

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	2	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)	1	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	1	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	4	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	3	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	0	-
9	MRP – UK as RMS: New MAs (Phase 2)	1	100%
10	MRP – UK as CMS: New MAs (Phase 2)	0	-
11	MRP – UK as RMS: Type IA Variations	5	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	15	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	15	100%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	12	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	24	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>	1	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	1		90	38.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	0	-		
	• 130 Day Clock	0		130	-
	• 180 Day Clock	0		180	-
18	New Homeopathic	0	-	-	-
19	Type IA Variations	9	100%	30	24.7
20	Type IB / II Variations: <i>Initial Assessment</i>	7	100%		
	• Type IB	5		30	4.0
	• Type II	2		60	29.0
	• Renewal	0		60	-
21	Type IB / II Variations: <i>Sign-Off</i>	7	100%		
	• Type IB	5		30	0
	• Type II	1		60	15.0
	• Renewals	1		60	0
22	Admin Variations	1	100%		
	• < 10 Changes	1		30	28.0
	• > 10 Changes	0		60	-
23	ATCs	1	100%		
	• Type A/S	1		30	25.0
	• Type B	0		50	-
	• Variations / Renewals	0		30	-
24	Batch Release	224	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	15	100%		
	• No questions asked	10		10	5.5
	• Questions asked	5		20	9.4
26	AVA	0	-	45	0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	51	100%
28	Validation	95	100%
29	Issue of authorisation documentation	115	100%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	160	98.8%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	14	100%	15	4.0
32	All other applications	50	100%		
	• Urgent	2		2	0.5
	• Non-Urgent	48		10	1.0
33	Export	55	100%	10	3.8

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	20	100%	30	1.0
35	Publish PAR within 120 days	5	100%	120	73.0

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	542	100%
38	Human, Animal & Environmental AERs – Follow Up	236	100%
39	PSURs	149	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	2	100%	-	-
42	GDP inspections within 5 years of last inspection	1	100%	-	-
43	Send deficiency or post inspections letter	14	100%		
	• GMP	6		30	24
	• GDP	8			
44	Issue GMP Certificates and final inspection reports	4	100%		
45	Send final inspection report to wholesaler site	3	100%	90	74

Key:

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