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	3	66.7%

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)	6	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	7	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	5	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	20	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	21	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	6	100%
9	MRP – UK as RMS: New MAs (Phase 2)	10	100%
10	MRP – UK as CMS: New MAs (Phase 2)	6	100%
11	MRP – UK as RMS: Type IA Variations	46	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	51	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	65	98.5%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	31	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	84	100%

Published Standard – No. 1 – Applications (National)

	App Type	No of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions: *Initial Assessment*	**12**	100%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	10		90	84.8
17	New MAs & Variation-Extensions *Sign-Off*	**7**	100%		
	• 130 Day Clock	0		130	-
	• 180 Day Clock	7		180	156.0
18	New Homeopathic	**0**	-	-	-
19	Type IA Variations	**46**	95.5%	30	25.2
20	Type IB / II Variations: *Initial Assessment*	**40**	100%		
	• Type IB	24		30	13.3
	• Type II	15		60	46.5
	• Renewal	1		60	55.0
21	Type IB / II Variations: *Sign-Off*	**40**	97.8%		
	• Type IB	26		30	2.7
	• Type II	10		60	31.6
	• Renewals	4		60	34.8
22	Admin Variations	**5**	100%		
	• < 10 Changes	5		30	27.2
	• > 10 Changes	0		60	-
23	ATCs	**8**	100%		
	• Type A/S	3		30	18.7
	• Type B	5		50	31.6
	• Variations / Renewals	0		30	-
24	Batch Release	**1049**	100%	10	0.9

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	**52**	100%		
	• No questions asked	33		10	4.4
	• Questions asked	19		20	10.7
26	AVA	**1**	100%	45	42.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	**193**	99.0%
28	Validation	**347**	100%
29	Issue of authorisation documentation	**451**	99.8%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	840	98.1%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	**86**	98.8%	15	3.0
32	All other applications	**159**	99.4%		
	• Urgent	6		2	1.0
	• Non-Urgent	153		10	2.0
33	Export	**222**	100%	10	4.2

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	**60**	100%	30	1.0
35	Publish PAR within 120 days	**11**	100%	120	82.0
36	Update PAA within 60 days	**0**	-	60	0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	2314	99.9%
38	Human, Animal & Environmental AERs – Follow Up	1043	100%
39	PSURs	688	99.9%
40	Inspections	4	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	15	100%	-	-
42	GDP inspections within 5 years of last inspection	6	100%	-	-
43	Send deficiency or post inspections letter	32	100%		
	• GMP	20			
	• GDP	12		30	23
44	Issue GMP Certificates and final inspection reports	16	100%		
45	Send final inspection report to wholesaler site	21	100%	90	75

Key:

Dark Green -   **Excellent 100%**

Light Green -   **Excellent, but some targets missed**

Amber -   **Effective**

Red -   **Ineffective**