PQT KPIs and Products	2023 Target	2023 (Q1-Q2) Status	Remarks
Vaccines			
Vx PQed (Presentations)	8	2(3*)	
Vx registrations under CRP[2]	3 - 5	TBP-2023 Final only	
% Vx PQed ≤ WHO target time for full assessment (270 days)	70%	50%	
% Vx PQed ≤ manuf target time for full assessment (450 days)	RO	100%	
% Vx PQed ≤ total target time for full assessment (720 days)	70%	50%	
% Vx PQed ≤ WHO target time for abridged assessment (100 days)	70%	N/A	Zero vaccines assessed under abridged procedure in Q1-Q2
% Vx PQed ≤ manuf target time for abridged assessment (80 days)	RO	N/A	
% Vx PQed ≤ total target time for abridged assessment (180 days)	70%	N/A	
% Vx post-PQ reportable change 1st actions ≤ target time (90 days)	80%	83%	
Medicines: Finished Pharmaceutical Products (FPPs)			
FPPs PQed	40	13	
FPPs registrations under CRP*	80	TBP-2023 Final only	
% FPPs PQed ≤ WHO target for full assessment (270 days)	50%	67%	Note: number of products were fewer than previous semesters
% FPPs PQed ≤ manuf target time for full assessment (450 days)	RO	50%	Note: number of products were fewer than previous semesters
% FPPs PQed ≤ total target time for full assessment (720 days)	50%	50%	Note: number of products were fewer than previous semesters
% FPPs PQed ≤ WHO target time for abridged assessment (100 days)	90%	100%	
% FPPs PQed ≤ manuf target time for abridged assessment (80 days)	RO	80%	
% 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%	89%	
% of FPPs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	80%	83%	
Medicines: Active Pharmaceutical Ingredients (APIs)			
APIs PQed	10	6	
% APIs PQed ≤ WHO target time for full assessment (270 days)	40%	50%	
% APIs PQed ≤ manuf target time for full assessment (540 days)	RO	100%	
% APIs PQed ≤ total target time for full assessment (900 days)	50%	83%	
% of APIs post-PQ change 1st actions ≤ target time: major variation (90 days)	40%	22%	
% of APIs post-PQ change 1st actions ≤ target time: minor variation (60 days)	40%	78%	
% of APIs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	40%	42%	
In Vitro Diagnostics (IVDs)			
IVDs PQed	8	1	
IVDs registrations under CRP*	5	14	
IVDs PQed / alt lab evaluation	30%	100.00%	
% IVDs PQed ≤ WHO target time for full assessment (350 days) with Lab Option 1	50%	NA	
% IVDs PQed ≤ manuf target time for full assessment (400 days)	RO	NA	
% IVDs PQed ≤ total target time for full assessment (720 days)	50%	NA	
% IVDs PQed ≤ WHO target time for abridged assessment (100 days)	30%	0%	
% IVDs PQed ≤ manuf target time for abridged assessment (100 days)	RO	100%	
% IVDs PQed ≤ total target time for abridged assessment (360days)	30%	0%	
% 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	0	
Specification Extension to New Manufacturers of VCAIs	3	7	
VCAI Change assessments	3	3	
Proportion of specification related assessments completed ≤ WHO target time (525 days)	80%	86%	
Prequalification			
VCPs PQed	4	4	
Protocol Reviews Completed	6	4	
Change Assessments Completed	25	21	
Proportion of Determination of Pathway submissions completed ≤ WHO target time (90 days)	90%	13%	
Proportion of Study Protocol submissions completed ≤ WHO target time (90 days)	80%	50%	
Proportion VCP PQed ≤ WHO target time (365 days)	80%	25%	
Proportion of VCP PQed 1st actions ≤ target time (180 days)	80%	25%	
Proportion of Minor Change submissions completed ≤ WHO target time (90 days)	80%	100%	
Proportion of Major Change submissions completed ≤ WHO target time (210 days)	80%	100%	
VCP Registrations under CRP	PILOT	TBP-2023 Final only	
IMD			
IMD PQed	50	17	
% IMDs PQed ≤ WHO target time for full assessment (120 days)	60%	94%	
% IMDs PQed ≤ manuf target time for full assessment (30 days)	RO	6%	
% 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%	Q1: 100% Q2: 71%	
% of planned and conducted inspections within 6 months (IVDs, Vx and VCP)	RO	Q1: 100% Q2: 95%	
% of desk assessments completed within 90 days (excludes EULs)	70%	75%	
% of inspection reports sent to site within 30 days	80%	Q1: 43% Q2: 38%	
% of CAPA reviews completed within 30 days	60%	Q1: 71% Q2: 90%	
% of product quality complaints handled within 60 days*	75%	Q1:100% Q2:100%	
Total number of inspections (including desk assessments and EULs)	90	87	
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.