

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	14	100%
2	Centralised – UK as Rapp: Variations / Renewals	3	66.7%

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)	18	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	17	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	8	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	24	95.8%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	25	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	13	100%
9	MRP – UK as RMS: New MAs (Phase 2)	11	100%
10	MRP – UK as CMS: New MAs (Phase 2)	6	100%
11	MRP – UK as RMS: Type IA Variations	61	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	87	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	97	99.0%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	46	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	112	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>	43	100%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	41		90	88.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	9	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	7		180	156.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	71	97.2%	30	22.8
20	Type IB / II Variations: <i>Initial Assessment</i>	58	100%		
	• Type IB	36		30	12.1
	• Type II	20		60	40.9
	• Renewal	2		60	52.0
21	Type IB / II Variations: <i>Sign-Off</i>	67	98.5%		
	• Type IB	36		30	1.9
	• Type II	26		60	34.7
	• Renewals	4		60	29.0
22	Admin Variations	8	100%		
	• < 10 Changes	8		30	27.3
	• > 10 Changes	0		60	-
23	ATCs	9	100%		
	• Type A/S	3		30	18.7
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	1674	100%	10	0.9

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	95	100%		
	• No questions asked	73		10	4.1
	• Questions asked	22		20	13.5
26	AVA	1	100%	45	42.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	290	99.3%
28	Validation	648	100%
29	Issue of authorisation documentation	703	99.7%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	1465	98.1%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	146	98.3%	15	3.0
32	All other applications	256	97.4%		
	• Urgent	9		2	1.0
	• Non-Urgent	247		10	2.0
33	Export	325	100%	10	4.5

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	82	100%	30	2.0
35	Publish PAR within 120 days	36	100%	120	78.0
36	Update PAA within 60 days	0	-	60	0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	3527	99.9%
38	Human, Animal & Environmental AERs – Follow Up	1640	100%
39	PSURs	944	100%
40	Inspections	6	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	22	100%	-	-
42	GDP inspections within 5 years of last inspection	13	100%	-	-
43	Send deficiency or post inspections letter	40	100%		
	• GMP	23		30	21.0
	• GDP	1417			
44	Issue GMP Certificates and final inspection reports	28	100%	90	73.0
45	Send final inspection report to wholesaler site	27	100%		

Key:

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