

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	22	100%
2	Centralised – UK as Rapp: Variations / Renewals	14	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)	29	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	24	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	30	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	48	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	55	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)	28	100%
9	MRP – UK as RMS: New MAs (Phase 2)	21	100%
10	MRP – UK as CMS: New MAs (Phase 2)	19	100%
11	MRP – UK as RMS: Type IA Variations	89	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	165	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	250	98.8%

	<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)	103	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	145	99.3%

**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>20</b>	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	20		90	74.3
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>15</b>	86.7%		
	• 130 Day Clock	2		130	37.5
	• 180 Day Clock	13		180	151
18	New Homeopathic	<b>1</b>	100%	-	-
19	Type IA Variations	<b>123</b>	100%	30	21.9
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>165</b>	99.4%		
	• Type IB	109		30	16.1
	• Type II	35		60	45.3
	• Renewal	21		60	57.5
21	Type IB / II Variations: <i>Sign-Off</i>	<b>195</b>	99.5%		
	• Type IB	141		30	4.6
	• Type II	36		60	28.1
	• Renewals	18		60	37.0
22	Admin Variations	<b>36</b>	100%		
	• < 10 Changes	36		30	24.6
	• > 10 Changes	0		60	-
23	ATCs	<b>15</b>	100%		
	• Type A/S	8		30	22.5
	• Type B	5		50	29.8
	• Variations / Renewals	2		30	0
24	Batch Release	<b>2951</b>	100%	10	1.1

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	21	100%	20	4.4
26	AVA	3	-	45	33.5

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

	App Type	No of Apps	Performance
27	Mock-Ups	469	98.9%
28	Validation	891	100%
29	Issue of authorisation documentation	1172	99.8%

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

	App Type	Total No	Performance
30	Authorisation Documentation	2260	97.7%

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

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	191	100%	15	3.0
32	All other applications	1909	99.7%		
	• Urgent	164		2	0.0
	• Non-Urgent	1745		10	2.0
33	Export	674	100%	10	6.0

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

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	143	100%	30	11.0
35	Publish PAR within 120 days	81	100%	120	95.0
36	Update PAA within 60 days	307	99.3%	60	9.0

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

	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Human, Animal & Environmental AERs	<b>6494</b>	100%
38	Human, Animal & Environmental AERs – Follow Up	<b>3001</b>	99.7%
39	PSURs	<b>1672</b>	99.6%
40	Inspections	<b>9</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>33</b>	100%	-	-
42	GDP inspections within 5 years of last inspection	<b>43</b>	100%	-	-
43	Send deficiency or post inspections letter	<b>74</b>	100%		
	• GMP	35		30	20
	• GDP	39			
44	Issue GMP Certificates and final inspection reports	<b>32</b>	100%	90	73
45	Send final inspection report to wholesaler site	<b>52</b>	100%		

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