

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	18	100%	210/180
2	Standard timetable (National VRA-S variations. New MA Copycats. New VHRs)	203	100%	120
3	Shortened timetable (VRA-R variations. New ATC (type A, B, S), ATC variations.	112	100%	60
4	Minor timetable (National) VNRA variations. Administrative VRA-R variations. ATC renewals.	516	99.2%	30
5	Batch timetable (National) specific Batch Control	22	100%	20
6	Autogenous Vaccines. New & Variations	3	100%	60
7	EU Procedures New & variations	149	98.7%	10/20

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
8	Mock-up period completed within 20 days	68	100%
9	Packaging surveillance	25	100%
10	Validation	636	99.1%
11	Issue of authorised documentation	1471	99.6%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
12	Publishing Summary of Product Characteristics (SPCs)	19	100%
13	Publishing Public Assessment Reports (PuARs)	26	100%
14	Updating PuARs	6	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
15	Unreturned Documents	2649	97.4%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance
16	Product Defects reports with 10 days	26	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	77	100%	15/25
18	Applications for previously imported products	200	100%	15
19	All other urgent applications	154	100%	-
	Urgent	1	-	2
	Non Urgent	153	-	10
20	Instant Import Certificates	15,831	-	-
21	Export	68	100%	10
22	Batch Release Requests (BRRs)	1061	99.9%	10

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
23	Human, Animal & Environmental AERs	698	99.6%
24	Send final inspection report to MAH	7	100%
25	Number of Benefit-Risk reports validated	674	99.9%
26	Number of Benefit-Risk reports undergoing full assessment	5	100%
27	Number of standard signal notifications	20	90%
28	Number of urgent signal notifications	-	-

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
29	Inspections within 3 years (GMP)	8	100%	-
	Within 5 years (GDP) of last inspection	23	Joint with above	-
30	Inspection Deficiency Reports	24	100%	30.0
31	GMP Certificates to manufacturers	7	100%	90.0
32	Approval of new Feed business operators and SQP retailer sites	7	100%	45.0
33	Final inspection report to Veterinary Practice Premises, Feed business operators and SQP retailers	316	100%	30.0

Published Standard Number 8 – Enforcement

Task number	Task	No.	Performance
34	Publication of GB enforcement notices	15	93.3%
35	Initiate removal of illegal listings	40	97.5%

Published Standard Number 9 – Residues

Task number	Task	No.	Performance
36	Quarterly publication of results	1	100%
37	Sample Testing	11,112	98.8%

Additional information

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