

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	17	100%
2	Centralised – UK as Rapp: Variations / Renewals	9	100%

Published Standard – No.1 – Applications (DCP)

	App Type	No. of Apps	Performance
3	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 70)	16	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	23	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	33	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	57	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	70	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	12	100%
9	MRP – UK as RMS: New MAs (Phase 2)	21	100%
10	MRP – UK as CMS: New MAs (Phase 2)	30	100%
11	MRP – UK as RMS: Type IA Variations	57	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	126	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	343	99.7%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	102	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	211	99.5%

Published Standard – No. 1 – Applications (National)

	App Type	No of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions: <i>Initial Assessment</i>	88	100%		
	• 75 Day Clock	13		75	54.2
	• 90 Day Clock	75		90	89.8
17	New MAs & Variation-Extensions <i>Sign-Off</i>	123	100%		
	• 130 Day Clock	8		130	124.0
	• 180 Day Clock	115		180	155.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	160	100%	30	18.3
20	Type IB / II Variations: <i>Initial Assessment</i>	169	98.2%		
	• Type IB	132		30	24.5
	• Type II	27		60	51.9
	• Renewal	7		60	58.0
21	Type IB / II Variations: <i>Sign-Off</i>	141	100%		
	• Type IB	106		30	10.2
	• Type II	31		60	31.7
	• Renewals	4		60	48.0
22	Admin Variations	48	100%		
	• < 10 Changes	48		30	25.6
	• > 10 Changes	0		60	-
23	ATCs	11	100%		
	• Type A/S	9		30	24.3
	• Type B	1		50	32.0
	• Variations / Renewals	1		30	20.0
24	Batch Release	3558	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	41	100%		
	• No questions asked	27		10	0.8
	• Questions asked	14		20	14.0
26	AVA*	8	75.0%	45	58.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	628	99.2%
28	Validation	962	99.8%
29	Issue of authorisation documentation	1293	99.8%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2815	98.9%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	401	99.8%	15	2.0
32	All other applications	413	99.3%		
	• Urgent	8		2	1.0
	• Non-Urgent	402		10	2.0
33	Export	445	100%	10	4.9

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	202	99.5%	30	2.0
35	Publish PuAR within 120 days	158	100%	120	49.0
36	Update PuAR within 60 days	98	100%	60	12.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	7979	99.8%
38	Human, Animal & Environmental AERs – Follow Up	4136	99.9%
39	PSURs	1757	99.8%
40	Inspections	19	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection**	40	97.5%	-	-
42	GDP inspections within 5 years of last inspection	40	100%	-	-
43	Send deficiency or post inspections letter	78	98.7%		
	• GMP	40		30	17.0
	• GDP	37			
44	Issue GMP Certificates and final inspection reports	40	100%		
				90	55.0
45	Send final inspection report to wholesaler site	48	97.9%		
46	Product defect reports	43	100%		
	• High risk <5 days	3			
	• Low risk <10 days	40			

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

*In the case of the AVA application, this one proved to be much more complex than a ‘normal’ application and additional assessment was required. This meant that the application couldn’t be completed in the normal timeframe. Due to the low volume of applications, the overall standard fell into the ineffective category.