Published Standard – No.1 – Applications (National)

	App Type	No. of Apps	Performance	Target Days	Average Days
1	Complex timetable (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives	0	-	210.0	-
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	9	100%	180.0	18.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	45	100%	120.0	7
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	218	99.5%	60.0	10
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	212	99.5%	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 – No.1 – Applications (Other)

	App Type	No. of Apps	Performance
8	Mock ups	567	98.1%
9	Validation	965	100%
10	Issue of authorised documentation	1476	99.9%

Published Standard – No.1 – Applications (European)

	App Type	No. of Apps	Performance
11	New Centralised (CAP)	22	100%
12	New Decentralised (DCP)	55	100%
13	New Mutual Recognition (MRP) and New DCP	54	100%
14	MRP Variations (Type IB & II) and Renewals	339	100%

Published Standard – No. 2 – Public Assessment Reports

	App Type	Total No	Performance
15	Publishing Summary of Product Characteristics (SPCs)	0	-
16	Publishing Public Assessment Reports (PuARs)	0	-
17	Updating PuARs	11	100%

Published Standard – No. 3 – Quality of Documentation

	App Type	No of Apps	Performance
18	Unreturned Documents	**2919**	97.7%

Published Standard – No. 4 – Import, Export and Batch Release Schemes

	App Type	No of Apps	Performance	Target Days	Average Days
19	Applications for new products	**218**	99.5%	15	2.0
20	All other applications	**638**	99.2%		
	• Urgent	0		2	-
	• Non-Urgent	638		10	2.0
	Instant Certificates (Apr-Feb)	23445	-	-	-
21	Export	**534**	100%	10	5.1
22	Batch Release	**3053**	99.9%	10	3.1

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
23	Human, Animal & Environmental AERs	10,012	99.61%
24	PSURs	1515	100%
25	Inspections	23	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
26	Inspections within 3 years (GMP) or 5 years (GDP) of last inspection.	91	97.8%	-	-
	• GMP	40		-	-
	• GDP	51			
27	Final Inspection Reports	91	97.8%	90.0	16.0
28	Product defect reports	49	100%	-	-
	• High risk <5 days	3			
	• Low risk <10 days	46			

Key:

Dark Green - **Excellent 100%**

Light Green - **Excellent, but some targets missed**

Amber - **Effective**

Red - **Ineffective**

Additional information about 'ambers' and 'reds'

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