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)	1	100%	180.0	73.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	4	100%	120.0	6.0
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	32	100%	60.0	13
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	29	100%	30.0	8.0
6	Batch timetable (National) specific Batch Control.	3	100%	20.0	0
7	Autogenous Vaccines. New & Variations	4	100%	45.0	34

Published Standard – No.1 – Applications (Other)

	App Type	No. of Apps	Performance
8	Mock ups	109	100%
9	Validation	188	100%
10	Issue of authorised documentation	298	100%

Published Standard – No.1 – Applications (European)

	App Type	No. of Apps	Performance
8	New Centralised (CAP)	1	100%
9	New Decentralised (DCP)	16	100%
10	New Mutual Recognition (MRP) and New DCP	11	100%
14	MRP Variations (Type IB & II) and Renewals	71	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	4	100%

Published Standard – No. 3 – Quality of Documentation

	App Type	No of Apps	Performance
18	Unreturned Documents	**474**	98.7%

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	**45**	100%	15	2.0
20	All other applications	**93**	100%		
	• Urgent	0		2	-
	• Non-Urgent	93		10	1.0
21	Export	**70**	100%	10	5.0
22	Batch Release	**563**	100%	10	4.1

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
23	Human, Animal & Environmental AERs	**1272**	99.76%
24	PSURs	**235**	100%
25	Inspections	**4**	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.	**15**	100%	-	-
	• GMP	9		-	-
	• GDP	6			
27	Final Inspection Reports	**17**	100%	90.0	20.0
28	Product defect reports	**16**	100%	-	-
	• High risk <5 days	**3**			
	• Low risk <10 days	**13**			

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