

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	19	100%
2	Centralised – UK as Rapp: Variations / Renewals	7	85.7%

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)	34	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	37	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	25	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	45	97.8%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	42	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	19	100%
9	MRP – UK as RMS: New MAs (Phase 2)	25	100%
10	MRP – UK as CMS: New MAs (Phase 2)	8	100%
11	MRP – UK as RMS: Type IA Variations	104	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	154	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	173	99.4%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	86	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	152	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>	74	59%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	72		90	89.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	21	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	19		180	149.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	114	98.2%	30	21.2
20	Type IB / II Variations: <i>Initial Assessment</i>	112	99.1%		
	• Type IB	57		30	15.4
	• Type II	27		60	41.7
	• Renewal	28		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	114	99.1%		
	• Type IB	60		30	3.7
	• Type II	33		60	31.1
	• Renewals	21		60	28.9
22	Admin Variations	20	100%		
	• < 10 Changes	20		30	24.2
	• > 10 Changes	0		60	-
23	ATCs	13	100%		
	• Type A/S	7		30	23.1
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	2753	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	115	100%		
	• No questions asked	93		10	3.5
	• Questions asked	22		20	13.5
26	AVA	2	100%	45	37.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	435	99.3%
28	Validation	906	99.9%
29	Issue of authorisation documentation	1070	99.6%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2118	98.0%

Published Standard – No. 3 – Import and Export Certificates


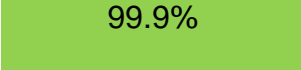


	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	211	98.6%	15	3.0
32	All other applications	369	99.7%		
	• Urgent	12		2	1.0
	• Non-Urgent	357		10	2.0
33	Export	511	100%	10	4.6

Published Standard – No. 4 – Public Assessment Reports

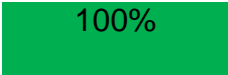

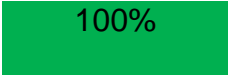

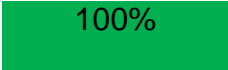
	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	110	100%	30	2.0
35	Publish PAR within 120 days	53	100%	120	77.0

36 Update PAA within 60 days **0**  60 0





Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	5787	 99.7%
38	Human, Animal & Environmental AERs – Follow Up	2962	 99.9%
39	PSURs	1460	 100%
40	Inspections	11	 100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	41	 100%	-	-
42	GDP inspections within 5 years of last inspection	39	 97%	-	-
43	Send deficiency or post inspections letter	78	 100%		
	• GMP	40		30	21.0
	• GDP	38			
44	Issue GMP Certificates and final inspection reports	46	 98.0%		
				90	73.0
45	Send final inspection report to wholesaler site	44	 100%		

Key:

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