

**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	2	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)	9	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	6	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)	11	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	8	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)	0	-
10	MRP – UK as CMS: New MAs (Phase 2)	6	100%
11	MRP – UK as RMS: Type IA Variations	16	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	31	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	71	100%

	<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)	23	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	44	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>66</b>	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	66		90	90.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>5</b>	100%		
	• 130 Day Clock	2		130	121.0
	• 180 Day Clock	3		180	147.0
18	New Homeopathic	<b>0</b>	-	-	-
19	Type IA Variations	<b>48</b>	100%	30	19.6
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>35</b>	94.3%		
	• Type IB	22		30	20.2
	• Type II	12		60	56.6
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	<b>31</b>	100%		
	• Type IB	22		30	3.0
	• Type II	6		60	38.7
	• Renewals	3		60	44.0
22	Admin Variations	<b>15</b>	100%		
	• < 10 Changes	15		30	20.0
	• > 10 Changes	0		60	-
23	ATCs	<b>0</b>	-		
	• Type A/S	0		30	-
	• Type B	0		50	-
	• Variations / Renewals	0		30	-
24	Batch Release	<b>859</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>19</b>	<b>100%</b>		
	• No questions asked	16		10	1.3
	• Questions asked	3		20	8.0
26	AVA	<b>0</b>	<b>-</b>	45	-

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>
27	Mock-Ups	<b>154</b>	<b>98.1%</b>
28	Validation	<b>248</b>	<b>100%</b>
29	Issue of authorisation documentation	<b>301</b>	<b>99.3%</b>

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

	<b>App Type</b>	<b>Total No</b>	<b>Performance</b>
30	Authorisation Documentation	554	<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>43</b>	<b>100%</b>	15	3.0
32	All other applications	<b>87</b>	<b>100%</b>		
	• Urgent	3		2	0
	• Non-Urgent	84		10	2.0
33	Export	<b>100</b>	<b>100%</b>	10	3.4

#### 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>39</b>	<b>100%</b>	30	3.0
35	Publish PuAR within 120 days	<b>32</b>	<b>100%</b>	120	83.0
36	Update PuAR within 60 days	<b>31</b>	<b>100%</b>	60	20.0

**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>10</b>	90.0%	-	-
42	GDP inspections within 5 years of last inspection	<b>9</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>16</b>	100%		
	• GMP	7		30	22.0
	• GDP	9			
44	Issue GMP Certificates and final inspection reports	<b>13</b>	100%		
				90	62.0
45	Send final inspection report to wholesaler site	<b>18</b>	89.0%		
46	Send final inspection reports to wholesale site within 90 days	<b>10</b>	100%		

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