

Published Standard Number 1 – Applications (National)

Application number	Application type	Number of applications	Performance	Target days
1	Complex/Major timetable (National new MA applications) Complex/Major new MA applications, e.g. novel therapies, new actives	9	100%	210/180
2	Standard timetable (National VRA-S variations. New MA Copycats. New VHRs)	70	100%	120
3	Shortened timetable (VRA-R variations. New ATC (type A, B, S), ATC variations.	52	100%	60
4	Minor timetable (National) VNRA variations. Administrative VRA-R variations. ATC renewals.	315	98.7%	30
5	Batch timetable (National) specific Batch Control	4	100%	20
6	Autogenous Vaccines. New & Variations	1	100%	60
7	EU Procedures New & variations	69	97%	10/20

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
8	Mock-up period completed within 20 days	48	100%
9	Packaging surveillance	-	-
10	Validation	349	98.9%
11	Issue of authorised documentation	870	99.5%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
12	Publishing Summary of Product Characteristics (SPCs)	15	100%
13	Publishing Public Assessment Reports (PuARs)	14	100%
14	Updating PuARs	1	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
15	Unreturned Documents	1678	98.2%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance
16	Product Defects reports with 10 days	15	100%

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

Application number	Application Type	No of Apps	Performance	Target Days
17	Applications for new products	45	100%	15/25
18	Applications for previously imported products	155	100%	15
19	All other urgent applications	85	100%	-
	Urgent	1	-	2
	Non Urgent	84	-	10
20	Instant Import Certificates	8087	-	-
21	Export	42	100%	10
22	Batch Release Requests (BRRs)	516	100%	10

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
23	Human, Animal & Environmental AERs	143	98.6%
24	Send final inspection report to MAH	4	100%
25	Number of Benefit-Risk reports validated	288	100%
26	Number of Benefit-Risk reports undergoing full assessment	4	100%
27	Number of standard signal notifications	9	100%
28	Number of urgent signal notifications	-	-

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
29	Inspections within 3 years (GMP)	2	100%	-
	Within 5 years (GDP) of last inspection	13	Joint with above	-
30	Inspection Deficiency Reports	14	100%	30.0
31	GMP Certificates to manufacturers	6	100%	90.0
32	Approval of new Feed business operators and SQP retailer sites	4	100%	45.0
33	Final inspection report to Veterinary Practice Premises, Feed business operators and SQP retailers	172	100%	30.0

Published Standard Number 8 – Enforcement

Task number	Task	No.	Performance
34	Publication of GB enforcement notices	3	100%
35	Initiate removal of illegal listings	16	100%

Published Standard Number 9 – Residues

Task number	Task	No.	Performance
36	Quarterly publication of results	-	-
37	Sample Testing	5438	98%

Additional information

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