

**Published Standard – No.1 – Applications (National)**

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
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)	1	100%	180.0	73.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	13	100%	120.0	8
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	97	100%	60.0	11
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	108	100%	30.0	7
6	Batch timetable (National) specific Batch Control.	13	100%	20.0	0
7	Autogenous Vaccines. New & Variations	4	100%	45.0	34

**Published Standard – No.1 – Applications (Other)**

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
8	Mock ups	289	97.0%
9	Validation	470	100%
10	Issue of authorised documentation	793	100%

**Published Standard – No.1 – Applications (European)**

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
11	New Centralised (CAP)	6	100%
12	New Decentralised (DCP)	30	100%
13	New Mutual Recognition (MRP) and New DCP	28	100%
14	MRP Variations (Type IB & II) and Renewals	170	100%

**Published Standard – No. 2 – Public Assessment Reports**

	<b>App Type</b>	<b>Total No</b>	<b>Performance</b>
15	Publishing Summary of Product Characteristics (SPCs)	0	-
16	Publishing Public Assessment Reports (PuARs)	0	-
17	Updating PuARs	10	100%




**Published Standard – No. 3 – Quality of Documentation**

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>
18	Unreturned Documents	1760	98.8%




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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
19	Applications for new products	94	100%	15	2.0
20	All other applications	168	100%		
	• Urgent	0		2	-
	• Non-Urgent	168		10	1.0
21	Export	204	100%	10	4.9
22	Batch Release	1406	100%	10	4.1

**Published Standard – No. 5 – Pharmacovigilance**

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
23	Human, Animal & Environmental AERs	<b>3177</b>	 99.53%
24	PSURs	<b>694</b>	 100%
25	Inspections	<b>9</b>	 100%

**Published Standard – No. 6 – Inspections**

	<b>Task</b>	<b>No.</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
26	Inspections within 3 years (GMP) or 5 years (GDP) of last inspection.	<b>67</b>		-	-
	• GMP	55		-	-
	• GDP	12			
27	Final Inspection Reports	<b>50</b>		90.0	19.0
28	Product defect reports	<b>64</b>		-	-
	• High risk <5 days	5			
	• Low risk <10 days	59			

**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