

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	6	100%
2	Centralised – UK as Rapp: Variations / Renewals	7	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)	13	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	20	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	33	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	47	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)	4	100%
9	MRP – UK as RMS: New MAs (Phase 2)	11	100%
10	MRP – UK as CMS: New MAs (Phase 2)	15	100%
11	MRP – UK as RMS: Type IA Variations	44	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	95	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	161	99.4%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	57	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	105	99.0%

**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>	<b>84</b>	100%		
	• 75 Day Clock	15		75	75.0
	• 90 Day Clock	69		90	89.9
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>61</b>	100%		
	• 130 Day Clock	2		130	121.0
	• 180 Day Clock	59		180	166.0
18	New Homeopathic	<b>0</b>	-	-	-
19	Type IA Variations	<b>101</b>	100%	30	17.7
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>91</b>	96.7%		
	• Type IB	71		30	23.2
	• Type II	19		60	52.8
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	<b>84</b>	100%		
	• Type IB	62		30	7.9
	• Type II	18		60	36.1
	• Renewals	4		60	48.0
22	Admin Variations	<b>29</b>	100%		
	• < 10 Changes	29		30	24.8
	• > 10 Changes	0		60	-
23	ATCs	<b>4</b>	100%		
	• Type A/S	2		30	28.5
	• Type B	1		50	32.0
	• Variations / Renewals	1		30	20.0
24	Batch Release	<b>2070</b>	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	26	100%		
	• No questions asked	22		10	1.0
	• Questions asked	4		20	15.3
26	AVA*	4	75.0%	45	84.3

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

	App Type	No of Apps	Performance
27	Mock-Ups	361	98.9%
28	Validation	571	100%
29	Issue of authorisation documentation	792	99.6%

**Published Standard – No. 2 – Quality of Documentation**

	App Type	Total No	Performance
30	Authorisation Documentation	1634	98.4%

**Published Standard – No. 3 – Import and Export Certificates**

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	109	100%	15	3.0
32	All other applications	206	100%		
	• Urgent	4		2	0
	• Non-Urgent	202		10	2.0
33	Export	245	100%	10	4.8

**Published Standard – No. 4 – Public Assessment Reports**

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	141	99.3%	30	2.0
35	Publish PuAR within 120 days	125	100%	120	49.0
36	Update PuAR within 60 days	62	100%	60	17.0

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

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Human, Animal & Environmental AERs	<b>4400</b>	99.9%
38	Human, Animal & Environmental AERs – Follow Up	<b>2315</b>	99.9%
39	PSURs	<b>976</b>	99.7%
40	Inspections	<b>10</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>23</b>	95.7%	-	-
42	GDP inspections within 5 years of last inspection	<b>25</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>45</b>	97.8%		
	• GMP	23		30	18.0
	• GDP	22			
44	Issue GMP Certificates and final inspection reports	<b>26</b>	100%		
				90	77.0
45	Send final inspection report to wholesaler site	<b>31</b>	96.8%		
46	Product defect reports	<b>25</b>	100%		
	• High risk <5 days	3			
	• Low risk <10 days	23			

**Key:**

<b>Dark Green</b>	-	<b>Excellent 100%</b>
<b>Light Green</b>	-	<b>Excellent, but some targets missed</b>
<b>Amber</b>	-	<b>Effective</b>
<b>Red</b>	-	<b>Ineffective</b>

### **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.