

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	22	100%
2	Centralised – UK as Rapp: Variations / Renewals	8	87.5%

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)	36	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	51	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	40	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	78	98.7%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	48	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)	29	100%
10	MRP – UK as CMS: New MAs (Phase 2)	10	100%
11	MRP – UK as RMS: Type IA Variations	120	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	196	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	211	99.5%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	114	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	170	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>	78	60%		
	• 75 Day Clock	4		75	70.5
	• 90 Day Clock	74		90	89.8
17	New MAs & Variation-Extensions <i>Sign-Off</i>	24	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	22		180	151.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	143	98.6%	30	21.5
20	Type IB / II Variations: <i>Initial Assessment</i>	140	99.3%		
	• Type IB	75		30	15.7
	• Type II	34		60	43.7
	• Renewal	31		60	50.1
21	Type IB / II Variations: <i>Sign-Off</i>	135	99.3%		
	• Type IB	72		30	3.4
	• Type II	36		60	30.8
	• Renewals	27		60	34.0
22	Admin Variations	25	100%		
	• < 10 Changes	25		30	23.9
	• > 10 Changes	0		60	-
23	ATCs	17	100%		
	• Type A/S	9		30	23.6
	• Type B	7		50	32.4
	• Variations / Renewals	1		30	29.0
24	Batch Release	3307	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	125	100%		
	• No questions asked	101		10	3.3
	• Questions asked	24		20	13.3
26	AVA	4	100%	45	38.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	548	99.5%
28	Validation	1094	99.9%
29	Issue of authorisation documentation	1278	99.6%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2394	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	232	98.3%	15	3.0
32	All other applications	418	99.8%		
	• Urgent	12		2	1.0
	• Non-Urgent	406		10	2.0
33	Export	573	100%	10	4.7

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	140	100%	30	2.0
35	Publish PuAR within 120 days	66	100%	120	77.0
36	Update PuAR within 60 days	114	99.2%	60	-

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	6898	99.7%
38	Human, Animal & Environmental AERs – Follow Up	3519	99.9%
39	PSURs	1776	100%
40	Inspections	14	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	51	100%	-	-
42	GDP inspections within 5 years of last inspection	50	98.0%	-	-
43	Send deficiency or post inspections letter	106	100%		
	• GMP	53		30	20.0
	• GDP	53			
44	Issue GMP Certificates and final inspection reports	51	98.0%		
				90	71.0
45	Send final inspection report to wholesaler site	52	100%		

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