

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

	<b>App Type</b>	<b>No. of Apps</b>	<b>Performance</b>
1	Centralised: New MAs / Extensions	19	100%
2	Centralised – UK as Rapp: Variations / Renewals	5	80.0%

**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)	27	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	37	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	19	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	31	96.8%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	36	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)	19	100%
9	MRP – UK as RMS: New MAs (Phase 2)	21	100%
10	MRP – UK as CMS: New MAs (Phase 2)	8	100%
11	MRP – UK as RMS: Type IA Variations	97	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	138	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	150	99.3%

	<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)	78	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	139	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>74</b>	59%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	72		90	89.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	<b>12</b>	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	10		180	145.0
18	New Homeopathic	<b>0</b>	-	-	-
19	Type IA Variations	<b>100</b>	98.0%	30	21.8
20	Type IB / II Variations: <i>Initial Assessment</i>	<b>101</b>	99.0%		
	• Type IB	52		30	14.9
	• Type II	26		60	41.0
	• Renewal	23		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	<b>87</b>	98.9%		
	• Type IB	50		30	3.6
	• Type II	31		60	31.5
	• Renewals	6		60	31.8
22	Admin Variations	<b>16</b>	100%		
	• < 10 Changes	16		30	24.8
	• > 10 Changes	0		60	-
23	ATCs	<b>11</b>	100%		
	• Type A/S	5		30	20.0
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	<b>2465</b>	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	107	100%		
	• No questions asked	85		10	3.7
	• Questions asked	22		20	13.5
26	AVA	2	100%	45	37.0

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

	App Type	No of Apps	Performance
27	Mock-Ups	390	99.2%
28	Validation	820	99.9%
29	Issue of authorisation documentation	960	99.7%

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

	App Type	Total No	Performance
30	Authorisation Documentation	1900	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	197	98.5%	15	3.0
32	All other applications	342	99.7%		
	• Urgent	11		2	1.0
	• Non-Urgent	331		10	2.0
33	Export	464	100%	10	4.6

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

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	101	100%	30	2.0
35	Publish PAR within 120 days	45	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>5357</b>	99.7%
38	Human, Animal & Environmental AERs – Follow Up	<b>2736</b>	99.9%
39	PSURs	<b>1331</b>	100%
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>34</b>	100%	-	-
42	GDP inspections within 5 years of last inspection	<b>30</b>	97%	-	-
43	Send deficiency or post inspections letter	<b>72</b>	100%		
	• GMP	38		30	20.0
	• GDP	34			
44	Issue GMP Certificates and final inspection reports	<b>43</b>	98.0%		
				90	73.0
45	Send final inspection report to wholesaler site	<b>41</b>	100%		

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