Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	18	100%
2	Centralised – UK as Rapp: Variations / Renewals	5	80.0%

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)	27	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	31	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	12	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	28	96.4%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	33	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)	17	100%
10	MRP – UK as CMS: New MAs (Phase 2)	7	100%
11	MRP – UK as RMS: Type IA Variations	82	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	129	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	130	99.2%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	68	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	128	100%

Published Standard – No. 1 – Applications (National)

	App Type	No of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions: *Initial Assessment*	**74**	59%		
	• 75 Day Clock	2		75	71.0
	• 90 Day Clock	72		90	89.6
17	New MAs & Variation-Extensions *Sign-Off*	**12**	100%		
	• 130 Day Clock	2		130	83.0
	• 180 Day Clock	10		180	145.0
18	New Homeopathic	**0**	-	-	-
19	Type IA Variations	**91**	97.8%	30	21.9
20	Type IB / II Variations: *Initial Assessment*	**90**	100%		
	• Type IB	43		30	14.1
	• Type II	24		60	42.5
	• Renewal	23		60	51.0
21	Type IB / II Variations: *Sign-Off*	**77**	98.7%		
	• Type IB	44		30	3.6
	• Type II	28		60	34.0
	• Renewals	4		60	29.0
22	Admin Variations	**11**	100%		
	• < 10 Changes	11		30	26.3
	• > 10 Changes	0		60	-
23	ATCs	**10**	100%		
	• Type A/S	4		30	20.5
	• Type B	5		50	31.6
	• Variations / Renewals	1		30	29.0
24	Batch Release	**2277**	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	**99**	100%		
	• No questions asked	77		10	3.9
	• 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	**361**	99.2%
28	Validation	**712**	99.9%
29	Issue of authorisation documentation	**858**	99.7%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	1727	97.7%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	**182**	98.9%	15	3.0
32	All other applications	**313**	99.7%		
	• Urgent	11		2	1.0
	• Non-Urgent	302		10	2.0
33	Export	**423**	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	**95**	100%	30	2.0
35	Publish PAR within 120 days	**43**	100%	120	80.0
36	Update PAA within 60 days	**0**	-	60	0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	4686	99.7%
38	Human, Animal & Environmental AERs – Follow Up	2330	99.96%
39	PSURs	1203	100%
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	31	100%	-	-
42	GDP inspections within 5 years of last inspection	26	96%	-	-
43	Send deficiency or post inspections letter	62	100%		
	• GMP	36			
	• GDP	26		30	21.0
44	Issue GMP Certificates and final inspection reports	35	97.0%		
45	Send final inspection report to wholesaler site	31	100%	90	73.0

Key:

Dark Green - **Excellent 100%**

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

Amber - **Effective**

Red - **Ineffective**