World Health Organization

PERFORMANCE QUALITY SAFETY

WHO PQS Immunization Cold Chain Manufacturer Consultation

- 2019 –

September 4
Geneva, Switzerland

Executive summary

On Wednesday 4th September 2019, the WHO Performance, Quality and Safety (PQS) Working Group 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 virtually by teleconference and was the first follow-up to the July 2018 face-to-face consultation. A link to the 2018 consultation report can be found here: https://www.technet-21.org/en/library/main/4926. Over 40 participants joined the teleconference, including industry representatives alongside non-industry members and partners of the WHO PQS Working Group (see *Annex 1*).

The purpose of the 2019 consultation was to present PQS' progress on the 2018 consultation action points to manufacturers and update them on next steps. The 2019 teleconference included updates on the prevailing technical themes discussed in the 2018 consultation, and it was organised as follows:

I. PQS progress report and updates on ten topics:

1. Open CCE data standards
2. Equipment monitoring systems
3. Humidity control TPP for ILRs & SDDs
4. Upcoming ILR and SDD TPPs
5. Energy harvesting control
6. Retroactive PQS requirements & CCE grandfathering
7. CCE post-market monitoring
8. Quality management systems inspections
9. CCE barcodes
10. Process for prequalifying products and devices

II. In addition, the 2019 consultation included:

1. Overview of the PQS 2019-2023 strategy,
2. Update on the Gavi cold chain equipment optimization platform, and
3. Update on progress towards accreditation of new product testing laboratories.

The *2019 WHO PQS Manufacturer Teleconference* built efficiently on the highly successful first step collaboration of 2018, ensuring manufacturers remain up to date and integral to the PQS process of standards-review and standards-setting.

Background to WHO PQS manufacturer engagement

The WHO PQS mission is to lead the enforcement and setting of performance, quality and safety standards for immunization products and devices, such that procurement agents and product end users can be assured of the adequate and appropriate characteristics of WHO prequalified products. Central to this mission is the development and improvement of product specifications, product testing protocols and description of future desired product features (`target product profiles`). Prior to the 2018 consultation, manufacturers usually provided inputs on PQS standards via ad-hoc electronic reviews of specifications, protocols or target product profiles. However, manufacturers expressed a desire to have earlier and more substantive

involvement in the PQS standard-setting process[1]. This consultation was an important step in continuing greater engagement between WHO PQS and manufacturers.

Consultation sessions

The ten topical sessions were each composed of a presenter-led introduction to the issues provided by a member of the WHO PQS Working Group, along with a description of the 2018 action point, progress and key updates. In many cases, a direct question related to the topic was put to manufacturers via MentiMeter[2] in order to gather their input and/or feedback on future action items. Participants were also invited to submit any additional questions or comments (anonymously) via MentiMeter.

Annexes to this document include:

Link to the thematic presentations (pdf) – *Annex 2*

Action items and decisions from each of the thematic presentations – *Annex 3*. They are also described in the session summaries below.

A list of manufacturers' responses to MentiMeter questions - *Annex 4a*.

[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.

[2] A software programme accessible to participants via their laptop or smartphone that allows anonymous questions or suggestions to be submitted to the session presenter in real time. It also enables voting/polling of participants on specific questions posed by the presenters.

I. PQS PROGRESS REPORT & UPDATES

1. CCE data standards: Improving data interoperability and use

In this session Mr. Isaac Gobina, PQS Technical Officer and PQS Working Group Chair, noted that PQS has completed and shared with manufacturers CCE data standards performance specifications and a verification protocol. The goal of CCE data standards is to promote real-time performance reporting and provide better overall performance visibility through integration into common management information systems and dashboards (e.g. open LMIS, DHIS2, IMPT[3]). Mr. Gobina also noted that manufacturers' review of these documents is in progress, as is therefore PQS' finalisation of the standards for publication and adoption, which will be completed by Q1 2020.

Discussion

- The Chair was asked whether PQS would consider establishing a working group for the CCE data standards that includes industry representatives. Mr. Gobina said this request will be considered and a decision made based on the feedback that will be provided by manufacturers as a first step.

Decision points from this session:
The standards remain planned for publication and adoption for Q1 2021

Action points from this session:

- *PQS to (re)send the standards to participating manufacturers to facilitate their feedback.*
- *PQS Working group to finalize standards by Q4 of 2019.*

2. Equipment monitoring systems (EMS)

Mr. Steve DeSandis, independent member of the PQS Working Group, provided an update on the standards for equipment monitoring systems (EMS), following the need established via a 2018 survey of RTMD manufacturers and users. Mr. DeSandis noted that the PQS group has deployed a Technology Memo *to elicit manufacturer feedback on EMS, and has received eight responses. He also noted that current device categories for 30-day temperature recorder (30 DTR) and Remote Temperature Monitoring Devices (RTMDs) will continue to be valid once an EMS category is created. Mr. DeSandis also noted that PQS is on track to draft and share EMS specifications and a verification protocol with manufacturers by Q4 2019, aiming to finalize EMS standards by Q1 2020. He noted that updates to these specifications based on Target Product Profile (TPP) for temperature monitoring devices (TMDs) will follow to enable EMS functionalities.*

[3] Intelligent Maintenance and Procurement Tool

Discussion

- Mr. DeSandis provided further description on the intention behind the Technology Memo that is meant to address the need for a more flexible and focused approach on TMD functionalities. The Memo explores new approaches with machine-to-machine interfaces and interoperable devices.
- Mr. DeSandis noted that manufacturers who have not yet provided feedback on the Memo can still do so if they wish.

Decision points from this session:
None.

Action points from this session:

- *PQS to (re)send the memo to participating manufacturers to facilitate their feedback.*
- *PQS Working Group to share draft specifications and a verification protocol with manufacturers by Q4 2019.*
- *PQS Working Group to finalize and publish performance specifications and a verification protocol by Q1 2020.*

3. Humidity Control target product profiles for ILRs and SDDs

In this session Mr. Steve DeSandis provided an update on the progress in revising a Humidity Control TPP for ice-lined refrigerators (ILRs) and solar direct-drive (SDD) refrigerators. These revisions are in response to vaccine refrigeration challenges caused by humidity and condensation (e.g. damage to vaccine labels, packaging and growth of mould) which have been observed in the field and were presented at the 2018 WHO PQS Manufacturer Consultation. He explained that PQS has now started to more rigorously enforce requirements for drains and compartment grates/routing/baskets, and that the PQS Working Group has shared a revised TPP with manufacturers for their feedback, although this feedback has been limited to only two responses so far. Mr. DeSandis noted that the PQS Working Group is currently revising the draft TPP based on the feedback received, and is on track to provide a final TPP for Humidity Control (as a part of ILR & SDD TPP revision) by Q1 2020. Lastly, he asked attended whether they would be prepared to provide an addition round of feedback on the TPP.

Discussion

- Mr. DeSandis underscored the extent and importance of the current humidity issues facing PQS device users. He acknowledged there are important implications for manufacturers in addressing and eliminating these issues, however.
- He stated that, due to the impact of the issue on vaccine potency, this TPP is of higher importance than others at the current time.
- In response to a manufacturer question, Mr. DeSandis also clarified that, whilst humidity control is the subject of this draft TPP, condensation control (drainage) is already a part of the current specification.
- All of the 13 participants who responded via MentiMeter confirmed that they would be prepared to submit an additional round of feedback on the Humidity Control TPP.

Decision points from this session:
A second round of feedback to be solicited from manufacturers on the draft TPP.

Action points from this session:

- *PQS Working Group to share with suppliers a revised TPP and responses to supplier feedback on first version of TPP.*
- *PQS to incorporate finalized TPP for Humidity Control as part of ILR & SDD TPP revision due to be released to suppliers in Q1 2020.*

4. Upcoming ILR and SDD target product profiles

Mr. Omileye Toyobo of the Clinton Health Access Fund (CHAI) was unable to present on this topic during the consultation due to technical issues.

The content of the written update is as follows. Mr. Toyobo described the PQS Working Groups' current revisions to TPPs for ILRs and SDDs, with a draft publication expected in Q1 2020 for manufacturer feedback. This topic was not discussed at the 2018 consultation and therefore does not have specific action points to address. In his note, Mr. Toyobo explained the current PQS approach to survey Country EPI programmes in order to acquire a systematic understanding of programme needs and country preferences, and the benefits of this approach. He also explained how PQS will, as a next step, prioritize the different product attributes and recommendation for inclusion in TPPs and work out their indicative timelines for inclusion in future specifications. He announced that a specific industry consultation will be organised as a part of the next steps to garner their inputs.

Discussion

- In response to the written question, out of the five respondents there was some support for providing feedback via document review and online surveys, and slightly less support for via teleconference.

Decision points from this session:
N/a

Action points from this session:

- *PQS working group to categorize the latest product attributes and recommendations being proposed for inclusion as future TPPs; with different indicative timelines for these future TPPs to be incorporated as mandatory specifications.*
- *PQS working group to organize an industry consultation in order to gain manufacturer feedback and inputs.*

5. Energy harvesting control: test options & user guidance

Mr. Steve McCarney, independent member of the PQS Working Group, provided an update on the work in progress to test EHC options and to develop EHC-user guidance. Mr. McCarney notably informed that manufacturers will be supported by PQS to undertake field testing of a range of load kit options and to identify associated opportunities. He explained that the first and second rounds of technical and financial support to manufacturers are already underway, through the Gavi-supported, PATH-managed project with technical support from Sunny Day LLC. This plan of action is informed in part by manufacturer inputs during the 2018 PQS consultation that indicated technical and market readiness as well as cost of testing to be a key barrier to the faster development of these technologies. Mr. McCarney also confirmed that the PQS Working Group is developing EHC-user guidance (a range of technical documents) which will be made available in the coming months. These guidance documents will serve as aids to potential users of EHC to comprehensively understand use-cases. In addition, the E007 section of the PQS device catalogue is under revision to include a list of prequalified EHC accessories and corresponding SDD devices approved for energy harvesting. Mr. McCarney concluded by asking participants what the most important technical support tools to inform buyers of EHC might be.

Discussion

- Mr. McCarney noted that there is now evidence that it is safe to harvest excess energy from SDD devices. In addition, to ensure vaccine safety, PQS prequalifies only specific combinations of a given SDD and EHC device. Moreover, field tests are required in addition to laboratory tests for prequalification of the combinations. Field testing places an onerous financial burden on manufacturers, and so – thanks to manufacturer input in the 2018 consultation – financial support is now available from Gavi for field testing.
- Mr. McCarney revealed to participants that three manufacturers have already been approved and three more devices are soon to be tested in Senegal. Additionally, one other manufacturer was selected in the first round of support, bringing the total number of manufacturers participating to four and the total number of different EHC/SDD combinations to six.
- Mr. McCarney described that user guidance is adding complexity because of the variety of equipment and user energy harvesting needs across countries. PATH is currently working to assess sites and understand the technical assessment that an installer needs to consider.
- One participant requested that Mr. McCarney share his insights from the Senegal study on use cases and experience from users. Mr. McCarney responded that, in general, the appetite for energy is more than what a typical solar array can provide. Some sites have received poor donations of electrical devices that have no power and determining if and how to utilize this equipment is challenging since it varies widely in type, voltage and condition.
- In response to the question put to participants (what might be the most important technical support tools to inform buyers of EHC?) participants were most strongly in favor or buyer guidance, and less so of a general factsheet. Two participants also suggested ‘market demand information’ and total cost of ownership (TCO) analysis.

Decision points from this session:
None.

Action points from this session:

- *PQS and Gavi to continue to support manufacturers field evaluate new technologies.*
- *PQS Working Group to continue developing EHC-user guidance that will be shared with manufacturers in the coming months.*
- *PQS Working Group to continue to engage with users and potential users of EHC to comprehensively understand use-cases.*

6. Retroactive PQS requirements and CCE grandfathering

In this session Mr. Isaac Gobina provided an update on the work in process to update relevant product standards with the new "grandfathering" time-limit, established at two years following manufacturer inputs during the 2018 PQS consultation. He noted that a relevant clause will be incorporated into all the specification documents by Q4 2019 and will go into force in January 2020. Mr. Gobina described a retro-active requirement as a change in a specification that will need to apply to products that were prequalified under the previous version of the specification.

Discussion

- None.

Decision points from this session:
None.

Action points from this session:

- *PQS Working Group to continue to update relevant standards based on decision to establish the new "grandfathering" time-limit at two years.*

7. CCE post-market monitoring (PMM)

Mr. Isaac Gobina provided an update on the project to put in place a complete post-market monitoring (PMM) system for CCE, as discussed at the 2018 PQS consultation. He noted that the PQS Working Group has completed a concept note on the opportunities and challenges of 'Sentinel surveillance' of CCE as a means of ensuring PMM, and that a pilot of the 'Sentinel Surveillance' project has been rolled out as of summer 2019, in collaboration with partner organizations and Ministries of Health in four countries. Mr. Gobina recalled that the goal of the PMM system is to enable timelier corrective and preventive action leading to improved CCE performance.

Discussion

- Mr. Gobina provided further details on the pilot, namely: the four countries are DRC, Bangladesh, Pakistan and Haiti. Sentinel officers will be empowered in each of these countries and they will carry out monthly reporting on a set of pre-defined CCE.
- Mr. Gobina noted that the data is owned by the Government of each country, and shared with the WHO. He explained that PMM data will be maintained with the highest level of confidentiality and only shared once PQS has analysed it.
- Root cause failure analyses (RCFAs) will be carried out locally to explore every failure – and whether it was human or device/technical failure.
- One participant asked if they have KPIs that can be shared with them. Mr. Gobina replied that indeed KPIs will be available to manufacturers in one month from the date of this consultation.

Decision points from this session:
None.

Action points from this session:

- *PQS Secretariat and PMM Working Group to continue the roll out of the pilot studies and the analysis of data.*

8. Quality management system (QMS) inspections

Mr. Isaac Gobina provided key updates on QMS inspections, notably that routine Quality Management System (QMS) inspections are planned to begin in Q4 2019, on a cost recovery basis and in alignment with standard practices of other WHO prequalification streams and certification norms. Mr. Gobina noted that, for CCE QMS inspections a typical Inspection Team would consist of three; a QMS expert, a technical expert and a WHO PQ representative. WHO PQ has a dedicated in-house Inspection Group, plus a roster of consultant Inspectors, from which these roles can be filled.

Discussion

- Mr. Gobina noted that the QMS audits of manufacturing sites will begin with PQS category E003, before moving on to other categories.
- One participant asked if manufacturers will be able to input on the SOP for QMS inspections? Mr. Gobina noted that, as they will be the same as other PQ product streams by definition, then they will not be open for external consultation and input. However, they will be available for view once approved.
- A second participant asked who will be responsible for covering the financial costs of these inspections? Mr. Gobina responded by confirming that the inspections will be carried out on a cost recovery basis and in alignment with standard practices of other WHO prequalification streams and certification norms.

Decision points from this session:
None.

Action points from this session:

- *PQS Secretariat to publish the QMS inspections SOP externally once it is completed.*

9. CCE barcodes

Mr. Pat Lennon, representative of PATH to the PQS Working Group, updated participants on the progress to develop specifications for CCE barcodes, as discussed during the 2018 PQS consultation. He noted that the specification for asset tags has been completed and is available to manufacturers online on the PQS website. Mr. Lennon also noted that, in response to manufacturer input in the 2018 consultation, the PQS Working Group has re-reviewed possibility to allow 2D vs. GS1-128 format barcodes. Lastly, he noted that the asset tag requirements are currently being incorporated into E003 equipment specifications.

Discussion

- When polled on whether a Q1 2020 deadline for manufacturers to include asset tags on new CCE is achievable, participating manufacturers responded for the most part that sometime early/mid 2021 way achievable; However, some manufacturers stated that only sometime in 2021 was achievable. As a result, it was decided to set the target deadline at Q2 2020.

Decision points from this session:
Asset tag requirement roll-in set for Q1 2021

Action points from this session:

- *None.*

10. Process for prequalifying products and devices

This topic was not discussed in the consultation. Rather, Mr. Isaac Gobina included a written update in the consultation presentation deck.

The written update informed participants that the PQS Working Group is currently monitoring laboratory testing requirements' impact on application timelines; which manufacturers identified as being the cause of the greatest bottleneck in the prequalification process for them during the 2018 PQS Consultation. However, the parallel project to review the generic field protocol and identify opportunities to improve guidance to manufacturers is delayed. Mr. Gobina explained that the review will necessitate a specific protocol tailored to each category.

Discussion

- N/a

Decision points from this session:
N/a

Action points from this session:

- *PQS Working Group to continue to monitor laboratory testing requirements' impact on application timelines.*
- *PQS Working Group to review generic field protocol to identify opportunities to improve guidance to manufacturers, with a new timeline to be established taking into account the additional scope.*

II. WHO PQS STRATEGY 2019-2023

Mr. Isaac Gobina provided an overview of the recently developed 2019 – 2023 WHO PQS Strategy. Mr. Gobina also highlighted the 2020 PQS goals and PQS Working Group workplan that will be working towards: guaranteeing consistent post-market monitoring, strengthening quality management systems, streamlining prequalification processes, improving communication and transparency, increasing stakeholder engagement in standard setting and increasing laboratory testing capacity.

Discussion

- When polled, the participating manufacturers indicated a preference to receive future strategy updates on the PQS process and quality management systems (QMS), and an interest in strategy updates on sentinel surveillance, laboratory accreditation, PQS standards pipeline, and future engagement opportunities with PQS.

Decision points from this session:
None.

Action points from this session:

- *PQS Secretariat to share strategy progress updates based on manufacturers' feedback.*

III. GAVI COLD CHAIN EQUIPMENT OPTIMIZATION PLATFORM UPDATE

Ms. Karuna Luthra of the Gavi Market Shaping team and representative to the PQS Working Group provided an update on the Gavi cold chain equipment optimization platform (CCEOP). The update included a recap of the goals and objectives of the CCEOP and its effect of better protecting vaccine potency, as well as the progress on procurement, deployment and demand forecasting. Thereafter she presented an update on the Gavi ILR/SDD market-shaping Roadmap action plan for 2019 *and the new* Healthy Markets Framework*. The link to the full Gavi presentation is available here:* https://drive.google.com/open?id=1U1dRjE5GXSXZzEXHiK0zWr1QJbMIhMMV*. Lastly, Ms. Luthra opened the discussion to comments or questions from participating manufacturers on the trial of de-linking the service bundle from the purchase of equipment, or other procurement changes (objective three of the 2019 Roadmap). Mr. Luthra also asked participants to provide their input on what information may be useful on objective four – the innovation driven by country preferences and future TPPs – to facilitate future discussions with Gavi and/or UNICEF Supply Division.*

Discussion

- Regarding the question posed by Ms. Luthra - what information would be helpful to facilitate discussions on innovation – participants indicated that guidance on how TPPs will be selected by Gavi would be valuable. Ms. Luthra noted that the Gavi Policy and Programme Committee (PPC) will most likely be responsible for this as a part of the CCEOP

review. Moreover, UNICEF Supply Division will hold a consultation in Q1 2020 to discuss this topic amongst others.

- One participant requested further information on the current ongoing pilots for de-linking the service bundle from product procurement. Ms. Luthra described how a set of countries will be running pilots. She notes that Gavi and Alliance partners have developed a set of protocols that can assess if a country is qualified to do a pilot. A subset of countries, i.e. some of the fragile countries such as Yemen, and accelerated transition countries such as Laos and Vietnam, will test out the model. Gavi aims to limit the number of countries due to the associated administrative burden.
- Another participant asked how warranties will be managed in the case of de-linking? Ms. Luthra deferred to a response from UNICEF Supply Division, but this representative was unable to address the question due to technical issues.
- A third participant asked whether de-linking means that the service bundle would then be linked to all types of equipment under a single service bundle? And if yes, for how many years? Ms. Luthra answered yes, in theory, but the details and duration(s) are still to be defined.

Decision points from this session:
None.

Action points from this session:

- *None*

IV. WHO PQS ACCREDITATION OF NEW TESTING LABORATORIES

Mr. Simon Leach, independent member of the PQS Working Group, was unable to present on this topic during the consultation due to technical issues.

Mr. Leach's written presentation introduced this new topic. He noted that in 2019 at least 334 PQS-approved products - of which 21 were newly listed – required a test-laboratory report in their dossier submission. He contrasted this with the fact that there are currently only 14 listed PQS labs, of which 9 alone are active and they are concentrated in North America, Europe and Asia. Following the suggestion of manufacturers, 11 new laboratories have been contacted about the possibility to apply for PQS accreditation. Additional PQS-accredited laboratories could deliver a greater range of expertise across PQs categories, and more convenience for some manufacturers.

Discussion

- N/a

Decision points from this session:
N/a

Action points from this session:

- *Applications from new test laboratories are currently under consideration. Outcomes of this process will be announced at the next PQS consultation.*

Closing remarks

The meeting was rounded off by **Mr. Isaac Gobina** who addressed thanks to the industry representatives present. He noted that, based on the success of this meeting, the *PQS Manufacturer Consultation* will continue to be repeated annually moving forwards. Participant evaluations, presented in Annex 4b, suggest that manufacturers have a high level of interest to receive information on the PQS strategy, prequalification dossier status, updates on specifications, technology presentations from peers at the next consultation, and a moderate level of interest to receive information on how to use PQS tools.

Mr. Gobina also noted that the PQS Working Group hopes to see ongoing productive engagement with manufacturers continue between the annual consultations. Lastly, Mr. Gobina informed manufacturers present that the various decisions and action items that have been reached during the meeting would be further addressed and discussed by the PQS Working Group.

Lastly, an upcoming webinar to introduce the new CCE area on TechNet-21 was announced and manufacturers were invited to attend. The new CCE area aims to provide comprehensive information about WHO PQS-prequalified CCE products. The webinar will take place in October 2019.

ANNEXES

Annex 1a: List of manufacturers participating in the meeting that self-identified

Manufacturers that participated in the meeting, in alphabetical order:

B Medical Systems
Berlinger & Co AG
Beyond Wireless
Blulog
Controllant
Dulas Ltd
ELPRO
Haier
Minus40
NexLeaf Analytics
Parsyl
SureChill
SunDanzer
Sensitech
Vestfrost
Zero Medical Systems

Annex 1b: List WHO PQS and partner organization participants

Representatives of the WHO PQS Working Group that participated were:

Isaac Gobina – WHO PQS
Pat Lennon – PATH
Joanie Robertson - PATH
Matt Morio - PATH
Denise Habimana – PATH
Edda Magnus - PATH
Steve McCarney – Sunny Day, LLC
Steve DeSandis – Independent Expert
Omileye Toyobo – Clinton Health Access Initiative (CHAI)
Sezgi Akcay – UNICEF Supply Division
Hamadou Dicko - Gavi, the Vaccine Alliance
Karuna Luthra – Gavi, the Vaccine Alliance
Simon Leach – Independent Expert

Additional non-industry participants included:

Kelly Hamblin – Bill & Melinda Gates Foundation
Dr. Guo Zihong – Global Good
Thomas Sorensen – Chief, Immunization, UNICEF Supply Division
Gemma Huckerby – Consultant to WHO PQS

Annex 2: Meeting presentations

The presentation given for each of the ten technical themes can be accessed https://drive.google.com/open?id=1U1dRjE5GXSXZzEXHiK0zWr1QJbMIhMMV.

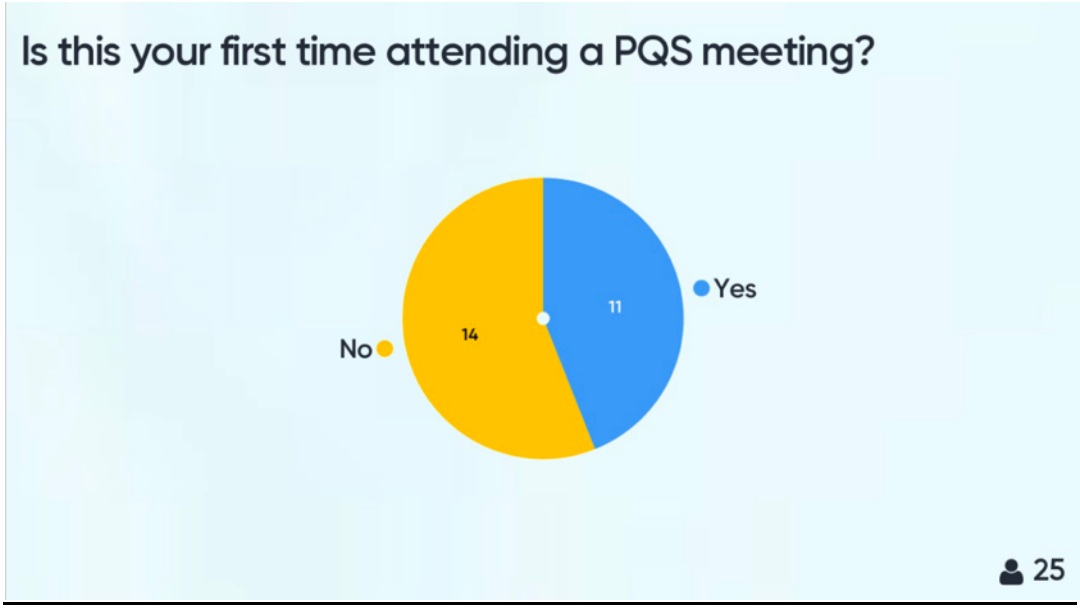
Annex 3: Consultation outcomes - Decision points & action points

Session	Decision points	Action points
Open CCE data standards	The standards remain planned for publication and adoption for Q1 2020.	PQS to (re)send the standards to participating manufacturers to facilitate their feedback.
		PQS Working Group to finalize standards by Q4 of 2019.
Equipment monitoring systems	None.	PQS Secretariat to (re)send the memo to participating manufacturers to facilitate their feedback.
		PQS Working Group to share draft specifications and a verification protocol with manufacturers by Q3 2019.
		PQS Working Group to finalize and publish performance specifications and a verification protocol by Q4 2019.
Humidity control TPP for ILRs & SDDs	A second round of feedback to be solicited from manufacturers on the draft TPP.	PQS Working Group to share with suppliers a revised TPP and responses to supplier feedback on first version of TPP.
		PQS to incorporate finalized TPP for Humidity Control as part of ILR & SDD TPP revision due to be released to suppliers in Q1 2020
Upcoming ILR and SDD TPPs	N/a	PQS Working Group to categorize the latest product attributes and recommendations being proposed for inclusion as future TPPs; with different indicative timelines for these future TPPs to be incorporated as mandatory specifications.
		PQS Working Group to organize an industry consultation in order to gain manufacturer feedback and inputs
Energy harvesting control	None.	PQS and Gavi to continue to support manufacturers to field evaluate new technologies.
		PQS Working Group to continue developing EHC-user guidance that will be shared with manufacturers in the coming months.
		PQS Working Group to continue to engage with users and potential users of EHC to comprehensively understand use-cases.

Retroactive PQS requirements & CCE grandfathering	None.	PQS Working Group to continue to update relevant standards based on decision to establish the new "grandfathering" time-limit at two years
CCE post-market monitoring	None.	PQS Secretariat and PMM Working Group to continue the roll out of the pilot studies and the analysis of data.
Quality management systems inspections	None.	PQS Secretariat to publish the QMS inspections SOP externally once it is completed.
CCE barcodes	Asset tag requirement roll-in set for Q1 2021.	None.
Process for prequalifying CCE	N/a	PQS Working Group to continue to monitor laboratory testing requirements' impact on application timelines. PQS Working Group to review generic field protocol to identify opportunities to improve guidance to manufacturers, with a new timeline to be established considering the additional scope.
Overview of the PQS 2019-2023 strategy	None.	PQS Secretariat to share strategy progress updates based on manufacturers' feedback.
Update on the Gavi cold chain equipment optimization platform	None.	None.
Update on progress towards accreditation of new product testing laboratories	N/a	Applications from new test laboratories are currently under consideration. Outcomes of this process will be announced at the next PQS consultation.

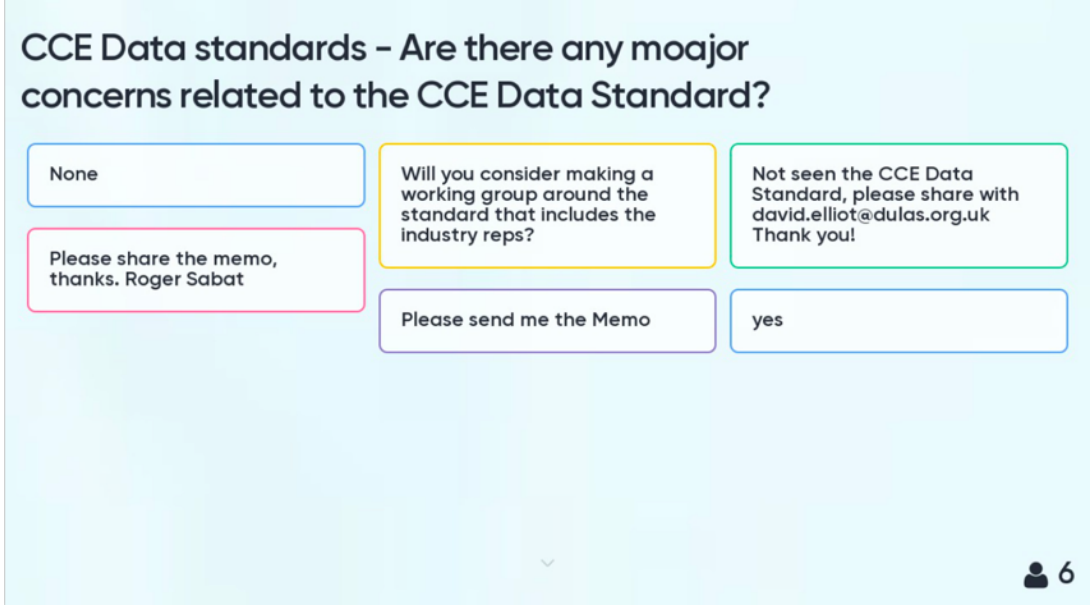
Annex 4a: MentiMeter manufacturer responses to PQS questions`

Note: PQS presenters' responses to these questions posed by participants are discussed in the respective sections of the main body of this report.



I. Progress report and updates

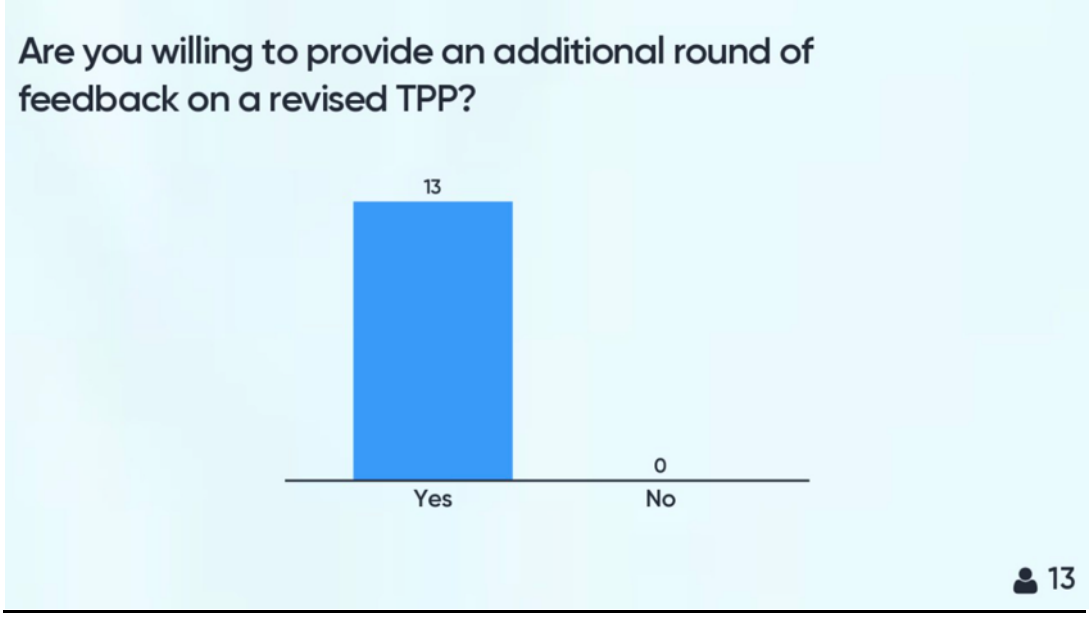
1. CCE data standards: Improving data interoperability and use



2. Equipment monitoring systems

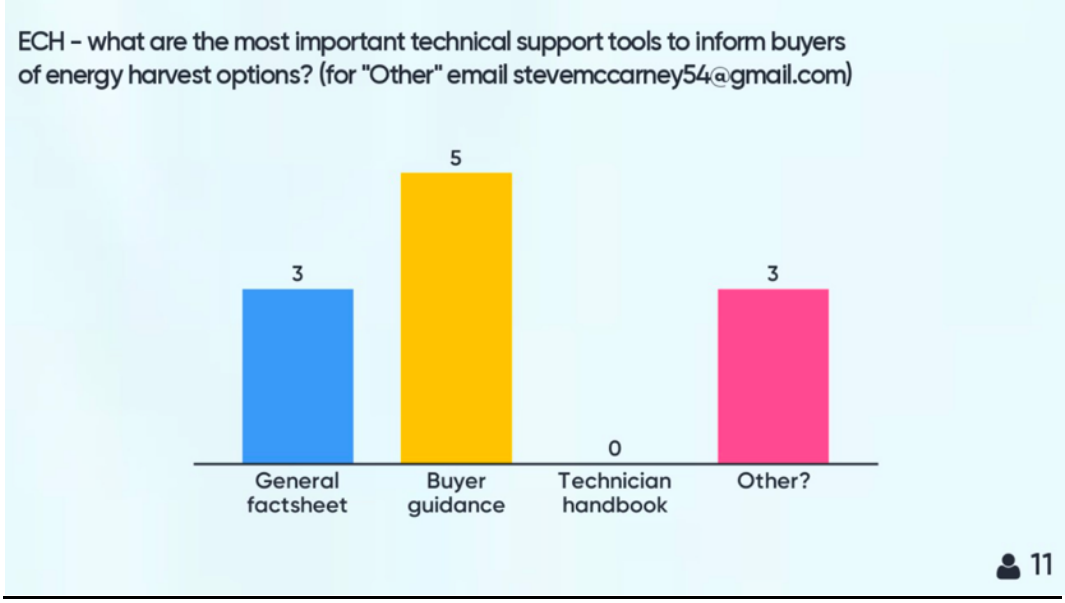
   No responses

3. Humidity control TPP for ILR & SDDs



4. Upcoming ILR & SDD target product profiles

5. Energy harvesting test options and user guidance



6. Retroactive PQS requirements and CCE grandfathering

   No question

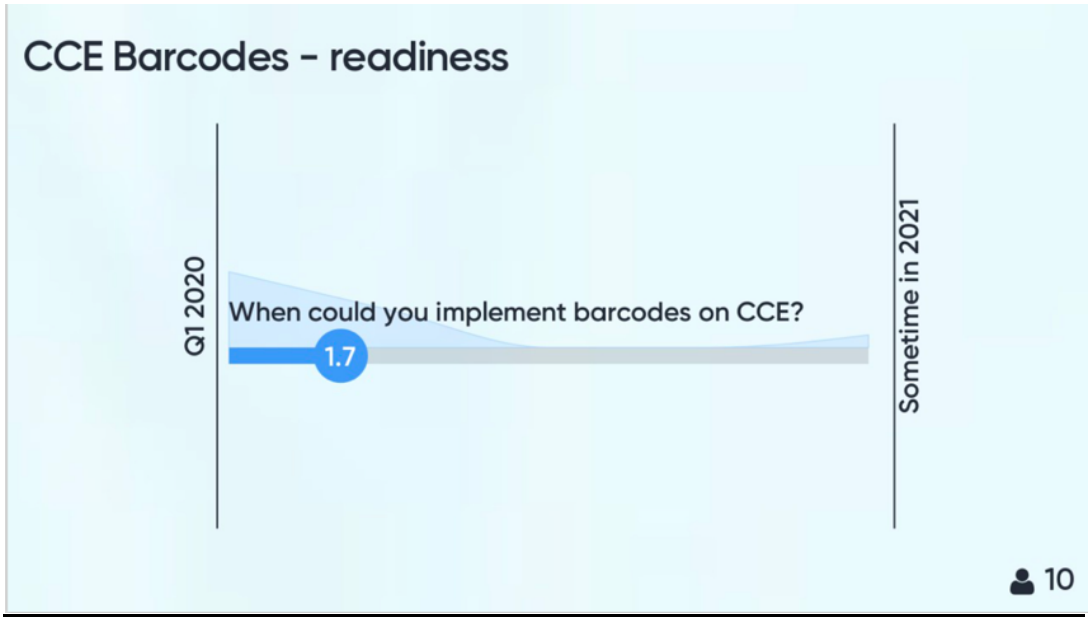
7. CCE post-market monitoring

   No question

8. Quality management systems (QMS) inspections

   No question

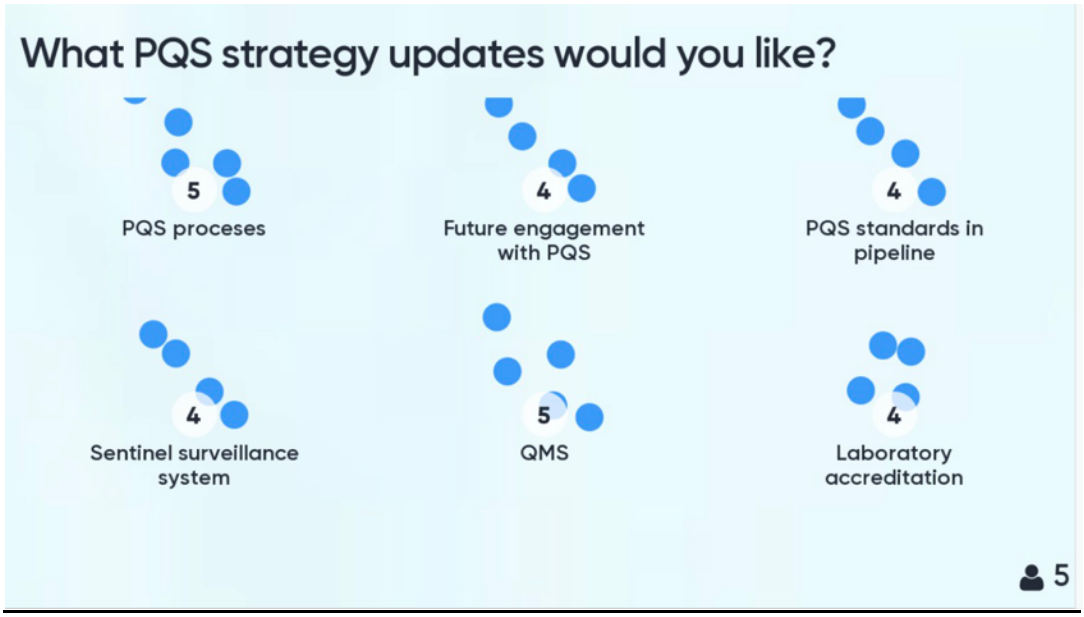
9. CCE barcodes



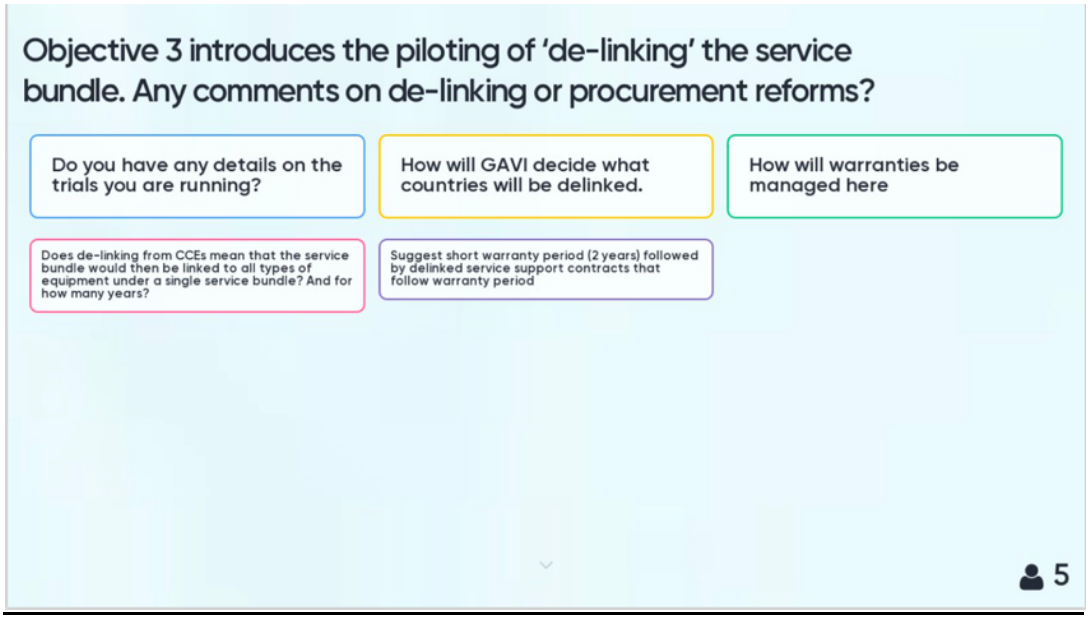
10. Process for prequalifying products and devices

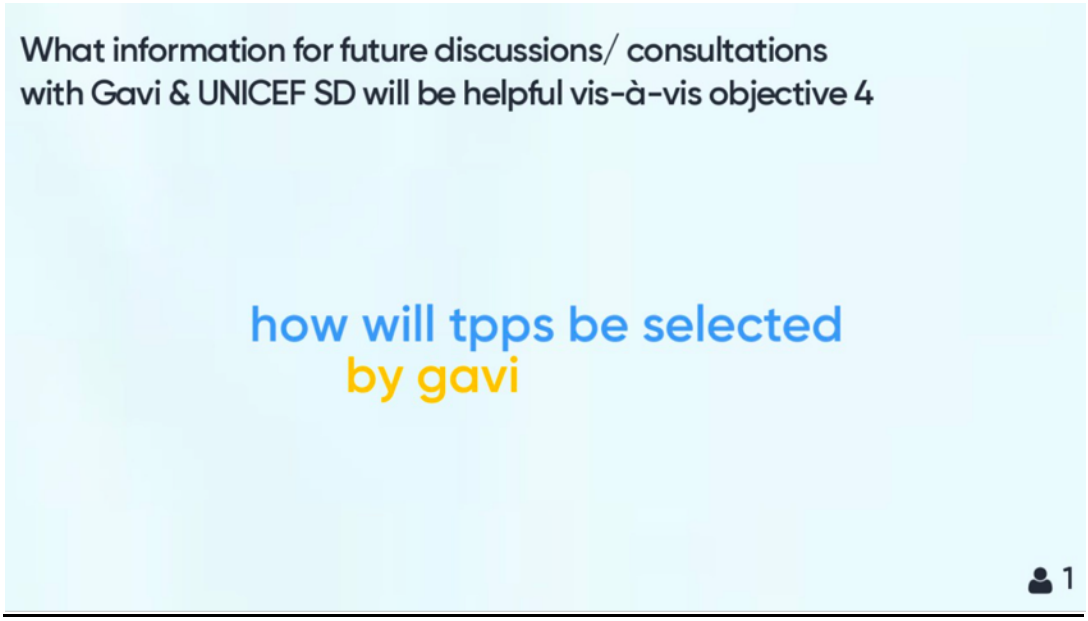
No question

II. WHO PQS Strategy 2019-2023



III. Gavi cold chain equipment optimization platform update





IV. PQS accreditation of new testing laboratories

No question

Annex 4b: Mentimeter participant evaluation responses