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	21	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	8	100%	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	69	100%	120.0
4	Shortened timetable (Type IB variations. New ATC (type B). Out of Scope MRLs)	133	78.2%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	611	86.1%	30.0
6	Parallel Assessment with EU Procedures	333	99.4%	-
7	Shared Assessment with International Partners	0	-	-
8	Batch timetable (National) specific Batch Control	46	100%	20.0
9	Autogenous Vaccines. New & Variations	3	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)	390	95.6%
11	Validation	776	38.3%
12	Issue of authorised documentation	1573	21.1%

Published Standard Number 1 – Applications (European - NI)

Application number	Application Type	Number of applications	Performance
13	New Decentralised (DCP)	6	100%
14	New Mutual Recognition (MRP)	7	100%
15	MRP Variations (Type IB & II)	196	100%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	70	100%
17	Publishing Public Assessment Reports (PuARs)	23	100%
18	Updating PuARs	4	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	2479	97.9%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance
20	Product Defects reports	27	100%
	High risk <5 days	1	-
	Low risk <10 days	26	-

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	107	98.1%	15/25
22	Applications for previously imported products	155	99%	15
23	All other urgent applications	109	99.3%	-
	Urgent	0		2
	Non Urgent	109		10
24	Instant Import Certificates	17,375	-	-
25	Export	106	100%	10
26	Batch Release	1059	99.5%	10

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	1927	97%
28	PSURs	721	100%
29	Inspections	9	86%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
30	Inspections within 3 years (GMP)	12	100%	-
	Within 5 years (GDP) of last inspection	14	Joint with above	-
31	Inspection Deficiency Reports	21	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	21	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	25	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	154	100%	30.0

Published Standard Number 8 – Enforcement

Task number	Task	No.	Performance
35	Quarterly VMR Breaches	1	100%
36	Intelligence Activity	16	100%

Published Standard Number 9 – Residues

Task number	Task	No.	Performance
37	Quarterly Non-Compliance Data	1	100%
38	Sample Testing	13,809	99.8%

Additional information

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