

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	8	100%
2	Centralised – UK as Rapp: Variations / Renewals	3	66.7%

**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)	11	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)	5	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	21	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	24	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)	11	100%
9	MRP – UK as RMS: New MAs (Phase 2)	10	100%
10	MRP – UK as CMS: New MAs (Phase 2)	6	100%
11	MRP – UK as RMS: Type IA Variations	53	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	77	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	84	98.8%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	37	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	91	100%

**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>	18	100%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	16		90	86.4
17	New MAs & Variation-Extensions <i>Sign-Off</i>	9	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	7		180	156.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	62	96.8%	30	23.7
20	Type IB / II Variations: <i>Initial Assessment</i>	49	100%		
	• Type IB	30		30	12.2
	• Type II	18		60	43.8
	• Renewal	1		60	55.0
21	Type IB / II Variations: <i>Sign-Off</i>	58	98.3%		
	• Type IB	30		30	2.3
	• Type II	23		60	36.5
	• Renewals	5		60	29.0
22	Admin Variations	7	100%		
	• < 10 Changes	7		30	27.4
	• > 10 Changes	0		60	-
23	ATCs	9	100%		
	• Type A/S	3		30	18.7
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	1351	100%	10	0.9

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	90	100%		
	• No questions asked	68		10	4.3
	• Questions asked	22		20	9.3
26	AVA	1	100%	45	42.0

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

	App Type	No of Apps	Performance
27	Mock-Ups	239	99.2%
28	Validation	483	100%
29	Issue of authorisation documentation	612	99.7%

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

	App Type	Total No	Performance
30	Authorisation Documentation	1212	98.3%

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

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	115	98.3%	15	3.0
32	All other applications	228	97.4%		
	• Urgent	7		2	1.0
	• Non-Urgent	221		10	2.0
33	Export	277	100%	10	4.4

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

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	68	100%	30	2.0
35	Publish PAR within 120 days	32	100%	120	79.0
36	Update PAA within 60 days	0	-	60	0

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

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Human, Animal & Environmental AERs	<b>2882</b>	99.9%
38	Human, Animal & Environmental AERs – Follow Up	<b>1318</b>	100%
39	PSURs	<b>839</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>17</b>	100%	-	-
42	GDP inspections within 5 years of last inspection	<b>10</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>36</b>	100%		
	• GMP	22		30	22
	• GDP	14			
44	Issue GMP Certificates and final inspection reports	<b>20</b>	100%		
				90	74
45	Send final inspection report to wholesaler site	<b>23</b>	100%		

**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>