World Health Organization

WHO PERFORMANCE, QUALITY & SAFETY

WHO IMD PQS
Immunization Cold Chain
Manufacturer Consultation

- 2023 –

November 30th
Video conference

Performance, Quality and Safety (PQS)
Vaccines Assessment Team (VAX)
Prequalification unit (PQ)
Regulation and Prequalification (RPQ)
World Health Organization

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Executive summary

On Monday 30th November 2023, the WHO Immunization Devices (IMD), Performance, Quality and Safety (PQS) team conducted its annual technical consultation with manufacturers of PQS-prequalified immunization products and devices from the E003 (Refrigerators and freezers) and E006 (Temperature Monitoring Devices) equipment categories. The meeting took place by videoconference Links to previous reports are available here:

- 2022 consultation https://www.technet-21.org/en/resources/report/who-pqs-immunization-cold-chain-manufacturer-consultation-2023
- 2021 consultation https://www.technet-21.org/en/knowledge-hub/main/16554
- 2020 consultation https://www.technet-21.org/en/library/main/7523
- 2019 consultation https://www.technet-21.org/en/library/main/6730
- 2018 consultation https://www.technet-21.org/en/library/main/4926

70 participants joined the consultation. Of the 70 participants this included industry representatives alongside non-industry members and partners of the WHO IMD PQS Working Group (*Annex 1*).

The purpose of the 2023 consultation was to present general IMD PQS progress updates; MFC commitment reminders; a deep-dive into Equipment Monitoring Systems (EMS) progress; and an update from partners (Gavi and UNICEF Supply Division):

1. Reminder on new E003 & E007 specification timelines
2. Introduction to the upcoming new Website and ePQS platform
3. Performance complaints & failures reporting
4. EMS update
5. Gavi & UNICEF SD update

The *2023 WHO IMD PQS Manufacturer Consultation* continued the trend of building efficiently on the highly successful first collaboration of 2018, and the annual consultations since. It remains a core element of the IMD PQS Annual Workplan for ensuring manufacturers remain up to date and integral to the IMD PQS standards development processes.

Background to WHO IMD PQS manufacturer engagement

The WHO IMD PQS mission is to lead the setting of performance, quality and safety standards for immunization equipment and devices, such that country immunization programmes, procurement agencies and product end users can be assured of the programmatic suitability and performance characteristics of WHO prequalified products. Central to this mission is the development and improvement of product specifications, product verification protocols and description of future desired product features (target product profiles, TPPs). Prior to 2018 manufacturers expressed a desire to have earlier and more substantive involvement in the PQS standard-setting process[1]. The 2018 consultation served as an initial forum to improve engagement with manufacturers, gather inputs on PQS standards and to signal new directions for TPPs. This (sixth) consultation was another important step in the ongoing work to drive greater engagement between WHO IMD PQS and manufacturers.

[1] This insight was collected via a summer-2017 McKinsey Management Review of the WHO PQS initiative and during the October 2017 TechNet-21 conference.

Consultation sessions

The general progress update and the topical sessions were each composed of a presenter-led introduction to the issues provided by a member of the WHO IMD PQS Working Group or a WHO IMD PQS Partner, along with a description of relevant action points, progress and key updates. After each presentation the discussion was open for participants to ask questions or provide input. Participants were also invited to any additional questions, comments or inputs in the Teams chat.

Annexes to this document include:

List of participating manufacturers – *Annex 1*

List of WHO IMD PQS and partner organization participants – *Annex 2*

Link to the conference presentations (.pdf) – *Annex 3*

I. PQS Updates: Specification timelines

In this session Dr. Isaac Gobina, WHO IMD PQS WHO Technical Officer, provided an update on the timelines for new product specifications implementation:

- *WHO IMD-PQS E003 Humidity control specification will be published in January 2024. As of publishing MFCs must test products according to this new specification, however it will NOT be mandatory.*
    - *The E003 Humidity control specification has previously benefited from test data from manufacturers which has been used to refine the specification.*
    - *WHO IMD PQS is open to the possibility of making this specification mandatory in future. In this eventuality there will be at least a two to three-year time for manufacturers to prepare for the transition.*
- *WHO IMD-PQS E007 Single phase voltage stabilizer specification WS01.6 will become a requirement to prequalify all new voltage stabilizers as of July 2024, and for all prequalified voltage stabilizers in July 2026 after a grandfathering period of two years.*
- *WHO IMD-PQS E003 Equipment Monitoring Systems (EMS) data logger specification WHO/PQS/E006/DL01.1 will be mandatory for any newly prequalified E003 ILR or SDD product as of January 2024, and for all prequalified E003 ILRs & SDDs. CCE that have Level 2 or 3 (described below) functionality in addition to data logger will also meet these requirements.*

Discussion

- No discussion

Action points from this session:

- *No action points.*

II. PQS Updates: Reminders MFC commitments

In this session Mr. Paul Mallins, WHO IMD PQS WHO Technical Officer, provided a reminder on manufacturer post-prequalification performance complaints, failures and product change reporting commitments:

- *WHO IMD-PQS acknowledges that the published guidance and instructions regarding manufacturer post-prequalification performance complaints, failures and product change reporting commitments is currently not as explicit as required. WHO IMD-PQS is close to concluding and publishing new Manufacturer Guidelines and new website content that will improve the communication around these commitments.*
- *Mr. Paul Mallins outlined the obligations of manufacturers and licensed resellers of PQS-prequalified products:*
    - *Prompt reporting of ALL performance complaints, failures and product changes (variations) are mandatory post-prequalification commitments*
    - *Manufacturers & resellers are obliged to report complaints, failures and product changes in real-time, throughout the period of prequalification, and to summarise them in the Annual Review*
- *Mr. Paul Mallins described that the performance reporting is crucial because it enables IMD PQS to identify areas to improve relevant IMD PQS product specifications, and therefore help improve equipment as per country needs. In addition, IMD PQS aims to work with manufacturers on their CAPA (corrective actions, preventative actions) processes to support in the resolution of performance issue and help lead to improved equipment. The aim is to ensure that country immunization programmes have complete and important information about products and equipment.*
- *Mr. Paul Mallins reminded manufacturers to also report any changes in product manufacturing processes in real-time.*

Discussion

- No discussion

Action points from this session:

- *No action points.*

III. PQS Updates: New Website & ePQS Portal

In this session Ms. Gemma Huckerby, WHO IMD PQS Communication Manager provided an overview of the upcoming launches of new communication and business process tools that will impact how all IMD PQS stakeholders, especially manufacturers and licensed resellers will interact with WHO IMD PQS.

- *Ms. Huckerby showed a snapshot of the new WHO Prequalification (PQT) web portal (common to all PQT divisions and the new ePQS (prequalification)) portal, and explained that IMD PQs stakeholders – including manufacturers – will benefit from an entirely*

redesigned and expanded website, plus the shift to the online, prequalification portal as of early 2024.
    - *Ms. Huckerby also showed screen shots of the new website and the ePQS portal*
- *Ms. Huckerby described the features and functionalities of the new website, notably better search and compare and online workflows, more comprehensive information, access pathways, stakeholder hubs and explanatory graphics, all designed for a better, more effective user-experience.*
- *Ms. Huckerby described how the new ePQS portal is both the site for all new prequalification applications workflows and post-prequalification commitments workflows, and is as well the source for the creation of the new data sheets and product catalogue that will be funneled to the new IMD PQS website. Data for existing prequalified products has been migrated over from the legacy IMD PQs database to the ePQS system.*
    - She informed the consultation participants that as of early 2024, when ePQS goes live, manufacturers will be required to review their new ePQS data sheets, to identify and omissions or errors. Detailed instructions will be provided at that time.
- *Ms Huckerby described that the benefits of collating and processing all these workflows, and associated communications and exchange of documents in one place will reduce possibilities of loss of information / multiple email exchanges, and will render the process smoother and more efficient.*
- *Ms Huckerby described how comprehensive technical guidance is being prepared for the transition to the ePQS portal; there is both general WHO guidance for all external users, and IMD-PQS has created IMD-specific guidance for manufacturers as well.*
- *Lastly, Ms. Huckerby explained that the general IMD PQS Manufacturer Guidelines have been revised and heavily updated, and that they will be launched in parallel to the new website and the ePQS portal. She showed a visual map of the new guidelines and its specific content elements, and explained that a parallel "pocket guide" has been created as a quick-reference.*

Discussion

- Carrier/Sensitech asked if WHO IMD PQS will continue to use email to communicate with manufacturers or will all communication be through the portal? Ms Huckerby replied that whilst all applications and post-Prequalification processes and document sharing will go through the website (wizard), and that the system will send emails with updates of pending actions and application updates, manufacturers can also still communicate on other items with PQS via email.
- MSupply asked whether the new database be available in an API format? Mr Gobina replied that, Yes, IMD PQS made that request to our IT colleagues as a core element to the website development, (ensuring external data transfer and integration with external systems).

Action points from this session:

- *In 2024 WHO IMD PQS to provide technical support/guidance to MFCs to ensure smooth transition to use of the new portal and for product sheet reviews.*

IV. Equipment Monitoring Systems (EMS) update

In this session Mr. Isaac Gobina, WHO IMD PQS Technical Officer provided a background on the EMS specifications and provided responses to EMS questions recently posed by manufacturers regarding specification and verification protocols, followed by Mr Rob Rallo who detailed the history of the EMS initiative and updates that have been made to the EMS specification and verification protocols.

- *Mr. Gobina reminded the group that the EMS specifications are intended as a measure to future-proof vital cold chain equipment, and that it has been a programme-led process, and well as a highly consultative process with manufacturers.*
- *He informed manufacturers that IMD-PQS has been coordinating with laboratories to ensure EMS testing readiness (including current testing of prototype devices (with the support of New Horizons)). Three laboratories are accredited to test E003 and E006, and IMD-PQs has reached out to onboard additional laboratories.*
- *Mr. Gobina informed the group that only single samples of a given electronics architecture needs to be tested, and that if existing prequalified CCE is updated with EMS, E003 tests will only need to be run on a case by case basis where changes could affect cooling. Full E003 re-testing is required only if: the controller is replaced, if the EMS system is providing control functions, or if the compressor is replaced.*
- *Mr. Gobina then discussed specific manufacturer feedback and questions that have recently been received during the 2023 TechNet conference. For full details see the consultation presentation (link Annex 3) slide 16. In summary: the M2M port is required; memory storage to reach one year of storage to be determined by the manufacturer; EMS device should not raise power consumption more than 5 Watts, no more than RTMDs; no specific brand of compressor is required; and humidity monitoring is optional in the specification.*
- *Mr Rallo then provided a on overview of the EMS specification E006/DS01.2 (data standards), E006/DL01.2 (data logger and M2M interface), and E006/EM01.2 (EMDs) – see presentation for full details, slides 17-19.*
- *Mr Rallo then described how there has been over 40 requests for edits/changes across the 7 specifications and VPs, of which 5 editorial, 18 clarifications and 20 minor changes. These changes have been implemented.*
- *Mr. Rallo concluded by explaining that one of the changes was to define the levels (see presentation for full details on levels 1 to 3, slide 23.*

Discussion

- No discussion

Action points from this session:

- *PQS to publish an EMS FAQ and EMS explainer documents to the website.*
- *IMD PQS to create a zip file with all the EMS documents, so MFCs may download them all at once. These documents will be update those as things change.*

V. Partner updates: Gavi & UNICEF Supply Division

In this session Ms Karuna Luthra of Gavi, and Mr Jacobus Schoevers of UNICEF Supply Division presented an update on status of Gavi and UNICEF's determination of their requirements for EMS, specifically the requirements from 2026 onwards, which is when the Gavi 6.0 strategic period will begin. Specifically they summarized the feedback received, the points of alignments and ongoing points of consideration.

- *Ms Luthra began by outlining the steps to land on EMS requirements for Gavi/UNICEF. Forums for aligning on a proposal include alliance partner discussions, country stakeholder feedback and ongoing supplier discussions. Remaining process steps include UNICEF RFI on pricing, review meetings between Gavi and UNICEF SD and PG, and communication from Gavi to the industry on final EMS requirements.*
- *Ms Luthra then went on to describe the technical areas with strong Gavi-UNICEF alignment as of end-October 2023, including principles and technical features and requirements. She noted that requirements will be finalized once results & implications from the ongoing UNICEF RFI are received and internal consultations held.*
- *Ms Luthra described how a new Market Shaping Roadmap is being developed for CCE Performance Monitoring Devices (PMDs), inclusive of 30-DTRs, RTDMs, and EMS. The proposed EMS-related objective being to effectively manage the launch of the EMS product market from January 2026 to ensure a healthy, competitive market with appropriate products / services that offers choice / flexibility to countries.*
- *Mr. Schroevers then went on to discuss options (still) being considered to achieve flexibility in EMS service providers for countries (UNICEF / Gavi's EMS Supplier consultations). He described how Gavi & UNICEF are aiming to preserve country choice and prevent them from being locked-in to a specific brand (fridge or EMD) when EMS rolls out, while minimizing / eliminating the funding of solutions that result in 'double monitoring' (e.g., duplication of hardware and subscription services**). Gavi holds a firm no 'double remote monitoring' position. See slide 5 for the full list of options currently retained for discussion.*
- *Mr. Schroevers detailed the key takeaways from Gavi – UNICEF meetings with E003 / E006 Suppliers regarding their EMS approach. Key points of supplier feedback included that the four options currently retained are technically feasible, that R&R for 'split' services subscription (e.g., option 3) need to be clear (technical, contracting, liability, etc.), that clarity requested on anticipated approach to bundling E-EMDs with fridges, that variance was noted in costs of hardware (all levels) and subscription services, and that humidity monitoring may be difficult though doable, but would add cost.*
- *Mr. Schroevers concluded by announcing that UNICEF issued a Request for Information (RFI) to all E003 and E006 suppliers currently on LTA with UNICEF, describing its components, and then outlining the next steps and key considerations for the Gavi-UNICEF position to be finalized. Key remaining steps include: UNICEF RFI on pricing of EMS configurations; review meeting(s) between Gavi and UNICEF SD & PG on final proposal (Dec 2023 / Jan 2024); and communication from Gavi/UNICEF to Industry on final EMS requirements (Q1 2024).*
- *The Gavi-UNICEF presentation as concluded with an update on the Gavi Cold Chain Equipment Optimization Platform (CCEOP) from Ms. Karuna Luthra, which detailed the CCEOP funded ILR/SDD forecast broken down by mains and SDD (Gavi 5.0 funding) ; the CCEOP Forecast for standalone RTMDs and 30-DTRs (Gavi 5.0 funding) ; and the list of 27 countries that plan to apply for CCEOP 5.0 funding in the next 18 months.*

Discussion

- *BMedical requested clarification on what is the difference between Level 2 and Level 3 if the manufacturer wishes to make the device remotely upgradable, given that it will mean that the device will require a modem and a subscription?*
    - *Mr. Schroevers replied that indeed Level 2 does not currently require remote transmission of data, but that the door is open to making this potentially a requirement in the future (remote activation). He noted that there is recognition that this comes with a cost implication for manufacturers. This is open to feedback from manufacturers. He noted that a possible solution could be to have a Level 3 device that functions like a Level 2, if the subscription is not activated.*
- *Mr. Schroevers described the intent behind the level classifications, noting that in many of the countries that will procure these devices, network connectivity may be an issue but that this may improve in future years; therefore they may not currently want a Level 3, but they may wish to be able to activate the functionality of their Level 2 to a 3 in future. Another scenario is that budgets may increase. Therefore should this potential requirement be implemented, the intention behind it will be to avoid future shipping/installation of new hardware.*
- *Mr. Toyobo asked whether, if a country procured a Level 2 from supplier A and they wanted to upgrade later on when that became a priority, Level 3, does that mean they don't necessarily need to opt for level three from that same supplier A, and they could go for level three from any other supplier?*
    - *Ms Luthra replied that there are multiple options: that ideally a country would know in the beginning which EMD they want if it's not the integrated option. She described how the overall aim is to provide countries with choice. In each case, depending on what the country is looking for, the pathway towards a Level 3 would depend on what equipment the country already had as a base.*
- *(Anon. chat) Will data sharing agreements ensure that fridge manufacturers are entitled to the data?*
    - *Mr. Schroevers replied that it is the aim to ensure that fridge suppliers will have access to their own fridge's data as well.*
- *(Anon. chat) Do you see any scenarios under which a Level 1 fridge would be procured? Do you have any visibility or insight into country preferences? If level 2 is required, might they all choose to buy the integrated Level 2 systems? If it is simpler because of no external component, this might lock out the level one only CCE manufacturers.*
    - *Ms Luthra responded that if Gavi makes it a requirement for level 2 to be the minimum, that does not preclude a non-Gavi country or a Gavi eligible country that's procuring with other funding sources to request a level 1 fridge from UNICEF. Secondly, the insight and visibility that Gavi has is primarily from feedback collected from countries. Thirdly, at this point Gavi's understanding is that country preferences seem more to be based on the actual product and the portal and the after-sale services that they're receiving from suppliers, rather than if the hardware is integrated or not integrated. Mr. Schroevers also noted that cost/price sensitivity of countries is a key decision factor.*
- *Gtek asked whether Gavi has ever considered the mobile application in place of a Level 3 alternative or EEMD alternative?*
    - *Mr. Schroevers replied that, they do know that there is work ongoing, although very preliminary, with some partners to look at how data could be accessed from*

a Level 1 only EMS system and have that synced up with external systems. This would be similar to current systems that are able to pull data from 30-day temperature recorders and to sync that data up to a cloud server where it can be analysed.

- *Beyond Wireless commented that their current plan is develop a single device that addresses both Level 1, 2 and 3 with the option of the M2M interface. They noted that optionality, preventing lock-in etc. is important, but that this would reduce scale and increase complexity, which ultimately increases price. In addition, in a scenario where a manufacturer of a Level 3 device uses it as a Level 2 (without full service), this would pose challenges for the manufacturer around how to generate the recurring revenue stream associated with the subscription".*

Action points from this session:

- *Gavi and UNICEF to inform manufacturers on what level(s) of EMS will be eligible in Q1 2024.*

ANNEXES

Annex 1: List of manufacturers that participated in the event

Manufacturers that participated in the meeting, in alphabetical order:

Berlinger & Co. AG
Blulog
B Medical Systems
Beyond Wireless
Carrier (Sensitech Inc.)
Coolfinity
Deltatrak Inc.
Dubai Instruments
Dulas Ltd.
Elpro-Buchs
Godrej & Boyce MFG. Co. Ltd.
Gtek
Haier Biomedical
Ikhaya Automation Systems
Nexleaf Analytics
Parsyl
Solar 23 (representatives of Aucma)
Surechill
The mSupply Foundation
Vestfrost Solutions
Western Equipments
Temptime Corporation (Zebra Techs. Co.)

Annex 2: List WHO PQS and partner organization participants

Representatives of the WHO PQS Working Group & other non-industry attendees were, in alphabetical order:

Brian Pal – New Horizons
David Elliot – Pole Star Cooling
Dominic Hein – Gavi, the Vaccine Alliance
Eugene Adu Afari – Gavi, the Vaccine Alliance
Gemma Huckerby – Consultant to WHO PQS
Greg Kiluva – Independent Expert
Isaac Gobina – WHO PQS Technical Officer
Jacobus Schoevers - UNICEF Supply Division
Jalia Nanfuka – Gavi, the Vaccine Alliance
Jan Komrska – UNICEF
Jean-Baptiste Certain - SELF
Jenny Hu – New Horizons
Joanie Robertson – PATH
Joyce Joan Munga – UNICEF Supply Division
Karuna Luthra – Gavi, the Vaccine Alliance
Kelly Hamblin - The Gates Foundation
Lauren Goodman – WHO PQS Project Manager
Matt Morio – PATH
Omileye Toyobo – Clinton Health Access Initiative (CHAI)
Paul Mallins – WHO PQS Technical Officer
Rob Rallo – Solar System Services
Simon Leach – White Box Thinking
Teshome Yemamu – UNICEF Supply Division
Thierry Copois – UNICEF Supply Division
Thomas Sorensen – UNICEF Supply Division

Annex 3: Meeting presentations

The consolidated presentations for the PQS progress update and the technical themes can be accessed here:

https://drive.google.com/drive/folders/1QlePImDJ7Mq_XPBmU9X3ChkNeCnwBlJl