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)	18	100%	180.0	10
2	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	36	100%	120.0	7
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	252	100%	60.0	7
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	254	100%	30.0	17
5	Batch timetable (National) specific Batch Control.	42	100%	20.0	0
6	Autogenous Vaccines. New & Variations	11	90.9%	45.0	32

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
7	Mock ups	615	99.3%
8	Validation	1024	100%
9	Issue of authorised documentation	1292	100%

Published Standard Number 1 – Applications (European)

Application number	Application Type	Number of applications	Performance
10	New Centralised (CAP)	9	100%
11	New Decentralised (DCP)	45	97.8%
12	New Mutual Recognition (MRP) and New DCP	63	100%
13	MRP Variations (Type IB & II) and Renewals	286	100%
14	Parallel Assessment with EU Procedures	0	-
15	Shared Assessment with International Partners	0	-
16	Referrals	0	-

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
17	Publishing Summary of Product Characteristics (SPCs)	0	-
18	Publishing Public Assessment Reports (PuARs)	1	100%
19	Updating PuARs	2	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
20	Unreturned Documents	2534	96.9%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance	Target Days	Average Days
21	Product Defects reports High risk <5 days	0	-	-	-
21	Product Defects reports Low risk <10 days	64	100%	-	-

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

Application number	Application Type	No of Apps	Performance	Target Days	Average Days
22	Applications for new products	151	99.3%	15	2
23	All other applications	862	99.1%	-	-
23	All other urgent applications	3	-	2	0
23	All other non-urgent applications	859	-	10	2
24	Instant Certificates	27,576	-	-	-
25	Export	315	100%	10	5.7
26	Batch Release	2741	99.9%	10	2.6

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	8214	98.99%
28	PSURs	1577	100%
29	Inspections	12	100%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days	Average Days
30	Inspections within 3 years (GMP)	14	90%	-	-
30	Within 5 years (GDP) of last inspection	46	Joint with above	-	-
31	Final Inspection Reports	**52**	100%	90.0	53

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.