World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
OBTAIN FEEDBACK ON THE PERFORMANCE OF AN IMD-PQS PRODUCT		
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1. OBJECTIVE

1.1. To describe the processes that relate to obtaining feedback on the performance of a prequalified IMD.

2. SCOPE

2.1. This SOP is applicable to all feedback on products performance obtained as part of the IMD-PQS initiative.

2.2. This SOP outlines techniques for obtaining user feedback.

2.3. It also establishes the administrative framework for capturing such information and for channelling it to where it is required to ensure the continued performance, quality and safety of WHO prequalified immunization devices.

2.4. *User feedback* can supply valuable information on the performance of equipment under field conditions.

2.5. Much of this information may be anecdotal and much will tend to be qualitative. Nevertheless, useful quantitative data on overall equipment reliability *can* be obtained from management reporting systems and also from field inspections carried out by review teams during exercises such as programme reviews and *Effective Vaccine Management* (EVM) inspections.

2.6. To be effective, this process requires the active cooperation of national EPI programme managers as well as the assistance of technical staff in WHO/UNICEF country and regional offices and partners.

2.7. The IMD-PQS Secretariat (Secretariat) and by the IMD-PQS Working Group (WG) follow this SOP.

3. CROSS-REFERENCES

Relevant KPI(s):	% of IMDs post-PQ reportable change 1st actions ≤ target time (30 days)

Background:	• https://extranet.who.int/pqweb/immunization-devices/post-market-monitoring • WHO/IMD-PQS/GENERIC/GUIDE.1.1: Generic Guide for the field evaluation of new technologies for IMD-PQS prequalification. https://extranet.who.int/prequal/sites/default/files/document_files/Generic%20Guide%20For%20Field%20evaluation_4.pdf • IMD-PQS product performance specifications. • IMD-PQS product verification protocols.
Under this SOP:	• IMD/TP/13a: Data entry format for electronic reporting system • IMD/TP/13b: Model format for a Feedback Schedule form • IMD/TP/13c: Model format for Annual Feedback Summary form • IMD/TP/13d: Model Product Alert form
Other QMS documents:	IMD/SOP/12: Field-testing an IMD-PQS product

4. DEFINITIONS

Device	A medical device such as a syringe or temperature monitor for example.
Evaluator	An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of IMD-PQS prequalified products.
IMD-PQS Secretariat	The WHO IMD-PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization devices and products, as well as product alerts. It ensures that the standards that apply to equipment maintenance, manufacturing and product testing are current. The Secretariat also coordinates product feedback reports and learnings from product field monitoring. The Secretariat holds ultimate responsibility for the IMD-PQS process and takes all final IMD-PQS decisions, including the decision to award prequalified status to a product or device.

IMD-PQS Working Group (WG)	The IMD-PQS WG is comprised of the WHO (IMD-PQS and Expanded Programme on Immunization), the United Nations Children's Fund (UNICEF) Supply and Programme Divisions, the Gavi, the Vaccine Alliance Secretariat, specialist agencies, partner organizations and other key stakeholders. In an advisory capacity through the WG structure, these actors offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.
In writing	Communication by letter, fax or email. (A hard copy will be kept on file.)
Legal manufacturer	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themself or on their behalf by a third party (Definition derived from Article 1 2.(f) of the EU Medical Device Directives). A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's name. A manufacturer that is contracted in this way is typically known as an Original Equipment Manufacturer, or OEM.
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
Product	In this document, where the word 'product' is used on its own, it includes device.
Reseller	A commercial entity, licensed to act on behalf of a legal manufacturer and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Verification protocol	An IMD-PQS product verification protocol describes in detail how the performance of a class of immunization-related products will

	be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure. See IMD/SOP/04: *Development and publishing an IMD-PQS product verification protocol*.

5. RESPONSIBILITIES

IMD-PQS Working Group (WG)	• Receives product performance data and feedback; • Monitors product performance data from all sources; and • Communicates feedback with the Secretariat
IMD-PQS Secretariat	• Establishes and maintains an electronic product performance reporting system; • Identifies and maintains a *Feedback Schedule* with the support, where requested, of the Working Group (WG). The Feedback Schedule records the type of feedback data required for each IMD-PQS product category; • Collates reports that highlight defective IMD-PQS products, received during the course of EVM inspections, programme reviews and other similar field evaluation exercises; • Requests UNICEF and WHO country and regional offices to report product defects observed in the field using the electronic reporting system; • Monitors product performance data from all sources; • Moderates and collates data as they are received and consolidates them into an *Annual Feedback Summary* which is distributed to relevant parties; and • Posts a *Product Alert* on the IMD-PQS website if major problems with a specific product are identified at any time.

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 characterizes the strengths and weaknesses of six principal methods that can be used to obtain feedback on equipment performance in the field. Only the first four are covered in detail by this SOP. The mailshot method is included for the sake of completeness; however, it is unlikely to be very useful in practice for the reasons stated. The field-testing option is fully described elsewhere[5]. These last two options are highlighted; neither is discussed further in this SOP.

Figure 1 –Methods for obtaining feedback on product performance in the field

Method	Strengths	Weaknesses
Electronic reporting (IMD-PQS website 'User Feedback Form'	• Relatively cheap to establish and maintain. • System administrator can easily call for feedback on a specific product. • Continuous real-time data resource. • Moderated and consolidated responses easily accessible by other users.	• Requires internet access. • Responses need to be moderated and collated before 'publication'. • Respondents are self-selecting. • Requires motivated country staff. • Data likely to be largely anecdotal.
Management reporting (IMD-PQS to request and source data already collected at country level that currently	• Relatively cheap to operate. • Provides data at regular time intervals.	• Relies on motivated country staff to achieve accuracy and timeliness. • Reliable data depends upon honest reporting and a no-blame management culture.

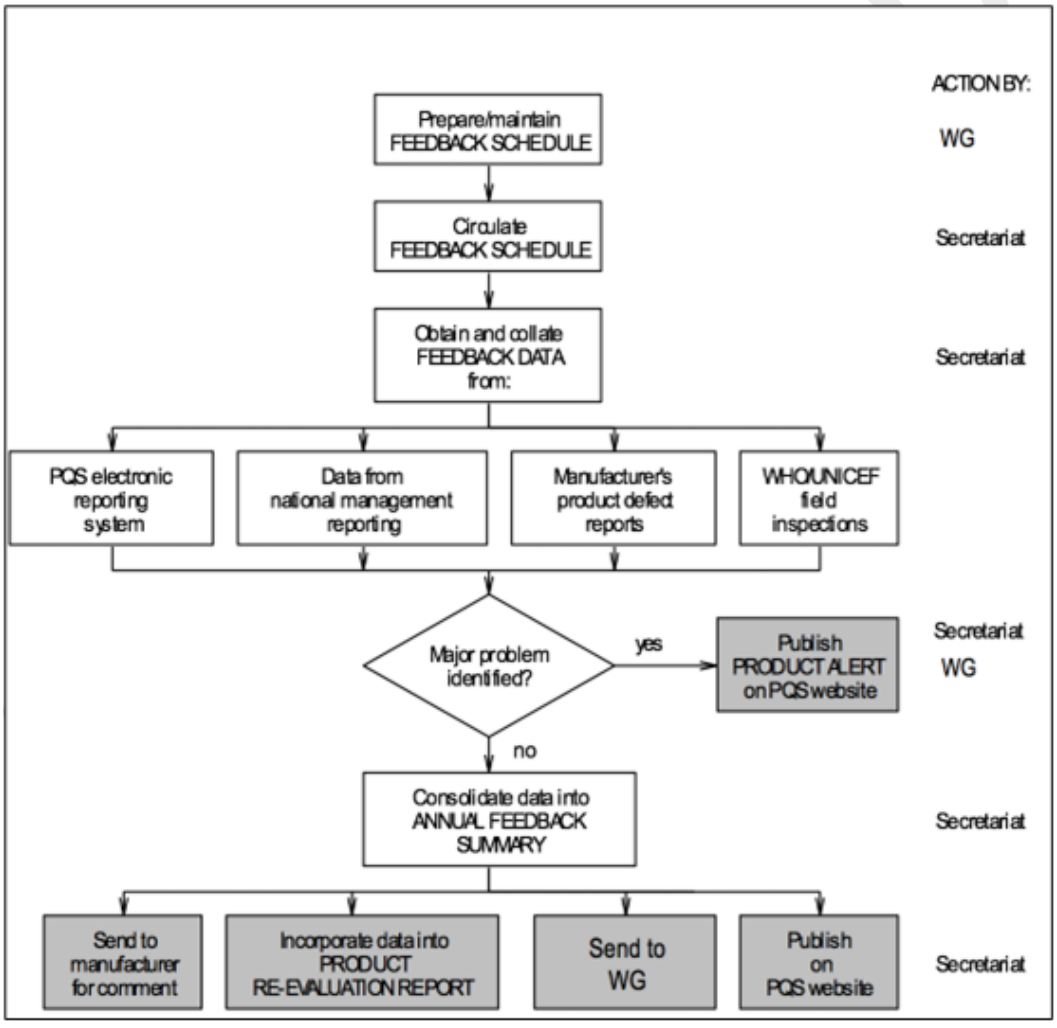
we have no visibility of – link into EPI MOH sources)	• Helps to build MoH management strength in depth. • MoH management may carry out analysis. • Data can be quantitative.	• Liaison needed with MoHs in order to collect data in a form that is useful to IMD-PQS.
Increase PQ feedback obligations	• Relatively cheap to operate. • Data can be quantitative.	• Desk exercise only
Annual Review	• Expand manufacturers product defect reporting to include zero reporting and analysis.	• Data can be quantitative.
Manufacturer's product defect reports	• No cost to IMD-PQS – part of prequalification conditions • Data most likely to be safety-related which may lead to product replacement or retrofit.	• None if properly implemented.
IMD-PQS Manufacturers meeting	• Face-to-face in-depth discussions	• None if properly implemented

Field inspections	• Targeted data collection method. • Data generally collected and analysed by specialists. • Data can be quantitative.	• May be expensive because generally administered by agency staff or consultants. • One-off or infrequent data source.
Mailshot/online survey questionnaire	• Cheap to administer.	• One-off or infrequent data source. • Respondents are a self-selecting. • No incentive to complete forms. • Questions may be misinterpreted. • Replies may be subjective, biased and incomplete. • Analysis and interpretation required before data are made available to other users.
Field-testing	• Can produce statistically reliable, quantitative results. • Able to capture multi-dimensional factors, including user behaviour.	• Can be time consuming and expensive to administer. • Dependent on skills and motivation of the survey team.

Sentinel Country monitoring and reporting	• Track equipment performance over time.	• None if properly implemented.

Figure 2 summarizes the procedure for identifying, collecting, collating and distributing data received from the various sources shown in Figure 1.

Figure 2 – Product feedback procedure streamline action and responsibilities



7. PROCESS STEPS

7.1. **Establish and maintain an electronic reporting system** (Secretariat)

7.1.1. The Secretariat establishes and maintains a web-based electronic reporting system to collect user feedback on the performance of IMD-PQS products: https://extranet.who.int/prequal/immunization-devices/post-market-monitoring.

7.1.2. The reporting system is used by WHO and UNICEF field staff and consultants. IMD/TP/13a shows the data entry format to be used.

7.1.3. The Secretarias and all others involved treat individual reports from non-UN users as confidential and moderate, collate and consolidate all data before releasing it to any third party.

7.2. **Prepare and maintain Feedback Schedule** (Secretariat)

7.2.1. The Secretariat identifies and maintains a schedule of management reporting indicators / essential feedback data for each IMD-PQS product category; this *Feedback Schedule* also identifies the various source(s) from which these data can be obtained, as described in Figure 1. In particular, the WG identifies a compact list of key indicators on product performance that can realistically be obtained from:

7.2.1.1. National management reporting systems; and/or

7.2.1.2. Routine field inspections that are regularly carried out by UN staff and consultants.

7.2.2. IMD/TP/13b provides a model format for the schedule.

7.3. **Circulate Feedback Schedule** (Secretariat)

7.3.1. The Secretariat circulates the completed *Feedback Schedule* to the WG for information and comment.

7.3.2. ***Management reporting indicators***

7.3.2.1. The Secretariat summarizes the key management reporting.

7.3.2.2. The Secretariat circulates the list to national programme managers in member countries and asks managers:

7.3.2.2.1. to collect and report data on these key indicators using their management reporting systems; and.

7.3.2.2.2. to encourage staff with internet access to post data on any product defects (performance and safety issues) that they observe whilst on duty in the field, as well as feedback on good performance.

7.3.3. ***Field inspection indicators***

7.3.3.1. The Secretariat summarizes the key field inspection indicators.

7.3.4. ***UNICEF and WHO offices***

7.3.4.1. The Secretariat contacts UNICEF and WHO regional and country offices with a request that field officers use the electronic reporting system to provide information on product defects observed during the course of their duties.

7.4. **Obtain and collate feedback data** (Secretariat)

7.4.1. The Secretariat monitors product performance data from all sources, including *product defect reports* received from product manufacturers.

7.4.2. Thes Secretariat moderates and collates these data as they are received and are then consolidates them into an *Annual Feedback Summary* which is distributed as follows:

7.4.2.1. Sent to the product manufacturer for comment;

7.4.2.2. Sent to the Working Group (WG) for information and action;

7.4.2.3. Included in the annual *Product Re-evaluation Report*[6]*;*

7.4.2.4. Published on the IMD-PQS website.

7.4.3. IMD/TP/13c provides a model layout for the summary.

7.5. **Publish Product Alerts** (Secretariat)

7.5.1. If a major problem with a specific product is identified at any time, the Secretariat consults with the WG and decides whether to post a *Product Alert* on the IMD-PQS website. In the circumstance that a product alert needs to be published, the IMD-PQS Secretariat issues the alert via the WHO Incidents and Substandard/Falsified Medical Products Team (ISF) alert system. In the circumstance that a Notice of Concern need to be issued, the IMD-PQS Secretariat refers to the procedure for identifying the need for, and for issuing a Notice of Concern, as described in INS/SOP/13 *Notice of Concern*.

7.5.2. In addition, the relevant product entry on the IMD-PQS database is overwritten with the words:

PRODUCT ALERT ISSUED ON <dd.mm.yy> REFER TO <link to the relevant Product Alert form>

7.5.3. IMD/TP/13d provides a model layout for a *Product Alert* form.

7.6. DISTRIBUTION

This SOP is distributed to the following individuals and groups:

- IMD-PQS Secretariat,
- IMD-PQS WG,
- RPQ ISF Team
- WHO Expanded Programme on Immunization (EPI),
- UNICEF Supply Division and UNICEF Programme Division,
- Each Technical Specialist commissioned to work on any aspect of the product prequalification process,
- All relevant manufacturers,
- IMD-PQS and TechNet-21 websites.

8. RECORDS

8.1. The Secretariat saves product performance register in WHO ePQS-Box / Sharepoint: Folder "Complaints".

8.2. The Secretariat saves product performance review schedule in WHO ePQS-Box / Sharepoint: Folder "PMM".

8.3. The Secretariat saves Annual Review dossiers in WHO ePQS-Box / Sharepoint: Folder "Annual Review <YEAR>" & "Annual Reviews".

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	1. ATT team was changed to QSS team due to the reorganization in the IVB Department. 2. The code VML was changed to IMD-PQS in the SOP No.s for easy reference. 3. The person responsible for giving no-objection clearance for the specifications was identified as the QSS Coordinator.	Drafted by O. Afsar Approved by U. Kartoğlu	06/01/2007
01	1. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 2. IMD-PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures). 3. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 4. Clause 7.6 'Distribution' edited to reflect new IMD-PQS system.	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

	5. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018.		
2	1. Updating to new RPQ format 2. New department, unit and team names 3. Changed supervisors name from Group Lead to Team Lead 4. Assignment of IMD as code for the product stream on PQ of immunization devices and equipment and used for numbering of QMS documents 5. Inclusion of KPIs and their targets where applicable 6. Transforming some annexes into templates related to the SOP 7. PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)	Approved by R. Gaspar	11/2024