

PQS TARGET PRODUCT PROFILE

PQS (Performance, Quality and Safety) is a WHO/UNICEF initiative with the objective to provide countries with access to appropriate technologies for the transport, storage and administration of vaccines. Working in close collaboration with UNICEF, the PQS secretariat located at WHO/HQ runs three main functions: (1) standards setting, including innovation integration, (2) prequalification processing and (3) collecting field monitoring information on performance and translating identified issues into new requirements.

In addition to the development and revision of performance specifications and verification protocols, part of the PQS team's standards setting function is the development of target product profiles (TPPs). These documents are used to guide stakeholders¹ and more particularly manufacturers², in their future product development programmes. The TPP-performance specification-prequalification-field monitoring cycle is an iterative and interactive process.

Definition: Target Product Profile (TPP)

A target product profile is a key strategic document that lists the principal desired features of a product category³ intended for future PQS prequalification. There are two ways in which a TPP can be used:

1. *As a first step in developing an entirely new product category.* The purpose here is to attract an initial response from stakeholders and manufacturers, leading to the development of a formal PQS specification and verification protocol and a new cycle of product development and prequalification.
2. *As a first step in initiating improvements or changes to an existing product category.* The purpose here is to address known technical or operational shortcomings based on collected field data on performance and to invite feedback from stakeholders and manufacturers. This process will then lead to a revision to an existing PQS performance specification and its companion verification protocol, followed by a further cycle of product development and prequalification.

Both types of TPP capture user needs and provide initial guidance to manufacturers. The purpose of this is to steer manufacturers towards product development programmes that respond to the operational needs and constraints of low and middle income countries and to the environmental conditions met in these settings. The TPP is a wish list of desired product characteristics intended to

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² "Manufacturers" includes product Developers

³ The PQS prequalification scheme concerns various product categories such as cold rooms and freezer rooms, refrigerators and freezers, cold box and vaccine carriers, coolant packs, temperature monitoring devices, safety box and vaccine administration devices. PQS also defines subcategories for example ILR and SDD in the E003 refrigerator and freezer category. A TPP is typically applicable to a specific subcategory

stimulate feedback and dialogue – it is not intended to establish legally enforceable responsibilities. The final outcome of a successful TPP process is the drafting of a realistic and technically achievable PQS specification and verification protocol, acceptable by all interested parties. These two documents remain the basis for prequalification.

A TPP does not impose an implicit or explicit obligation on the manufacturer’s part to achieve all the desired product characteristics. During the dialogue process it may emerge that some of these are technically difficult to achieve or will have a negative impact on cost. In such circumstances, these characteristics may appear as optional performance requirements in the final PQS specification; manufacturers that are able to satisfy these optional requirements may be at a competitive advantage that should serve as an incentive to other manufacturers in reaching that same level of performance.

A well-designed TPP process will offer advantages to manufacturers because it will help to mitigate the risk of product development failures, optimize product performance through improved characteristics, and possibly decrease the total time involved in product development. On the other hand, the product without ‘optional extras’ may be cheaper and countries may wish to take the price advantage in preference to the options. In that sense the optional extra route helps provide a measure of flexibility.

PQS roles and responsibilities

The objective of PQS, in its normative role, is to set minimum performance standards for equipment and devices used in immunization programmes. In order to remain useful, these standards have to develop over time as technologies evolve, knowledge improves and experience accumulates. PQS also has a role in stimulating the development of new and improved product categories which will enable countries to deliver immunization services in new or improved ways.

Recent CCL (Cold Chain and Logistics) Task Team discussions have emphasized the need to strengthen and formalize the use of TPPs so that PQS can better achieve this objective. Accordingly, this additional activity will be formally incorporated into the existing PQS management process.

The TPP process is a way to respond proactively to evidence based feedback from all stakeholders, including end-users, manufacturers and test laboratories. For existing equipment, a TPP document can list new and improved product characteristics that will better address user needs, list ways in which identified problems can be resolved and describe new and improved test methods. Where

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feedback, and information from other sources, identifies an unmet technical or operational need, a TPP can be developed to characterize an entirely new category of products that could respond to this need.

An effective way to embed TPPs into the PQS process will be to develop a TPP for each product category. These documents will be used to capture evidence based feedback data from stakeholders and will be updated and reviewed at least once every two years by a review panel. This panel will decide on the priority list of TPPs to be developed/revised in accordance with the importance of the new and improved characteristics that have been captured. The TPP will be formally circulated to key public sector stakeholders for comment. These comments will be incorporated in a ‘public consultation draft’. This version will be sent to manufacturers for industry feedback and will be published on the PQS website. Further revisions may then be made before a ‘final’ version is published. The content of this final version will then be incorporated into the relevant PQS specification and verification protocol, either as a revision to an existing set of documents or as a completely new set. A new prequalification cycle will then begin.

For easy reference all TPPs will be structured the same way, as follows:

Contents

1. Need
Background information on the proposed TPP
2. Normative references
Existing standards referenced in the document
3. Terms and definitions
Glossary of terms used in the document
4. Design criteria
List of criteria subjected to changes or not
Includes justifications if criteria amended
5. Revision history
Track of all changes to the document from the time it is published

PQS, as a standard setting body, provides advice on product selection strictly on the basis of technical performance against known environmental conditions as well as end-users requirements. PQS is not involved in the procurement process and is not entitled to recommend any specific prequalified product by name or brand.

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In line with the prequalification process of WHO, a PQS listed product does not guarantee sales for the manufacturer. A procurement agency is free to express additional technical specifications or characteristics in addition to the PQS performance specifications in their solicitation documents. UNICEF would include additional characteristics in the specifications whereas product characteristics that are considered 'preferred' would be listed and explained in special notes to bidders. that To be eligible for award the product needs to meet minimum the PQS standard. Any tender will be awarded according to a transparent methodology and published criteria as outlined in the bid provisions...

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