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DEFINING PRODUCT NEEDS: PERFORMANCE REQUIREMENTS

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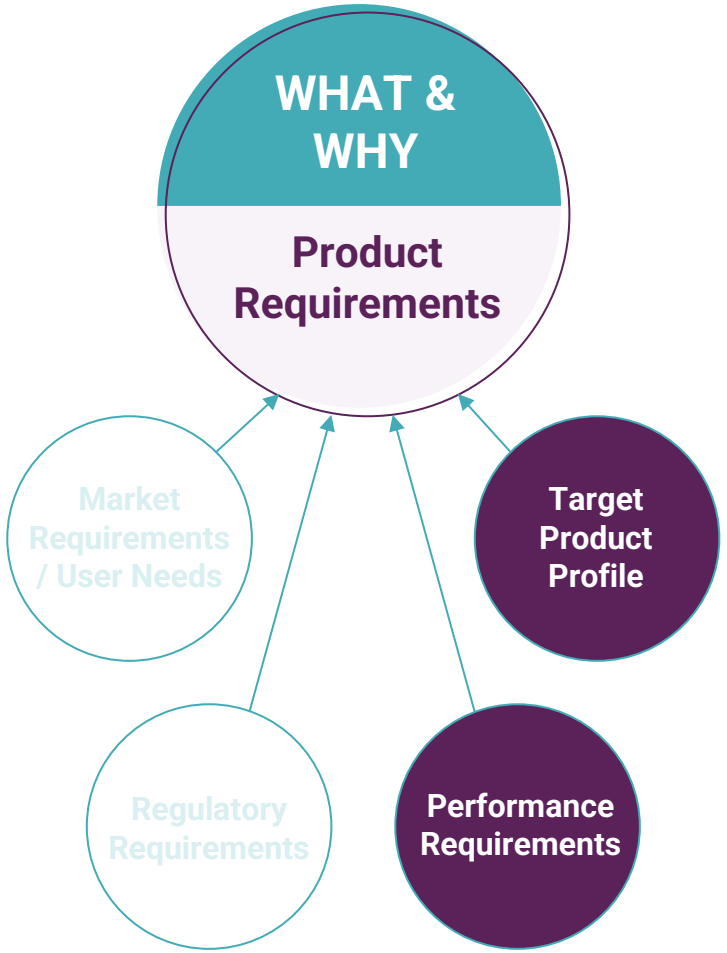
TOPICS

1. Performance Requirements
2. Target Product Profile for Diagnostics: what is it, who does it and how to use it
3. Target Product Profile vs Product Requirement Document
4. Other resources

PRODUCT REQUIREMENTS



Examples of relevant categories/aspects for product requirements consideration:

Market Need Why is the product needed?	**Intended Use** Purpose of your device What the test does / how it works	**Indications for Use** Circumstances under which the test will be used
Target Markets Where is the test going to be sold?	**Procurement** Who will buy the product?	**Target Settings** Where the test will be used?
Target Analyte Which analyte to test?	**Specimen Type** (e.g. swap, urine, blood…)	**Analytical & Clinical Performance** (e.g. LoD, sen., spe.)
Operational Characteristics (e.g. shelf life, stability)	**Test Format** (e.g. LFT, strip, ELISA)	**Target COGs** What is the target cost?
Device Classification Based on Risk associated with Intended Use of test	**Waste Management** Test disposal after use	**Digital / Connectivity** Data storage, sharing…

PERFORMANCE / OPERATIONAL REQUIREMENTS

Analytical & Clinical Performance	Test Procedure	Operational Characteristics	Instrument/reader characteristics
Clinical sensitivity	Sample preparation	Shelf Life	Size (W x H x B)
Clinical specificity	Specimen collection	Storage conditions	Weight
Limit of detection	Sample volume	Open test kit stability	Power requirements
Assay interference	Test kit components	Operating range	Connectivity
Cross-reactivity	User training	Shipping and transport conditions	Data Export
Test failure (invalid) rate	Ease of use	Biosafety	Service, maintenance
Precision: Repeatability	Sample-to-result time	Waste disposal	Results processing
Precision: Reproducibility	Stability valid result		

TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

WHAT IS IT?

Requirement documents for **products that are currently not available** on the market but that fulfil a priority need **in the context of Global Health**.

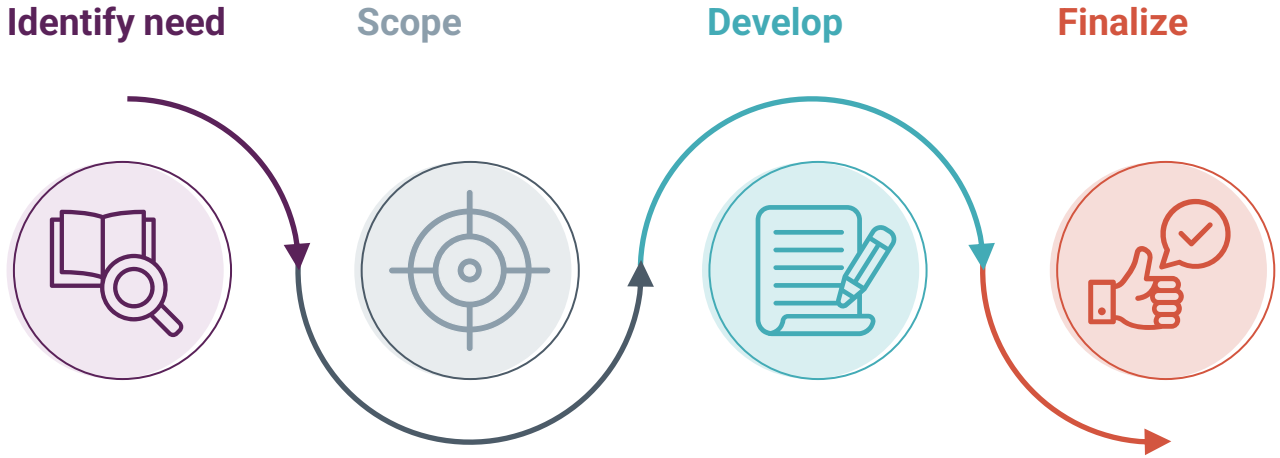
All TPPs are publicly available.

WHAT ARE USED FOR?

To ensure that R&D activities are **focused on relevant products** and designed for the contexts and needs of end-users by researchers, developers and manufacturers.

HOW IS DONE?

It is a **consensus-based document** created by a large and diverse group of experts submitted to public consultation.



TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

WHO DEVELOPS TPPs?

World Health Organization (WHO):

A target product profile authored by WHO indicates that the organization determines there is a significant unmet health need for the product in question, and the product profile preferences promote the development of products with high public health impact and suitable for use in low to middle-income countries.

https://www.who.int/tools/target-product-profile-database

Non-World Health Organization (WHO):

Several public health-oriented funders develop their own TPPs (e.g. UNICEF, PATH, GAVI, MSF, FIND, etc.) to fulfil needs in the context in which they operate.

FIND TPP

FIND created **+40 TPPs** in close collaboration with WHO, for diagnostic tools for poverty-related diseases.

https://www.finddx.org/tools-and-resources/rd-and-innovation/target-product-profiles/

TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

TPP KEY ELEMENTS:

- Intended use
- Target populations
- Performance (minimum and optimal)
- Operational characteristics (minimum and optimal)
- Costs (minimum and optimal)
- Regulatory pathway

EXAMPLE

Target Product Profiles for improved antimicrobial stewardship for gonococcal infection

EXAMPLE

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World Health Organization

Target Product Profiles for improved antimicrobial stewardship for gonococcal infection

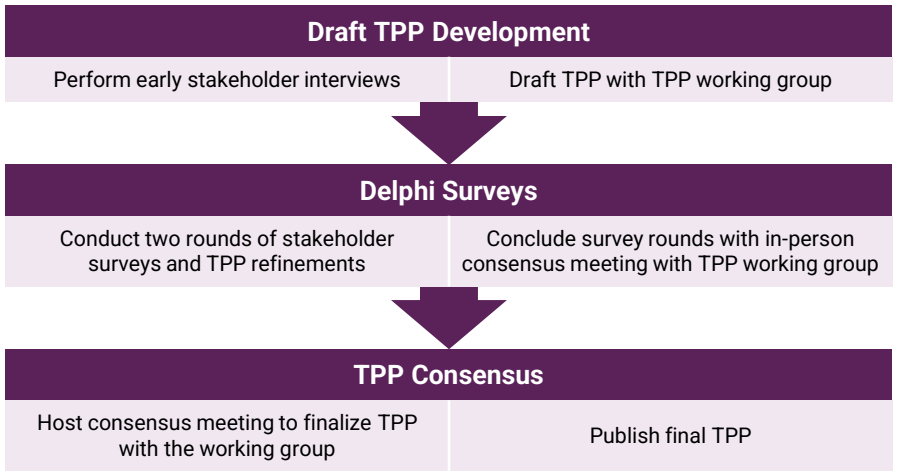


Figure 3: TPP development process

Characteristic	Minimal requirement	Optimal requirement
Scope of test		
Intended use	To detect *Neisseria gonorrhoeae* (NG) only or NG and *Chlamydia trachomatis* (CT) infection to improve patient management and facilitate appropriate antibiotic use	Same as minimal, plus to assist in screening to identify previously undetected NG or NG and CT infections
Target use setting	Primary health care setting including health posts (Level 1); to be used after initial clinical evaluation (referring to Step 2 in the WHO vaginal/urethral discharge flowchart) to guide treatment decision	
Test format / Equipment	A non-instrumented, single-use, disposable diagnostic test preferred; ideally no additional power required for operation, but if required, batter power with 8-hour operation between charges Reader optional and only appropriate if its inclusion supports enhanced test performance	
Performance characteristics		
Clinical sensitivity to predict resistance	>80% required to achieve the minimal intended use for a non-molecular test >95% required to achieve the minimal intended use for a molecular test	>90% required to achieve the minimal intended use for a non-molecular test >95% required to achieve the minimal intended use for a molecular test
Clinical specificity to predict resistance	>95% required to achieve the minimal intended use	>98% required to achieve the optimal intended use
Time to result	≤30 minutes	≤10 minutes
Pricing		
Target list price per test (excluding the cost of a reader)	<$3 USD for a low complexity test (e.g. rapid diagnostic test) that meets the minimal intended use and clinical sensitivity and specificity TPP specifications	<$12 USD for moderate/high complexity test (e.g. disposable single-use molecular test) that meets the optimal intended use and clinical sensitivity and specificity TPP specifications

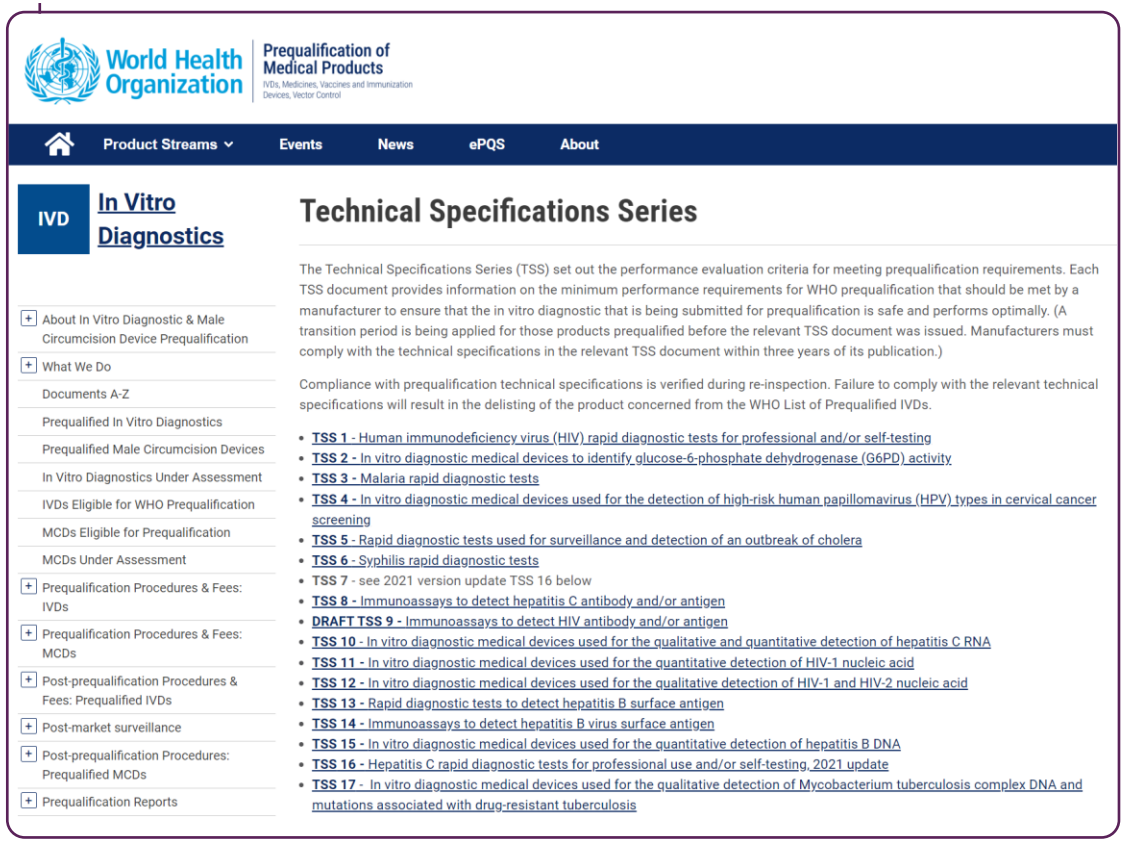
TARGET PRODUCT PROFILE VS PRODUCT REQUIREMENT DOCUMENT

PRODUCT REQUIREMENT DOCUMENT	TARGET PRODUCT PROFILE
internal and confidential document	public guidance created by a broad number of experts
provide details on the specific product	is quite generic and sometimes test agnostic
ranges (minimal to optimal) more specific	ranges (minimal to optimal) often quite broad

The product should try to comply with TPP, acknowledging that sometime some characteristics may fall outside of TPP range.

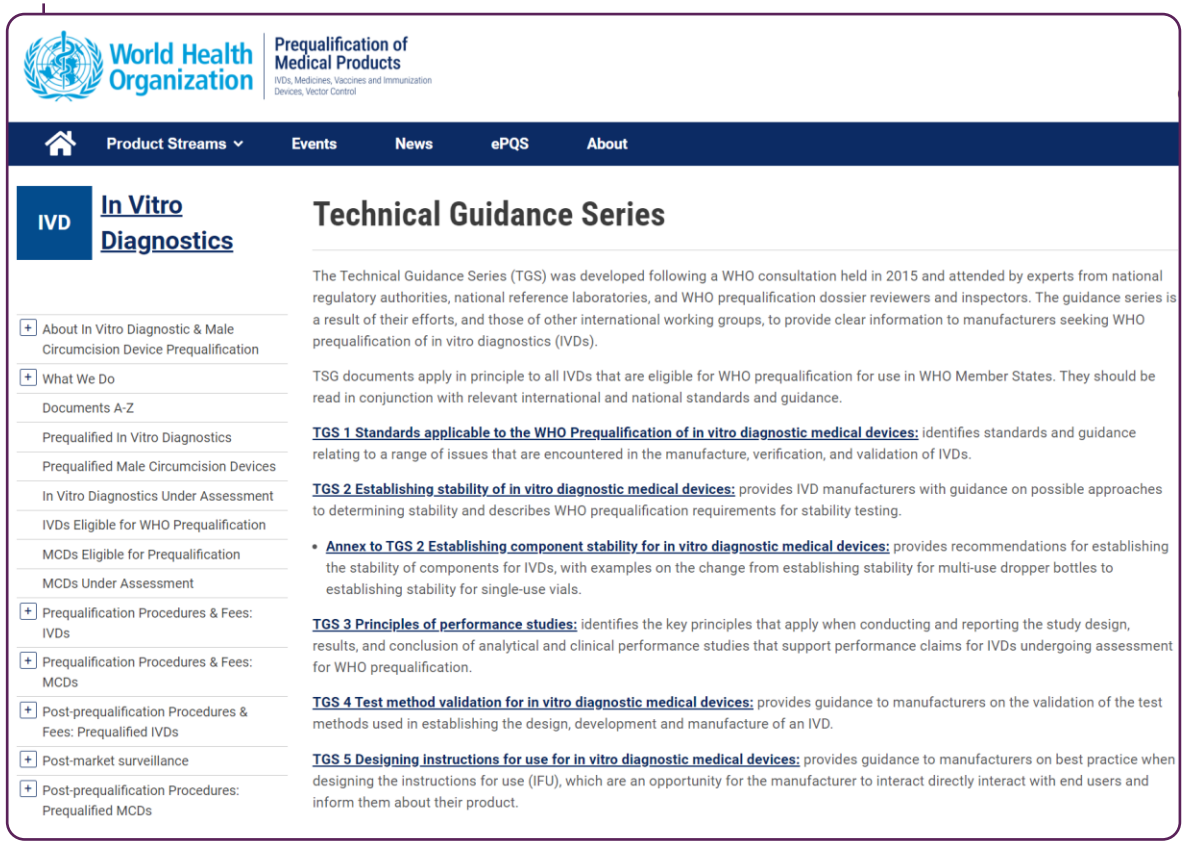
OTHER RESOURCES

- **Technical Specification Series (TSS)** describe WHO's interpretation of the minimum validation and verification studies to be undertaken by the manufacturer in support of in vitro diagnostic (IVD) performance claims.



https://extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series

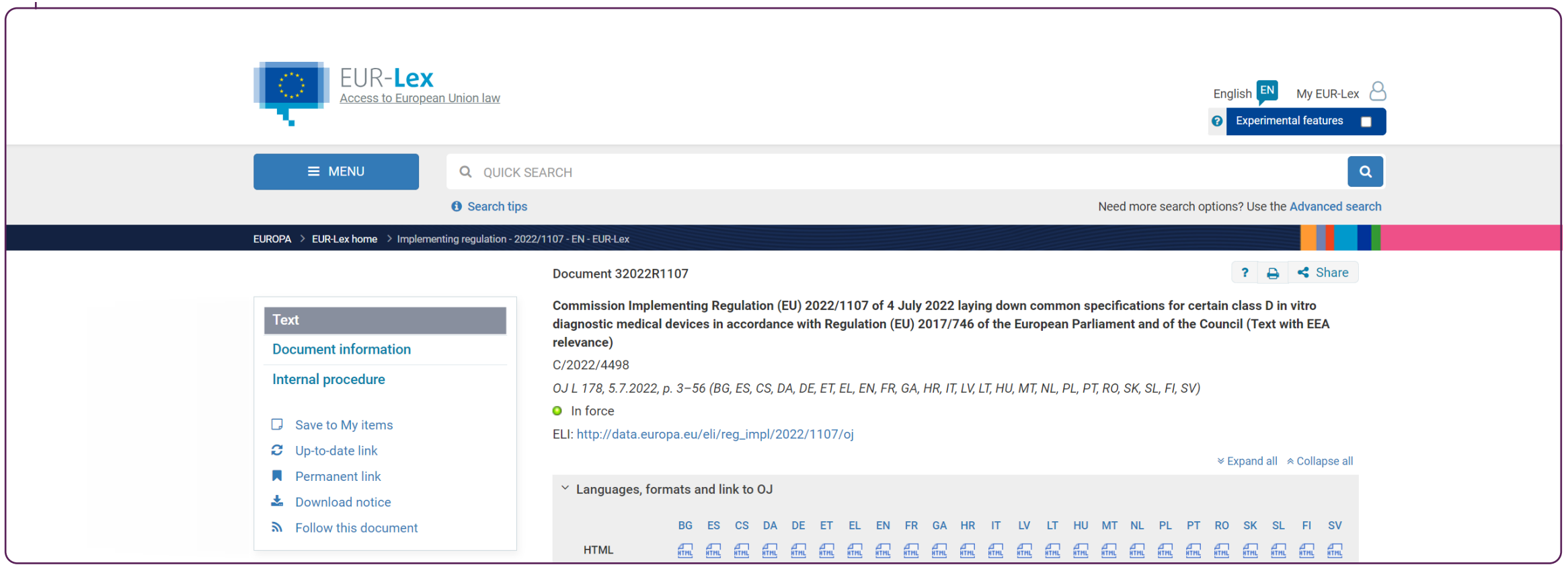
- **Technical Guidance Series (TGS)** contain valuable information on a range of issues that are encountered in the manufacture, verification, and validation of specific categories of IVD. TGS apply in to all IVDs that are eligible for WHO PQ.



https://extranet.who.int/prequal/vitro-diagnostics/technical-guidance-series

OTHER RESOURCES

- The **Common Specification (EU CS)** are a set of uniform and consistently requirements for class D (highest risk) in vitro diagnostic (e.g. HIV, HTLV, Hepatitis) in relation to the IVD Regulation 2017/746 (IVDR).



https://eur-lex.europa.eu/eli/reg_impl/2022/1107/oj

KEY TAKEAWAYS

1

If a TPP is available, use it as a reference to define your Product Requirements.

2

If a TPP is not available, use your market research and KOL consultation as well as available local and international guidance to define your Product Requirements.

3

If you are planning to submit for WHO PQ use TSS as a reference to define your PRD.

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QUESTIONS & FEEDBACK