

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

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

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
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)**

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
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%

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
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)**

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

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

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

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