Published Standard 1: National applications

Application number	Application Type	Number of Applications	Performance	Target Days	Average Days
1	Complex timetable (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives	0	n/a	210.0	n/a
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	10	100%	180.0	17.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	48	100%	120.0	6
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	233	99.6%	60.0	10
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	228	99.6%	30.0	8
6	Batch timetable (National) specific Batch Control.	29	100%	20.0	1
7	Autogenous Vaccines. New & Variations	10	100%	45.0	39

Published Standard 1: Other applications

Application number	Application Type	Number of Applications	Performance
8	Mock ups	637	98.3%
9	Validation	1025	100%
10	Issue of authorised documentation	1646	99.9%

Published Standard 1: European applications

Application number	Application Type	Number of Applications	Performance
11	New Centralised (CAP)	24	100%
12	New Decentralised (DCP)	61	100%
13	New Mutual Recognition (MRP) and New DCP	60	100%
14	MRP Variations (Type IB & II) and Renewals	377	100%

Published Standard 2: Public Assessment Reports

Application number	Application Type	Total Number	Performance
15	Publishing Summary of Product Characteristics (SPCs)	0	n/a
16	Publishing Public Assessment Reports (PuARs)	0	n/a
17	Updating PuARs	11	100%

Published Standard 3: Quality of documentation

Application number	Application Type	Number of Applications	Performance
18	Unreturned Documents	3205	98.1%

Published Standard: Import, export and batch release schemes

Application number	Application Type	Number of Applications	Performance	Target Days	Average Days
19	Applications for new products	256	99.6%	15	2.0
20	Other Urgent applications	0	n/a	2	n/a
20	Other Non-Urgent applications	724	98.9%	10	2.0
	Instant Certificates (Apr-Mar)	26185	n/a	n/a	n/a
21	Export	567	100%	10	5.0
22	Batch Release	3285	99.9%	10	3.0

Published Standard: Pharmacovigilance

Application number	Task	Number	Performance
23	Human, Animal & Environmental AERs	**10,864**	99.63%
24	PSURs	**1643**	100%
25	Inspections	**23**	100%

Published Standard: Inspections

Application number 26: Inspections within 3 years (GMP) or 5 years (GDP) of last inspection.

99 Inspections of which:

- 44 GMP Inspections within 3 years of last inspection.
- 55 GDP Inspections within 5 years of last inspection

Performance rating 98%

Application number 27: Final Inspection reports

- 98 reports
- Performance rating 98%
- Target days 90
- Average days 16

Application number 28: Product defect reports

55 reports of which:

- 3 Product defect reports High risk <5 days
- 52 Product defect reports Low risk <10 days

Performance rating 100%

Performance ratings:

- 100% Excellent
- >97% -100% Excellent, but some targets missed
- 92% - 97% Effective
- < 92% Ineffective

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