

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	1	100%
2	Centralised – UK as Rapp: Variations / Renewals	0	-

**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)	0	-
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	4	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	0	-
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	4	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	0	-

**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)	0	-
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	3	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	11	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	29	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)	4	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	15	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>17</b>	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	17		90	90.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>2</b>	100%		
	• 130 Day Clock	2		130	0
	• 180 Day Clock	0		180	-
18	New Homeopathic	<b>0</b>	-	-	-
19	Type IA Variations	<b>6</b>	100%	30	21.0
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>7</b>	100%		
	• Type IB	7		30	26.1
	• Type II	0		60	-
	• Renewal	0		60	-
21	Type IB / II Variations: <i>Sign-Off</i>	<b>7</b>	100%		
	• Type IB	7		30	2.7
	• Type II	0		60	-
	• Renewals	0		60	-
22	Admin Variations	<b>8</b>	100%		
	• < 10 Changes	8		30	24.4
	• > 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>266</b>	100%	10	0.6

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>	<b>Target Days</b>	<b>Average Days</b>
25	Specific Batch Control	8	100%		
	• No questions asked	5		10	1.4
	• Questions asked	3		20	8.0
26	AVA	0	-	45	-

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

	<b>App Type</b>	<b>No of Apps</b>	<b>Performance</b>
27	Mock-Ups	46	95.7%
28	Validation	91	100%
29	Issue of authorisation documentation	83	97.6%

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

	<b>App Type</b>	<b>Total No</b>	<b>Performance</b>
30	Authorisation Documentation	160	96.25%

#### 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	8	100%	15	4.0
32	All other applications	27	100%		
	• Urgent	2		2	0
	• Non-Urgent	25		10	2.0
33	Export	26	100%	10	5.3

#### 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	12	100%	30	1.0
35	Publish PuAR within 120 days	1	100%	120	118.0
36	Update PuAR within 60 days	14	100%	60	24.0

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

Task	No.	Performance
37 Human, Animal & Environmental AERs	523	100%
38 Human, Animal & Environmental AERs – Follow Up	283	100%
39 PSURs	219	100%
40 Inspections	1	100%

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

Task	No.	Performance	Target Days	Average Days
41 GMP Inspections within 3 years of last inspection	4	100%	-	-
42 GDP inspections within 5 years of last inspection	3	100%	-	-
43 Send deficiency or post inspections letter	6	100%		
• GMP	4		30	3.0
• GDP	2			
44 Issue GMP Certificates and final inspection reports	7	100%	90	0
45 Send final inspection report to wholesaler site	9	100%		

**Key:**

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