Published Standard Number 1 – Applications (National)

Application number	Application type	Number of applications	Performance	Target days	Average days
1	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	0	-	180.0	-
2	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	5	100%	120.0	28
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	35	100%	60.0	5
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	113	96.5%	30.0	21
5	Parallel Assessment with EU Procedures	93	100%	-	11
6	Shared Assessment with International Partners	0	-	-	0
7	Batch timetable (National) specific Batch Control	0	-	20.0	0
8	Autogenous Vaccines. New & Variations	2	100%	45.0	44

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
9	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	101	96%
10	Validation	294	100%
11	Issue of authorised documentation	334	100%

Published Standard Number 1 – Applications (European - NI)

Application number	Application Type	Number of applications	Performance
12	New Decentralised (DCP)	3	100%
13	New Mutual Recognition (MRP)	1	100%
14	MRP Variations (Type IB & II) and Renewals	56	100%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
15	Publishing Summary of Product Characteristics (SPCs)	15	93.3%
16	Publishing Public Assessment Reports (PuARs)	0	-
17	Updating PuARs	2	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
18	Unreturned Documents	610	98.2%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance	Target Days	Average Days
19	Product Defects reports	10	100%		
	High risk <5 days	0	-		
	Low risk <10 days	10	-		

Published Standard Number 5 – Import, Export and Batch Release Schemes

Application number	Application Type	No of Apps	Performance	Target Days	Average Days
20	Applications for new pharmaceutical products	14	100%	15	-
21	Applications for new Immunological products	4	100%	25	-
22	Applications for previously imported products	49	100%	15	-
23	All other urgent applications	83	100%	2	0
	Urgent	0			
	Non Urgent	83			
24	Instant Import Certificates	5860	-	-	-
25	Export	55	100%	10	6.5
26	Batch Release	536	100%	10	2.7

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	1501	99.81%
28	PSURs	277	100%
29	Inspections	3	100%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
30	Inspections within 3 years (GMP)	6	100%	-
	Within 5 years (GDP) of last inspection	4	Joint with above	-
31	Inspection Deficiency Reports	7	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	20	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	9	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	39	100%	30.0

Our inspection procedures enable us to extend our GMP inspections beyond 3 years and our GDP inspections beyond 5 years where there are exceptional circumstances, provided a documented risk-assessment is carried out. Risk-assessments have been conducted for all sites where it has not been possible for us to inspect them within 3 years due to covid-19 related restrictions.

Key:

100% Excellent

>97% - 100% Excellent, but some targets missed

92% - 97% Effective

< 91% Ineffective

Additional information

The VMD continuously monitors all targets and puts in place countermeasures, where possible, to ensure targets are met.

However, sometimes a performance standard may fall into the effective or ineffective category and there are a number of reasons why this may happen, e.g. high volume of applications, staff resource, complexity of applications requiring additional input, etc.