

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	5	100%
2	Centralised – UK as Rapp: Variations / Renewals	5	100%

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)	14	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	10	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	17	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	23	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	14	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	2	100%
9	MRP – UK as RMS: New MAs (Phase 2)	9	100%
10	MRP – UK as CMS: New MAs (Phase 2)	7	100%
11	MRP – UK as RMS: Type IA Variations	36	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	64	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	128	99.2%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	45	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	68	98.5%

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>	68	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	68		90	90.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	31	100%		
	• 130 Day Clock	2		130	121.0
	• 180 Day Clock	29		180	166.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	80	100%	30	18.6
20	Type IB / II Variations: <i>Initial Assessment</i>	67	95.5%		
	• Type IB	48		30	22.0
	• Type II	18		60	52.7
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	47	100%		
	• Type IB	35		30	4.1
	• Type II	8		60	29.5
	• Renewals	4		60	48.0
22	Admin Variations	22	100%		
	• < 10 Changes	22		30	22.9
	• > 10 Changes	0		60	-
23	ATCs	1	100%		
	• Type A/S	1		30	27.0
	• Type B	0		50	-
	• Variations / Renewals	0		30	-
24	Batch Release	1477	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	23	100%		
	• No questions asked	19		10	1.2
	• Questions asked	4		20	8.5
26	AVA	4	75.0%	45	84.3

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	270	98.7%
28	Validation	390	100%
29	Issue of authorisation documentation	582	99.5%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	1055	98.2%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	89	100%	15	3.0
32	All other applications	142	100%		
	• Urgent	4		2	0
	• Non-Urgent	138		10	2.0
33	Export	167	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	93	100%	30	3.0
35	Publish PuAR within 120 days	81	100%	120	58.0
36	Update PuAR within 60 days	55	100%	60	17.0

Published Standard – No. 5 – Pharmacovigilance

Task	No.	Performance
37 Human, Animal & Environmental AERs	2408	99.96%
38 Human, Animal & Environmental AERs – Follow Up	1236	99.84%
39 PSURs	571	99.48%
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	15	93.3%	-	-
42 GDP inspections within 5 years of last inspection	16	100%	-	-
43 Send deficiency or post inspections letter	30	96.7%		
• GMP	14		30	23.0
• GDP	16			
44 Issue GMP Certificates and final inspection reports	18	100%		
			90	79.0
45 Send final inspection report to wholesaler site	27	96.0%		
46 Product defect reports	14	100%		
• High risk <5 days	3			
• Low risk <10 days	11			

Key:

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