

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	19	100%
2	Centralised – UK as Rapp: Variations / Renewals	7	85.7%

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)	35	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	39	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	98.0%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	46	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	23	100%
9	MRP – UK as RMS: New MAs (Phase 2)	27	100%
10	MRP – UK as CMS: New MAs (Phase 2)	8	100%
11	MRP – UK as RMS: Type IA Variations	112	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	169	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	189	99.5%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	101	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	158	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>	76	61%		
	• 75 Day Clock	4		75	70.5
	• 90 Day Clock	72		90	89.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	21	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	19		180	149.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	128	98.5%	30	21.4
20	Type IB / II Variations: <i>Initial Assessment</i>	123	99.2%		
	• Type IB	63		30	15.8
	• Type II	29		60	42.3
	• Renewal	31		60	51.1
21	Type IB / II Variations: <i>Sign-Off</i>	122	99.2%		
	• Type IB	65		30	3.4
	• Type II	35		60	31.1
	• Renewals	22		60	29.0
22	Admin Variations	23	100%		
	• < 10 Changes	23		30	23.7
	• > 10 Changes	0		60	-
23	ATCs	15	100%		
	• Type A/S	7		30	23.1
	• Type B	7		50	32.4
	• Variations / Renewals	1		30	29.0
24	Batch Release	3039	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	123	100%		
	• No questions asked	101		10	3.3
	• Questions asked	22		20	13.5
26	AVA	3	100%	45	39.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	493	99.4%
28	Validation	1024	99.9%
29	Issue of authorisation documentation	1177	99.7%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2268	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	98.2%	15	3.0
32	All other applications	407	99.8%		
	• Urgent	12		2	1.0
	• Non-Urgent	395		10	2.0
33	Export	541	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	126	100%	30	2.0
35	Publish PuAR within 120 days	56	100%	120	77.0
36	Update PuAR within 60 days	99	99.0%	60	14.3

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	6424	99.7%
38	Human, Animal & Environmental AERs – Follow Up	3228	99.9%
39	PSURs	1607	100%
40	Inspections	12	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	46	100%	-	-
42	GDP inspections within 5 years of last inspection	46	98.0%	-	-
43	Send deficiency or post inspections letter	93	100%		
	• GMP	47		30	20.0
	• GDP	46			
44	Issue GMP Certificates and final inspection reports	47	98.0%		
				90	73.0
45	Send final inspection report to wholesaler site	48	100%		

Key:

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