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)	33	100%	120.0	6
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	235	100%	60.0	7
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	224	100%	30.0	17
5	Batch timetable (National) specific Batch Control.	36	100%	20.0	0
6	Autogenous Vaccines. New & Variations	10	90.9%	45.0	32

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
7	Mock ups	555	99.5%
8	Validation	827	100%
9	Issue of authorised documentation	1186	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)	41	97.6%
12	New Mutual Recognition (MRP) and New DCP	58	100%
13	MRP Variations (Type IB & II) and Renewals	266	100%
14	Parallel Assessment with EU Procedures	0	n/a
15	Shared Assessment with International Partners	0	n/a
16	Referrals	0	n/a

Published Standard Number 2 – Public Assessment Reports

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

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
20	Unreturned Documents	2271	97.2%

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	n/a	n/a	n/a
21	Product Defects reports Low risk <10 days	59	100%	n/a	n/a

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	134	99.3%	15	3
23	All other applications	809	99%	-	-
23	All other urgent applications	3	-	2	0
23	All other non-urgent applications	806	-	10	2
24	Instant Certificates (Apr-May)	20,060	-	-	-
25	Export	267	100%	10	5.6
26	Batch Release	2493	99.9%	10	2.7

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	7286	99.09%
28	PSURs	1295	100%
29	Inspections	10	100%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days	Average Days
30	Inspections within 3 years (GMP)	14	87%	n/a	n/a
30	Within 5 years (GDP) of last inspection	32	Joint with above	n/a	n/a
31	Final Inspection Reports	**47**	100%	90.0	52

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.