

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	14	100%
2	Centralised – UK as Rapp: Variations / Renewals	8	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)	14	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	19	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	28	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	42	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	32	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)	18	100%
9	MRP – UK as RMS: New MAs (Phase 2)	9	100%
10	MRP – UK as CMS: New MAs (Phase 2)	14	100%
11	MRP – UK as RMS: Type IA Variations	60	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	134	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	157	98.7%

	<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)	72	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	97	100%

**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>16</b>	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	16		90	76.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>14</b>	85.7%		
	• 130 Day Clock	2		130	72.5
	• 180 Day Clock	12		180	159
18	New Homeopathic	<b>0</b>	-	50	-
19	Type IA Variations	<b>83</b>	100%	30	21.2
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>117</b>	99.1%		
	• Type IB	72		30	15.2
	• Type II	28		60	51.8
	• Renewal	17		60	57.6
21	Type IB / II Variations: <i>Sign-Off</i>	<b>143</b>	99.3%		
	• Type IB	101		30	5.1
	• Type II	31		60	27.5
	• Renewals	11		60	50.4
22	Admin Variations	<b>23</b>	100%		
	• < 10 Changes	23		30	24.7
	• > 10 Changes	0		60	-
23	ATCs	<b>14</b>	100%		
	• Type A/S	7		30	22.1
	• Type B	5		50	29.8
	• Variations / Renewals	2		30	0
24	Batch Release	<b>2162</b>	100%	10	1.2

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
25	Specific Batch Control	10	100%	20	1.3
26	AVA	3	-	45	33.5

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>
27	Mock-Ups	342	98.5%
28	Validation	663	100%
29	Issue of authorisation documentation	848	99.9%

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

	<b>App Type</b>	<b>Total No</b>	<b>Performance</b>
30	Authorisation Documentation	1699	97.6%

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
31	Applications for new products	117	100%	15	4.0
32	All other applications	1792	99.9%		
	• Urgent	160		2	0
	• Non-Urgent	1632		10	2
33	Export	484	100%	10	6.2

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
34	Publish link to SPC, or EMA	115	100%	30	13.0
35	Publish PAR within 120 days	66	100%	120	96.0
36	Update PAA within 60 days	307	99.3%	60	9.0

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

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Human, Animal & Environmental AERs	<b>4866</b>	100%
38	Human, Animal & Environmental AERs – Follow Up	<b>2257</b>	99.6%
39	PSURs	<b>1279</b>	99.5%
40	Inspections	<b>8</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>25</b>	100%	-	-
42	GDP inspections within 5 years of last inspection	<b>30</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>54</b>	100%		
	• GMP	25		30	21
	• GDP	29			
44	Issue GMP Certificates and final inspection reports	<b>25</b>	100%		
				90	75
45	Send final inspection report to wholesaler site	<b>41</b>	100%		

**Key:****Dark Green** -**Excellent 100%****Light Green** -**Excellent, but some targets missed****Amber** -**Effective****Red** -**Ineffective**