Published Standard Number 1 – Applications (National)

Application number	Application type	Number of applications	Performance	Target days
1	Complex timetable (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives	5	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	0	-	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	12	100%	120.0
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	32	84.4%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	111	72.1%	30.0
6	Parallel Assessment with EU Procedures	52	100%	-
7	Shared Assessment with International Partners	0	-	-
8	Batch timetable (National) specific Batch Control	8	100%	20.0
9	Autogenous Vaccines. New & Variations	1	100%	45.0

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
10	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	88	86.4%
11	Validation	139	46%
12	Issue of authorised documentation	344	19.5%

Published Standard Number 1 – Applications (European - NI)

Application number	Application Type	Number of applications	Performance
13	New Decentralised (DCP)	0	-
14	New Mutual Recognition (MRP)	0	-

15	MRP Variations (Type IB & II) and Renewals	30	100%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	6	100%
17	Publishing Public Assessment Reports (PuARs)	2	100%
18	Updating PuARs	1	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	506	94.1%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance
20	Product Defects reports	6	100%
	High risk <5 days	1	-
	Low risk <10 days	5	-

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

Application number	Application Type	No of Apps	Performance	Target Days
21	Applications for new products	25	100%	15/25
22	Applications for previously imported products	22	100%	15
23	All other urgent applications	20	100%	-
	Urgent	0		2
	Non Urgent	20		10
24	Instant Import Certificates	3813	-	-
25	Export	30	100%	10
26	Batch Release	204	99.5%	10

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	474	78.3%
28	PSURs	151	100%
29	Inspections	1	100%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
30	Inspections within 3 years (GMP)	2	100%	-
	Within 5 years (GDP) of last inspection	4	Joint with above	-
31	Inspection Deficiency Reports	5	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	2	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	4	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	26	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, which were in place until March 2022.

Published Standard Number 8 – Enforcement

Task number	Task	No.	Performance
35	Quarterly VMR Breaches	0	-
36	Intelligence Activity	0	-

Published Standard Number 9 – Residues

Task number	Task	No.	Performance
37	Quarterly Non-Compliance Data	0	-
38	Sample Testing	2655	100%

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, for example high volume of applications, staff resource, complexity of applications requiring additional input and so on.