

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	3	100%
2	Centralised – UK as Rapp: Variations / Renewals	0	-

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)	3	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	3	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	3	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	7	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	7	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	1	-
9	MRP – UK as RMS: New MAs (Phase 2)	9	100%
10	MRP – UK as CMS: New MAs (Phase 2)	1	-
11	MRP – UK as RMS: Type IA Variations	18	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	24	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	27	100%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	20	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	48	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>	5	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	5		90	79.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	1	-		
	• 130 Day Clock	0		130	-
	• 180 Day Clock	1		180	55.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	16	93.8%	30	29.6
20	Type IB / II Variations: <i>Initial Assessment</i>	23	100%		
	• Type IB	13		30	16.6
	• Type II	9		60	56.0
	• Renewal	1		60	55.0
21	Type IB / II Variations: <i>Sign-Off</i>	20	95.0%		
	• Type IB	13		30	0
	• Type II	3		60	33.0
	• Renewals	4		60	32.8
22	Admin Variations	3	100%		
	• < 10 Changes	3		30	27.0
	• > 10 Changes	0		60	-
23	ATCs	2	100%		
	• Type A/S	1		30	28.0
	• Type B	1		50	23.0
	• Variations / Renewals	0		30	-
24	Batch Release	443	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	27	100%		
	• No questions asked	12		10	4.6
	• Questions asked	15		20	10.3
26	AVA	0	-	45	0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	107	99.1%
28	Validation	156	100%
29	Issue of authorisation documentation	254	100%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	381	98.7%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	33	97.0%	15	3.0
32	All other applications	99	97.0%		
	• Urgent	8		2	1.0
	• Non-Urgent	91		10	2.0
33	Export	124	100%	10	4.1

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	29	100%	30	1.0
35	Publish PAR within 120 days	7	100%	120	82.0

36	Update PAA within 60 days	0	-	60	0
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Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	1079	99.9%
38	Human, Animal & Environmental AERs – Follow Up	510	100%
39	PSURs	300	100%
40	Inspections	2	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	5	100%	-	-
42	GDP inspections within 5 years of last inspection	1	100%	-	-
43	Send deficiency or post inspections letter	17	100%		
	• GMP	11		30	23
	• GDP	13			
44	Issue GMP Certificates and final inspection reports	11	100%		
45	Send final inspection report to wholesaler site	13	100%	90	73

Key:

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