WHO Prequalification Process Scorecard

The World Health Organization (WHO) prequalification (PQ) process assesses the quality, safety, and efficacy of medical products for priority diseases and conditions. At the end of 2023, WHO announced plans to significantly improve the PQ website and add functionality to facilitate the PQ process. However, despite these promises, the website is missing some essential resources across all six PQ product streams, and some of the announced website revisions have not been implemented. GHTC developed this scorecard to review and analyze which updates are complete, what is still in progress, and where the PQ program is still falling short.

OVERVIEW

Key: Fully functionable and available | Incomplete/partially complete or insufficient | Unavailable | Not applicable

Key Performance Indicators (KPIs)

Is the PQ program defining, achieving, and publicly reporting on KPIs? This includes metrics such as number of products prequalified annually, time for assessment, and number of collaboratively registered products.

PRODUCT STREAM	GRADE	SUMMARY
OVERALL		KPIs listed for each product stream for 2023-2025 WHO published 2023 KPI progress report 45/62 KPIs met in 2023 across product streams
IMMUNIZATION DEVICES		KPIs present 3/4 KPIs met for 2023
IN VITRO DEVICES		KPIs present 5/10 KPIs met for 2023
MEDICINES		KPIs present 16/18 KPIs met for 2023
VACCINES		KPIs present 7/9 KPIs met for 2023
VECTOR CONTROL PRODUCTS		KPIs present 9/14 KPIs met for 2023
INSPECTION SERVICES		All KPIs present 5/7 KPIs met for 2023

Product Pipeline

Does WHO publish a list of products currently undergoing PQ assessment? Does it indicate the products' status in the process, are relevant product details provided, and has it been recently updated?

PRODUCT STREAM	GRADE	SUMMARY
OVERALL		Pipelines published for 3/5 relevant streams Inconsistency in level of detail provided across streams

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IMMUNIZATION DEVICES		● Pipeline not published
IN VITRO DEVICES		● Pipeline published ● Status/stage indicators listed ● Relevant product details provided ● Recently updated
MEDICINES		● Pipeline published ● Status/stage indicators listed ● Relevant product details missing ● Unclear when last updated
VACCINES		● Pipeline not published
VECTOR CONTROL PRODUCTS		● Pipeline published ● No status/stage indicators listed ● Relevant product details provided ● Unclear when last updated
INSPECTION SERVICES		● Not applicable

Product Dossiers

Does the WHO PQ program provide quality guidance and resources to assist applicants in preparing product dossiers and set clear expectations regarding the process? Do guidance documents exist, and do they include dossier examples or templates? Is the information comprehensive, understandable, and functional?

PRODUCT STREAM	GRADE	SUMMARY
OVERALL		● Guidance documents are provided for most product streams ● Information is of inconsistent quality and comprehensiveness across streams
IMMUNIZATION DEVICES		● Guidance documents provided ● Information is clear, comprehensive, and consistent ● Examples/templates provided ● Functional hyperlinks
IN VITRO DEVICES		● Guidance documents provided ● Not all information is clear, comprehensive, and consistent ● No examples/templates provided ● Functional hyperlinks
MEDICINES		● Guidance documents provided ● Not all information is clear, comprehensive, and consistent ● Examples/templates provided ● Functional hyperlinks

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VACCINES		● Guidance documents provided ● Information is clear, comprehensive, and consistent ● No examples/templates provided ● Functional hyperlinks
VECTOR CONTROL PRODUCTS		● Guidance documents provided ● Information is clear, comprehensive, and consistent ● No examples/templates provided ● Functional hyperlinks
INSPECTION SERVICES		● Not applicable

PQ Product/Process Milestones

Does the WHO PQ program publish a comprehensive and updated list of prequalified products for each product stream as applicable? Does it include data about the different PQ process milestones, such as when dossiers were submitted?

TOPIC	GRADE	SUMMARY
LIST OF PREQUALIFIED PRODUCTS/ PROCESSES		● Complete lists of prequalified products/processes are available for each product stream
DOSSIER SUBMISSION DATES		● Dossier submission dates for products/processes across all streams are no longer listed on the WHO PQ website

ePQS

Is the new externally facing platform, ePQS, for processing PQ materials for each product stream implemented, and what sort of functionality does it offer?

TOPIC	GRADE	SUMMARY
OVERALL		● ePQS announced January 2024, several announced updates ● Delays in release

WHO Prequalification Process Scorecard

DETAILS

Key: Fully functionable and available | Incomplete/partially complete or insufficient | Unavailable | Not applicable

PRODUCT STREAM	Key Performance Indicators (KPIs) Is the PQ program defining, achieving, and publicly reporting on KPIs? This includes metrics such as number of products prequalified annually, time for assessment, and number of collaboratively registered products.	
	GRADE	DETAILED EXPLANATION
OVERALL		The WHO PQ team established and publicly shared KPIs for 2023 to 2025 and published a 2023 progress report on whether it met these KPIs, which showed that most (45/62 or 73%) KPIs across product streams had been met in 2023. The establishment, review, and regular reporting of KPIs is critical to ensuring that the WHO PQ program is rigorously monitoring performance, identifying areas for improvement, and strengthening transparency and accountability for stakeholders, including manufacturers, researchers, and WHO member states. These actions demonstrate WHO's commitment to improving effectiveness and adapting to evolving global health challenges.
IMMUNIZATION DEVICES		All KPIs were listed for the Immunization Devices (IMD) product stream, and most (3/4 or 75%) of its KPIs were met in 2023.
IN VITRO DEVICES		Although all KPIs are listed for the In Vitro Devices (IVD) product stream, only half (5/10) of its KPIs were met in 2023. The 2023 KPI report explains that the capacity of WHO and manufacturers was significantly negatively impacted by the COVID-19 pandemic and that WHO's prioritization of emergency use listing assessments delayed PQ processes.
MEDICINES		All KPIs were listed for the Medicines product stream, and the majority of its KPIs (16/18 or 89%) were met in 2023.
VACCINES		All KPIs were listed for the Vaccines product stream, and the majority of its KPIs (7/9 or 78%) were met in 2023.
VECTOR CONTROL PRODUCTS		All KPIs were reported for the Vector Control Products (VCP) product stream, but slightly fewer than two-thirds (7/9 or 64%) were met in 2023. The 2023 KPI report did not comment on why some KPIs were not achieved, though it is likely related to COVID-19 pandemic-related demands on WHO, similar to the IVDs product stream.
INSPECTION SERVICES		All KPIs were listed for the Inspection Services product stream, and most (5/7 or 71%) of its KPIs were met in 2023.

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Product Pipeline

Does WHO publish a list of products currently undergoing PQ assessment? Does it indicate the products' status in the process, are relevant product details provided, and has it been recently updated?

PRODUCT STREAM	GRADE	DETAILED EXPLANATION
OVERALL		The WHO PQ program's efforts to create and share pipelines of products currently undergoing PQ evaluation for each product stream are essential for transparency, providing manufacturers and health decision-makers with valuable insights into where products stand in the process. Currently, WHO publishes pipelines for only three out of five product streams. Additionally, there are inconsistencies in the formatting and in the level of relevant information provided across product stream pipelines, which can create confusion and hinder accessibility. The delayed launch of the ePQS portal, intended to supplement these pipelines by providing product status updates to manufacturers, underscores the need for standardized and timely updates that ensure clarity and reliability across all PQ product streams.
IMMUNIZATION DEVICES		With no publicized pipeline for the IMDs product stream, it is unclear what IMDs are undergoing PQ evaluation or their status in the process.
IN VITRO DEVICES		The IVDs product pipeline is available and has been recently updated (between September 2023 to June 2024) to reflect the accurate statuses of each IVD product in the PQ process. Additionally, the IVD product pipelines clearly state which step the product is in along the PQ process and the role of relevant parties (i.e., whether the next step falls to the PQ team or the manufacturing facility) and lists the product application number for further reference. These pipelines are accessible, clear, and understandable. The IVD product stream also provides applicants with a comprehensive target PQ process timeline to outline expectations, which other product streams could emulate.
MEDICINES		The Medicines product pipeline exists but lacks the level of detail and understanding other product pipelines provide (i.e., the Medicines product pipeline does not list product application numbers or the role of relevant parties and their next steps). Furthermore, it does not indicate when the Medicines pipeline was last updated, so it is unclear how relevant or appropriate each product's status is in the PQ process. Without each product's application number, it may be difficult for manufacturers to reference their product on the product pipeline.
VACCINES		With no publicized pipeline for the Vaccines product stream, it is unclear what vaccines are undergoing PQ evaluation or their status in the process.
VECTOR CONTROL PRODUCTS		The VCPs product stream pipeline exists, but it lacks the level of detail and understanding other product pipelines provide, offering significantly less information (i.e., the VCPs product pipeline does not list the role of relevant parties and their next steps). Furthermore, it does not indicate when the pipeline was last updated, so it is unclear how relevant or appropriate each product's status is in the PQ process.
INSPECTION SERVICES		The Inspection Services product stream conducts inspections to assess and verify compliance of a manufacturer/laboratory and publishes completed inspection service reports rather than product pipelines, thus it has not been examined in this scorecard.

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Product Dossiers

Does the WHO PQ program provide quality guidance and resources to assist applicants in preparing product dossiers and set clear expectations regarding the process? Do guidance documents exist, and do they include dossier examples or templates? Is the information comprehensive, understandable, and functional?

PRODUCT STREAM	GRADE	DETAILED EXPLANATION
OVERALL		Dossier preparation materials provided by WHO are critical for manufacturers navigating the PQ assessment process. While WHO provides these materials across most product streams, inconsistencies in the content and depth of information for dossier preparation materials across the different product streams may create confusion in completing dossiers. Standardizing, as is feasible, and ensuring uniform access to comprehensive dossier preparation guidance can promote clarity and efficiency in the PQ process.
IMMUNIZATION DEVICES		Dossier preparation guidance for the IMD product stream is available, comprehensive, and functional compared to other product streams. The WHO PQ site offers comprehensive information on submitting a dossier for IMD products, with clear details, functional hyperlinks, and relevant example dossiers. Manufacturers seeking to submit IMD dossiers have ample resources to do so via the WHO PQ site.
IN VITRO DEVICES		The IVD pre-submission form page offers a guidance document for manufacturers with clear steps. However, example dossiers or templates are not provided, and there are some inconsistencies in PQ process terminology, which may confuse product developers. For example, the IVD dossier preparation information is posted under the "Pre-Submission Form" information rather than "product dossier." Under the "Pre-Submission Form", the IVD product stream lists a comprehensive guidance document.
MEDICINES		The Medicines product stream offers substantial information about the PQ process through many guidance documents and templates, including example dossiers. This product stream has two types of products, and dossier preparation materials are available for both product types.* **The Medicines product stream comprises two forms of Medicines: Finished Pharmaceutical Products (FPPs) and Active Pharmaceutical Ingredients (APIs). An API can be used in the manufacturing of an FPP, for which dossier guidance documents are also provided.*
VACCINES		Dossier preparation guidance for the Vaccines product stream is available, comprehensive, and functional compared to other product streams. The WHO PQ site offers comprehensive information on submitting a dossier for Vaccine products, with details, functional hyperlinks, example dossiers, and clear deadlines for dossier submission. Manufacturers seeking to submit Vaccine dossiers have ample resources to do so via the WHO PQ site.
VECTOR CONTROL PRODUCTS		Dossier preparation guidance for the VCP product stream is available, comprehensive, and functional compared to other product streams. The WHO PQ site offers comprehensive information on submitting a dossier for VCPs, with clear details and functional hyperlinks. Manufacturers seeking to submit VCP dossiers have ample resources to do so via the WHO PQ site.
INSPECTION SERVICES		Usually, inspections are carried out in connection with a prequalification application (e.g., product dossier) and do not require their own individual dossier.

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PQ Product/Process Milestones

Does the WHO PQ program publish a comprehensive and updated list of prequalified products for each product stream as applicable? Does it include data about the different PQ process milestones, such as when dossiers were submitted?

TOPIC	GRADE	DETAILED EXPLANATION
LIST OF PREQUALIFIED PRODUCTS/ PROCESSES		The WHO PQ program provides complete lists of prequalified products across all product streams, including Immunization Devices, In Vitro Devices, Medicines, Vaccines, and Vector Control Products, as well as finalized inspection reports under the Inspection Services stream.
DOSSIER SUBMISSION DATES		The absence of dossier submission dates on the WHO PQ site hampers stakeholders' ability to accurately gauge the timeline of the PQ process. These dates are crucial for manufacturers and researchers to plan resources and anticipate milestones, ensuring transparency and efficiency in the PQ process.

ePQS

Is the new externally facing platform, ePQS, for processing PQ materials for each product stream implemented, and what sort of functionality does it offer?

TOPIC	GRADE	DETAILED EXPLANATION
OVERALL		The ePQS portal promises to enhance transparency and functionality to help facilitate the PQ process for applicants. It is also meant to increase efficiency within WHO through its proposed resources and tools. However, the delays in its release raise concerns about its timely implementation and effectiveness. Continued evaluation of the WHO's ePQS commitments, outlined below, will be crucial to assess the actual impact and usability of the portal in improving PQ procedures. Earlier this year, WHO listed several commitments related to the ePQS portal's release, including establishing a single repository for applications, sharing out process-related milestones with manufacturers, and improving the dossier submission process on the PQ website. A single repository will improve access and management of dossier submissions across product streams. Listing process-related milestones, captured in greater detail, improve alignment and reporting of KPIs. Commitments to improve the dossier submission process include sharing dossier applications and options for electronic Common Technical Document submissions.

Information current as of September 2024.