA and TP in their decision on whether to allow grant funds to be used for the time-limited procurement of the diagnostics reviewed by the ERPD.

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Purpose

ERPD risk/benefit assessment does not replace WHO PQ/SRA assessment but should be seen as a step towards a WHO PQ or SRA full regulatory review.

The ERPD mechanism should facilitate access to IVDs for neglected diseases, as well as innovative devices, if the associated risks are deemed to be lower than the potential benefits

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Eligible products

For new IVD or IVD technologies **high public health impact** in **specific settings**.

Only where there is an **Expression of Interest** (EoI) developed and published by a PA or TP with IVD specifications.

Regulatory status

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Questionnaire Application

- A cover letter expressing interest sent to PA/TP
- Evidence that the product is under WHO PQ or SRA process or a letter of commitment from the manufacturer to submit product to a stringent assessment
- QMS documents substantiated by one or two most recent and valid audit reports, certificates, etc.
- A completed **ERPD questionnaire** as per generic instructions outlined in the EoI

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Questionnaire documentation

Product regulatory version and description

Design, Manufacturing & QC information

Product performance specifications, associated analytical and clinical validations studies

Labelling

Customer support and PMS

QMS major procedures

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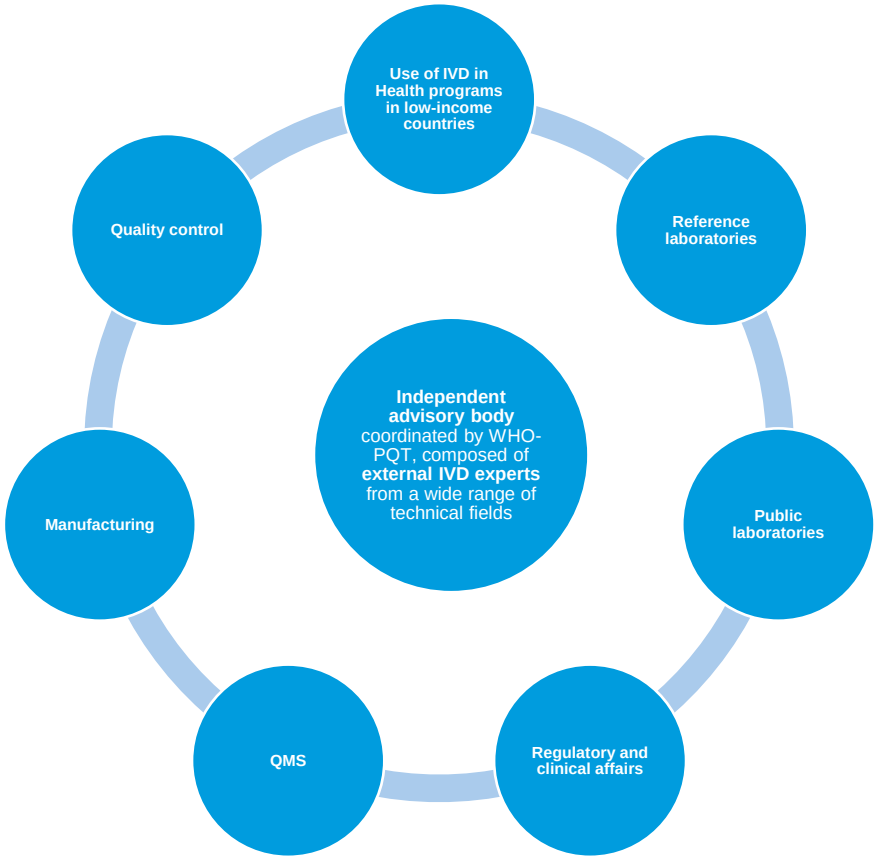
ERPD Membership



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Responsibilities

PA or TP

- Prepares and posts invitation to Mx (EOI)
- Screens applications and sends to PQT-IVD
- Informs manufacturers of ERPD outcomes

WHO PQT-IVD

- Assigns experts to review applications & shares documents
- Arranges and chairs meeting of ERPD
- Compiles and finalizes reports for procurement agency

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Responsibilities

The selected ERPD members assess data provided in the submissions, draft the corresponding reports, and allocate each product a **risk category**,

The assessors present their findings to the WHO team at ERPD meetings and provide advice on measures to mitigate identified risks, and advice on which products can be considered as **acceptable for time-limited procurement.**

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ERPD Implementation

- Depending on the number of submissions, the ERPD may review products in pre-planned sessions or ad-hoc, at the request of a PA/TP
- Desk review
- The Expert Panel will consider the intended end user and testing environment
- IVDs may not have the same quantity of validation and clinical evidence if not assessed by an SRA
- The outcome of the ERPD is a decision on the Risk Category supported by a product report the PA/TP will share with the Manufacturer

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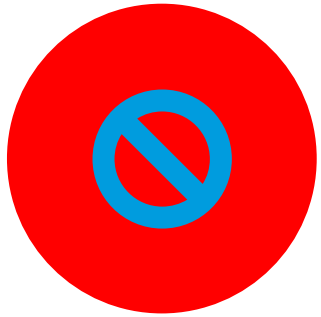
ERPD Risk Categories

RISK CATEGORY 1 & 2:

NO OBJECTION TO TIME-LIMITED PROCUREMENT

RISK CATEGORY 3:

OBJECTION TO PROCUREMENT BUT MAY BE CONSIDERED WHEN THERE ARE NO ALTERNATIVES, AND PROVIDED THE BENEFIT OUTWEIGHS THE RISK OF PROCURING A PRODUCT WHICH IS NOT FULLY QUALITY ASSURED



RISK CATEGORY 4:

OBJECTION TO PROCUREMENT

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Risk Category Criteria

	RC 1	RC 2	RC 3	RC 4
QMS Compliance	QMS compliant site.	QMS compliant site.	Generally QMS compliant, but some minor non-conformities that are being addressed.	Not sufficient evidence that the site is QMS compliant.
Risk Management & Control of Manufacturing	Adequate risk management and appropriate control of manufacturing processes.	Adequate risk management and appropriate control of manufacturing processes.	Limited risk management and/or control of manufacturing processes.	Evidence of risk management and control of manufacturing processes is inadequate.
Evidence of Analytical Performance	Adequate evidence.	Adequate evidence for most key aspects. Additional studies ongoing.	Analytical methods not sufficiently validated/limited performance data and/or comparator/reference method not acceptable.	Inadequate study design and insufficient evidence to substantiate analytical performance.

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Risk Category Criteria

	RC 1	RC 2	RC 3	RC 4
Evidence of Clinical Performance	Adequate evidence, including data in the intended use settings and with all relevant specimen types.	Well controlled, but limited, clinical performance data in intended use settings. Additional studies ongoing.	Clinical methods not sufficiently validated (i.e.: limited data available and/or inappropriate reference method).	Inadequate study design and insufficient evidence to substantiate clinical performance.
Stability studies	Submitted study data support claimed shelf life on at least 3 production lots and minimum of 6-12 months for shelf life.	Acceptable accelerated stability data on 3 lots; real time studies in progress with 6 months data.	Submitted stability data on 1 or 2 lots and the potential for stability issues.	Current stability data are not satisfactory and do not allow assignment of shelf life.
Labelling, including IFU	Consistent with international standards (IMDRF, ISO)	Consistent with international standards. Minor improvements identified.	Partially compliant with international standards. Need for improvements identified.	Labelling and IFU are not satisfactory.
Customer support & PMS	Test suitable for LMIC, customer support network.	Most aspects suitable for LMIC, customer support network.	Operational aspects adequate, poor customer support.	Operational aspects incompatible with LMIC.

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Extension request

Risk category assignment is for a time-limited period

- 12 months
- During this period, it is expected that the manufacturer will make progress in addressing the deficiencies observed during the ERPD assessment.

1 extension assessment may be considered with a new of risk category assignment

- New questionnaire with updated evidence
- PMS data

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Conclusion & Perspective

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Conclusion & Perspective

To assess the potential risks/benefits associated with the procurement of diagnostic products that may have a high public health impact, but have not yet undergone a stringent assessment, either by WHO Prequalification or by a SRA.

Independent IVD Experts panel coordinated by the WHO PQT

Desk Review of Quality Safety Appropriateness of new or innovative IVD

ERPD Risk Categorization For **time limited** procurement With specific **binding conditions** for use

Commitment of the manufacturer to apply for WHO PQ or SRA approval

Will be opened to new PA/TP EoI and new range of devices for access to innovation when there is an urgent need, for NTD and when there is no other PQ or SRA approved alternative

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Thank you!

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