Report on the performance of PQT on key performance indicators on prequalification activities for 2023

The table below presents the performance achievements of the Prequalification Unit (PQT) in 2023, as measured against the established Key Performance Indicators (KPIs). It is important to note that the provided performance metrics focus solely on prequalification (PQ) activities and do not encompass other areas such as emergency use listing (EUL), capacity building, technical guidance development, and specialized scientific advice.

In May 2023, the end of the COVID-19 pandemic as a Public Health Emergency of International Concern (PHEIC) was declared. Subsequently, PQT gradually phased out EUL activities while ensuring the continuity of supply chains for emergency response products and transitioning EUL-listed products to PQ status. The performance of PQ activities for 2023 was significantly impacted by pandemic-related restrictions imposed by various countries. Particularly, the Vaccines and Immunization Devices Assessment (VAX) and In Vitro Diagnostics Assessment (IVD) teams experienced challenges due to increased workloads and resource prioritization towards EUL demands.

The performance outputs of 2023 have been analysed by PQT to identify areas for improvement and implementation in 2024. The conclusion of EUL activities related to the COVID-19 pandemic allows for the full allocation of available resources to PQ efforts. Furthermore, the implementation of the electronic Prequalification System (ePQS) in 2024 offers additional opportunities to enhance performance and efficiency in conducting PQ activities.

PQT encourages stakeholders to engage in prior consultation before utilizing the data provided in the table for any additional interpretation. Comments and inquiries can be directed to the Unit Head, Prequalification Unit at prequal@who.int.

PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
Vaccines			
Vx PQed (Presentations)	8	7(9)	
Vx registrations under CRP	3 - 5	0	13 Expressions of Interest from applicants 11 countries registered malaria vaccine through vaccines direct facilitation
% Vx PQed ≤ WHO target time for full assessment (270 days)	70%	100%	
% Vx PQed ≤ manuf target time for full assessment (450 days)	RO	100%	
% Vx PQed ≤ total target time for full assessment (720 days)	70%	80%	
% Vx PQed ≤ WHO target time for abridged assessment (100 days)	70%	100%	
% Vx PQed ≤ manuf target time for abridged assessment (80 days)	RO	100%	
% Vx PQed ≤ total target time for abridged assessment (180 days)	70%	100%	
% Vx post-PQ reportable change 1st actions ≤ target time (90 days)	80%	72%	

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PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
Medicines: Finished Pharmaceutical Products (FPPs)			
FPPs PQed	40	46	
FPPs registrations under CRP	80	76	
% FPPs PQed ≤ WHO target for full assessment (270 days)	50%	77%	
% FPPs PQed ≤ manuf target time for full assessment (450 days)	RO[1]	66%	
% FPPs PQed ≤ total target time for full assessment (720 days)	50%	63%	
% FPPs PQed ≤ WHO target time for abridged assessment (100 days)	90%	100%	
% FPPs PQed ≤ manuf target time for abridged assessment (80 days)	RO	86%	
% FPPs PQed ≤ total target time for abridged assessment (180 days)	70%	100%	
% of FPPs post-PQ change 1st actions ≤ target time: major variation (90 days)	80%	80%	
% of FPPs post-PQ change 1st actions ≤ target time: minor variation (60 days)	80%	93%	
% of FPPs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	80%	88%	
Medicines: Active Pharmaceutical Ingredients (APIs)			
APIs PQed	10	13	
% APIs PQed ≤ WHO target time for full assessment (270 days)	40%	77%	
% APIs PQed ≤ manuf target time for full assessment (540 days)	RO	100%	
% APIs PQed ≤ total target time for full assessment (900 days)	50%	92%	
% of APIs post-PQ change 1st actions ≤ target time: major variation (90 days)	40%	25%	Legacy of Covid-19. Note, many were close to 90 days as evidenced by a median of 94
% of APIs post-PQ change 1st actions ≤ target time: minor variation (60 days)	40%	64%	

[1] RO: Reported Only-targets are not set but the performance is reported retrospectively

PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
% of APIs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	40%	49%	
In Vitro Diagnostics (IVDs)			
IVDs PQed	8	5	In addition to 6 IVDs listed under the EUL, overall 11 IVDs listed
IVDs registrations under CRP	5	7	
IVDs PQed / alt lab evaluation	30%	60%	
% IVDs PQed ≤ WHO target time for full assessment (350 days) with Lab Option 1	50%	0	Delays in PQ assessments were experienced due to prioritization of EUL assessments during the pandemic and the overall workload across EUL and PQ, including the respective change requests.
% IVDs PQed ≤ manuf target time for full assessment (400 days)	RO	100%	
% IVDs PQed ≤ total target time for full assessment (720 days)	50%	0	The ability of WHO and manufacturers to deliver their duties was challenged by specific conditions related to the pandemic. Assessment timelines were negatively impacted by several challenges related to the scheduling and implementation of performance evaluations (particularly the availability of evaluating laboratories to plan, conduct and finalize evaluations), the implementation of dossier assessments (the limited availability of experts was directed mainly towards EUL assessments) and inspections (including travel restrictions). Impediments to target performance resulted in delays both on WHO assessments and manufacturers' ability to respond to WHO's requests.
% IVDs PQed ≤ WHO target time for abridged assessment (100 days)	30%	0	Delays in PQ assessments were experienced due to prioritization of EUL assessments during the pandemic

PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
			and the overall workload across EUL and PQ, including the respective change requests.
% IVDs PQed ≤ manuf target time for abridged assessment (100 days)	RO	33%	
% IVDs PQed ≤ total target time for abridged assessment (360days)	30%	0	The ability of WHO and manufacturers to deliver their duties was challenged by specific conditions related to the pandemic. Assessment timelines were negatively impacted by several challenges related to the scheduling and implementation of performance evaluations (particularly the availability of evaluating laboratories to plan, conduct and finalize evaluations), the implementation of dossier assessments (the limited availability of experts was directed mainly towards EUL assessments) and inspections (including travel restrictions). Impediments to target performance resulted in delays both on WHO assessments and manufacturers' ability to respond to WHO's requests.
% of IVD post-PQ reportable change 1st actions ≤ target time (90 days)	80%	100%	
Vector Control Products			
Specifications			
New Specifications established for VCAI Source Materials	1	1	
Specification Extension to New Manufacturers of VCAIs	3	11	
VCAI Change assessments	3	4	
Proportion of specification related assessments completed ≤ WHO target time (525 days)	80%	67%	
Prequalification			
VCPs PQed	4	4	
Protocol Reviews Completed	6	6	

World Health Organization

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PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
Change Assessments Completed	25	42	
Proportion of Determination of Pathway submissions completed ≤ WHO target time (90 days)	90%	48%	
Proportion of Study Protocol submissions completed ≤ WHO target time (90 days)	80%	100%	
Proportion VCP PQed ≤ WHO target time (365 days)	80%	25%	
Proportion of VCP PQed 1st actions ≤ target time (180 days)	80%	75%	
Proportion of Minor Change submissions completed ≤ WHO target time (90 days)	80%	82%	
Proportion of Major Change submissions completed ≤ WHO target time (210 days)	80%	57%	
VCP Registrations under CRP	PILOT	PILOT	
IMD			
IMD PQed	50	37	
% IMDs PQed ≤ WHO target time for full assessment (120 days)	60%	95%	
% IMDs PQed ≤ manuf target time for full assessment (30 days)	RO	8%	
% of IMDs post-PQ reportable change 1st actions ≤ target time (30 days)	70%	100%	
INSPECTIONS			
% of planned and conducted inspections within 6 months (Mx-APIs and FPPs)	50%	73%	
% of planned and conducted inspections within 6 months (IVDs, Vx and VCP)	RO	100% (for IVDs), 71% (for VCP)	Information not available yet for vaccine inspections as they are not yet in ePQS and also because this number cannot be accurately calculated for some of the vector control inspections.
% of desk assessments completed within 90 days (excludes EULs)	70%	44%	
% of inspection reports sent to site within 30 days	80%	37%	

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PQT KPIs and Products	2023 Target	2023 Achieved	Remarks (if any)
% of CAPA reviews completed within 30 days	60%	74%	
% of product quality complaints handled within 60 days*	75%	100%	
Total number of inspections (including desk assessments and EULs)	90	157	
RO: Reported Only-targets are not set but the performance is reported retrospectively			

* this refers to requests for investigation sent to the companies and to the receipt and review of investigation reports, as the closure of a complaint can take longer if an investigation inspection is required.

Type of Inspections	FPP	API	CROs	QCL	Vxs	IVDs with EUL	VCPs	Total
Onsite	31	15	13	11	14*	21	12	**117**
Desk review	10	10	1	0	0	12	7	**40**
Remote	0	0	0**	0	0	0	0	**0**
Total	41	25	14	11	14	33	19	**157**

* this included 2 antivenom inspections

** remote inspections used only for follow-up of CAPA in 2023