

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	23	100%
2	Centralised – UK as Rapp: Variations / Renewals	15	100%

Published Standard – No.1 – Applications (DCP)

	App Type	No. of Apps	Performance
3	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 70)	33	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	25	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	34	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	50	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	59	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
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	105	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	179	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	295	99.0%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	110	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	170	99.4%

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>	20	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	20		90	74.3
17	New MAs & Variation-Extensions <i>Sign-Off</i>	17	88.2%		
	• 130 Day Clock	2		130	72.5
	• 180 Day Clock	15		180	144
18	New Homeopathic	1	100%	-	-
19	Type IA Variations	137	100%	30	21.9
20	Type IB / II Variations: <i>Initial Assessment</i>	170	99.4%		
	• Type IB	111		30	16.2
	• Type II	36		60	45.2
	• Renewal	23		60	54.8
21	Type IB / II Variations: <i>Sign-Off</i>	203	99.5%		
	• Type IB	145		30	4.6
	• Type II	36		60	28.1
	• Renewals	22		60	38.8
22	Admin Variations	37	100%		
	• < 10 Changes	37		30	24.5
	• > 10 Changes	0		60	-
23	ATCs	18	100%		
	• Type A/S	11		30	20.8
	• Type B	5		50	29.8
	• Variations / Renewals	2		30	0
24	Batch Release	3205	100%	10	1.1

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	23	100%	20	4.1
26	AVA	3	-	45	22.3

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	512	99.0%
28	Validation	958	100%
29	Issue of authorisation documentation	1283	99.8%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2415	97.9%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	223	100%	15	3.0
32	All other applications	1940	99.7%		
	• Urgent	164		2	0.0
	• Non-Urgent	1776		10	2.0
33	Export	735	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	147	100%	30	11.0
35	Publish PAR within 120 days	85	100%	120	95.0
36	Update PAA within 60 days	307	99.3%	60	9.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	7103	100%
38	Human, Animal & Environmental AERs – Follow Up	3456	99.7%
39	PSURs	1769	99.6%
40	Inspections	10	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	41	97.6%	-	-
42	GDP inspections within 5 years of last inspection	59	100%	-	-
43	Send deficiency or post inspections letter	85	100%		
	• GMP	37		30	19
	• GDP	48			
44	Issue GMP Certificates and final inspection reports	32	100%		
				90	70
45	Send final inspection report to wholesaler site	61	100%		

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