

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	4	100%
2	Centralised – UK as Rapp: Variations / Renewals	3	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)	13	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	8	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	13	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	17	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	12	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)	2	100%
9	MRP – UK as RMS: New MAs (Phase 2)	9	100%
10	MRP – UK as CMS: New MAs (Phase 2)	7	100%
11	MRP – UK as RMS: Type IA Variations	25	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	52	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	107	99.1%

	<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)	38	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	53	98.1%

**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>68</b>	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	68		90	90.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>25</b>	100%		
	• 130 Day Clock	2		130	121.0
	• 180 Day Clock	23		180	165.0
18	New Homeopathic	<b>0</b>	-	-	-
19	Type IA Variations	<b>71</b>	100%	30	18.4
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>50</b>	96.0%		
	• Type IB	33		30	21.1
	• Type II	16		60	51.9
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	<b>39</b>	100%		
	• Type IB	29		30	2.9
	• Type II	7		60	33.7
	• Renewals	3		60	44.0
22	Admin Variations	<b>20</b>	100%		
	• < 10 Changes	20		30	23.6
	• > 10 Changes	0		60	-
23	ATCs	<b>1</b>	100%		
	• Type A/S	1		30	27.0
	• Type B	0		50	-
	• Variations / Renewals	0		30	-
24	Batch Release	<b>1205</b>	100%	10	0.9

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
25	Specific Batch Control	<b>22</b>	<b>100%</b>		
	• No questions asked	18		10	1.1
	• Questions asked	4		20	8.5
26	AVA	<b>1</b>	<b>0%</b>	45	223.0

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>
27	Mock-Ups	<b>234</b>	<b>98.7%</b>
28	Validation	<b>334</b>	<b>100%</b>
29	Issue of authorisation documentation	<b>446</b>	<b>99.6%</b>

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

	<b>App Type</b>	<b>Total No</b>	<b>Performance</b>
30	Authorisation Documentation	797	<b>97.7%</b>

#### 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	<b>66</b>	<b>100%</b>	15	3.0
32	All other applications	<b>114</b>	<b>100%</b>		
	• Urgent	4		2	0
	• Non-Urgent	110		10	2.0
33	Export	<b>124</b>	<b>100%</b>	10	3.6

#### 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	<b>62</b>	<b>100%</b>	30	3.0
35	Publish PuAR within 120 days	<b>39</b>	<b>100%</b>	120	87.0
36	Update PuAR within 60 days	<b>46</b>	<b>100%</b>	60	19.0

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

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Human, Animal & Environmental AERs	<b>1809</b>	99.9%
38	Human, Animal & Environmental AERs – Follow Up	<b>892</b>	99.8%
39	PSURs	<b>443</b>	100%
40	Inspections	<b>5</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>12</b>	91.7%	-	-
42	GDP inspections within 5 years of last inspection	<b>14</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>24</b>	100%		
	• GMP	12		30	21.0
	• GDP	12			
44	Issue GMP Certificates and final inspection reports	<b>14</b>	100%		
				90	73.0
45	Send final inspection report to wholesaler site	<b>20</b>	90.0%		
46	Send final inspection reports to wholesale site within 90 days	<b>15</b>	100%		

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