

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	16	100%
2	Centralised – UK as Rapp: Variations / Renewals	4	75.0%

**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)	19	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	21	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	11	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	26	96.2%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	27	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)	16	100%
9	MRP – UK as RMS: New MAs (Phase 2)	16	100%
10	MRP – UK as CMS: New MAs (Phase 2)	7	100%
11	MRP – UK as RMS: Type IA Variations	68	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	111	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	114	99.1%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	60	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	123	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>	43	100%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	41		90	88.6
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	80	97.5%	30	22.2
20	Type IB / II Variations: <i>Initial Assessment</i>	70	100%		
	• Type IB	39		30	13.2
	• Type II	24		60	42.5
	• Renewal	7		60	56.3
21	Type IB / II Variations: <i>Sign-Off</i>	73	98.6%		
	• Type IB	40		30	1.8
	• Type II	28		60	34.0
	• Renewals	4		60	29.0
22	Admin Variations	10	100%		
	• < 10 Changes	10		30	27.2
	• > 10 Changes	0		60	-
23	ATCs	10	100%		
	• Type A/S	4		30	20.5
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	1979	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	98	100%		
	• No questions asked	76		10	3.9
	• Questions asked	22		20	13.5
26	AVA	1	100%	45	42.0

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

	App Type	No of Apps	Performance
27	Mock-Ups	323	99.1%
28	Validation	627	100%
29	Issue of authorisation documentation	793	99.7%

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

	App Type	Total No	Performance
30	Authorisation Documentation	1621	98.1%

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

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	159	98.7%	15	3.0
32	All other applications	274	99.6%		
	• Urgent	10		2	1.0
	• Non-Urgent	264		10	2.0
33	Export	395	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	90	100%	30	2.0
35	Publish PAR within 120 days	40	100%	120	81.0
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>4134</b>	99.7%
38	Human, Animal & Environmental AERs – Follow Up	<b>2000</b>	100%
39	PSURs	<b>1080</b>	100%
40	Inspections	<b>7</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>29</b>	100%	-	-
42	GDP inspections within 5 years of last inspection	<b>19</b>	95%	-	-
43	Send deficiency or post inspections letter	<b>54</b>	100%	30	21.0
	• GMP	32			
	• GDP	22			
44	Issue GMP Certificates and final inspection reports	<b>31</b>	100%	90	73.0
45	Send final inspection report to wholesaler site	<b>29</b>	100%		

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