PQT KPIs and Products	2023 Target	2024 Target	2025 Target
Vaccines			
Vx PQed (Presentations)	8	10	10
Vx registrations under CRP[2]	3 - 5	5 - 8	8 - 12
% Vx PQed ≤ WHO target time for full assessment (270 days)	70%	70%	70%
% Vx PQed ≤ manuf target time for full assessment (450 days)	RO	RO	RO
% Vx PQed ≤ total target time for full assessment (720 days)	70%	70%	70%
% Vx PQed ≤ WHO target time for abridged assessment (100 days)	70%	70%	70%
% Vx PQed ≤ manuf target time for abridged assessment (80 days)	RO	RO	RO
% Vx PQed ≤ total target time for abridged assessment (180 days)	70%	70%	70%
% Vx post-PQ reportable change 1st actions ≤ target time (90 days)	80%	80%	80%
Medicines: Finished Pharmaceutical Products (FPPs)			
FPPs PQed	40	40	40
FPPs registrations under CRP*	80	80	80
% FPPs PQed ≤ WHO target for full assessment (270 days)	50%	50%	50%
% FPPs PQed ≤ manuf target time for full assessment (450 days)	RO	RO	RO
% FPPs PQed ≤ total target time for full assessment (720 days)	50%	50%	50%
% FPPs PQed ≤ WHO target time for abridged assessment (100 days)	90%	90%	90%
% FPPs PQed ≤ manuf target time for abridged assessment (80 days)	RO	RO	RO
% FPPs PQed ≤ total target time for abridged assessment (180 days)	70%	70%	70%
% of FPPs post-PQ change 1st actions ≤ target time: major variation (90 days)	80%	80%	80%
% of FPPs post-PQ change 1st actions ≤ target time: minor variation (60 days)	80%	80%	80%
% of FPPs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	80%	80%	80%
Medicines: Active Pharmaceutical Ingredients (APIs)			
APIs PQed	10	10	10
% APIs PQed ≤ WHO target time for full assessment (270 days)	40%	40%	40%
% APIs PQed ≤ manuf target time for full assessment (540 days)	RO	RO	RO
% APIs PQed ≤ total target time for full assessment (900 days)	50%	50%	50%
% of APIs post-PQ change 1st actions ≤ target time: major variation (90 days)	40%	60%	60%
% of APIs post-PQ change 1st actions ≤ target time: minor variation (60 days)	40%	60%	60%
% of APIs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	40%	60%	60%
In Vitro Diagnostics (IVDs)			
IVDs PQed	8	12	12
IVDs registrations under CRP*	5	5	5
IVDs PQed / alt lab evaluation	30%	30%	30%
% IVDs PQed ≤ WHO target time for full assessment (350 days) with Lab Option 1	50%	70%	70%
% IVDs PQed ≤ manuf target time for full assessment (400 days)	RO	RO	RO
% IVDs PQed ≤ total target time for full assessment (720 days)	50%	50%	50%
% IVDs PQed ≤ WHO target time for abridged assessment (100 days)	30%	50%	70%
% IVDs PQed ≤ manuf target time for abridged assessment (100 days)	RO	RO	RO
% IVDs PQed ≤ total target time for abridged assessment (360days)	30%	50%	50%
% of IVD post-PQ reportable change 1st actions ≤ target time (90 days)	80%	80%	80%
Vector Control Products			
Specifications			
New Specifications established for VCAI Source Materials	1	1	1
Specification Extension to New Manufacturers of VCAIs	3	3	3
VCAI Change assessments	3	3	3
Proportion of specification related assessments completed ≤ WHO target time (525 days)	80%	80%	80%
Prequalification			
VCPs PQed	4	4	4
Protocol Reviews Completed	6	6	6
Change Assessments Completed	25	25	25
Proportion of Determination of Pathway submissions completed ≤ WHO target time (90 days)	90%	90%	90%
Proportion of Study Protocol submissions completed ≤ WHO target time (90 days)	80%	80%	80%
Proportion VCP PQed ≤ WHO target time (365 days)	80%	80%	80%
Proportion of VCP PQed 1st actions ≤ target time (180 days)	80%	80%	80%
Proportion of Minor Change submissions completed ≤ WHO target time (90 days)	80%	80%	80%
Proportion of Major Change submissions completed ≤ WHO target time (210 days)	80%	80%	80%
VCP Registrations under CRP	PILOT	TBD	TBD
IMD			
IMD PQed	50	50	50
% IMDs PQed ≤ WHO target time for full assessment (120 days)	60%	65%	70%
% IMDs PQed ≤ manuf target time for full assessment (30 days)	RO	RO	RO
% of IMDs post-PQ reportable change 1st actions ≤ target time (30 days)	70%	70%	70%
INSPECTIONS			
% of planned and conducted inspections within 6 months (Mx-APIs and FPPs)	50%	50%	50%
% of planned and conducted inspections within 6 months (IVDs, Vx and VCP)	RO	RO	RO
% of desk assessments completed within 90 days	70%	70%	70%
% of inspection reports sent to site within 30 days	80%	80%	80%
% of CAPA reviews completed within 30 days	60%	60%	60%
% of product quality complaints handled within 60 days	75%	75%	75%
Total number of inspections	90	150	150
RO: Reported Only-targets are not set but the performance is reported retrospectively			