

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	6	100%
2	Centralised – UK as Rapp: Variations / Renewals	6	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)	16	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	12	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	18	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	31	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	43	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)	10	100%
10	MRP – UK as CMS: New MAs (Phase 2)	13	100%
11	MRP – UK as RMS: Type IA Variations	42	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	76	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	146	99.3%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	49	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	82	98.8%

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>	83	100%		
	• 75 Day Clock	15		75	-
	• 90 Day Clock	68		90	75.0
17	New MAs & Variation-Extensions <i>Sign-Off</i>	61	100%		
	• 130 Day Clock	2		130	121.0
	• 180 Day Clock	59		180	166.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	93	100%	30	17.7
20	Type IB / II Variations: <i>Initial Assessment</i>	77	96.1%		
	• Type IB	58		30	22.3
	• Type II	18		60	52.7
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	60	100%		
	• Type IB	41		30	6.3
	• Type II	15		60	33.7
	• Renewals	4		60	48.0
22	Admin Variations	24	100%		
	• < 10 Changes	24		30	24.6
	• > 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	1773	100%	10	0.7

	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	297	98.7%
28	Validation	462	100%
29	Issue of authorisation documentation	661	99.5%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	1312	98.4%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	103	100%	15	3.0
32	All other applications	171	100%		
	• Urgent	4		2	0
	• Non-Urgent	167		10	2.0
33	Export	197	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	98	99.0%	30	3.0
35	Publish PuAR within 120 days	85	100%	120	59.0
36	Update PuAR within 60 days	61	100%	60	17.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	3614	99.9%
38	Human, Animal & Environmental AERs – Follow Up	1958	99.9%
39	PSURs	805	99.6%
40	Inspections	9	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	17	100%		
	• High risk <5 days	3			
	• Low risk <10 days	14			

Key:

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