Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	9	100%
2	Centralised – UK as Rapp: Variations / Renewals	9	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)	21	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	24	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	39	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	59	100%

Published Standard – No.1 – Applications (MRP)

	App Type	No. of Apps	Performance
8	MRP – UK as RMS: New MAs (Phase 1)	12	100%
9	MRP – UK as RMS: New MAs (Phase 2)	11	100%
10	MRP – UK as CMS: New MAs (Phase 2)	16	100%
11	MRP – UK as RMS: Type IA Variations	50	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	118	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	244	99.6%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	82	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	140	99.3%

Published Standard – No. 1 – Applications (National)

	App Type	No of Apps	Performance	Target Days	Average Days
16	New MAs & Variation-Extensions: *Initial Assessment*	**74**	100%		
	• 75 Day Clock	5		75	75.0
	• 90 Day Clock	69		90	89.9
17	New MAs & Variation-Extensions *Sign-Off*	**76**	100%		
	• 130 Day Clock	7		130	125.3
	• 180 Day Clock	69		180	161.0
18	New Homeopathic	**0**	-	-	-
19	Type IA Variations	**121**	100%	30	17.2
20	Type IB / II Variations: *Initial Assessment*	**124**	97.6%		
	• Type IB	96		30	23.5
	• Type II	27		60	53.5
	• Renewal	1		60	51.0
21	Type IB / II Variations: *Sign-Off*	**115**	100%		
	• Type IB	89		30	8.4
	• Type II	22		60	33.8
	• Renewals	4		60	48.0
22	Admin Variations	**37**	100%		
	• < 10 Changes	37		30	25.5
	• > 10 Changes	0		60	-
23	ATCs	**4**	100%		
	• Type A/S	2		30	28.5
	• Type B	1		50	32.0
	• Variations / Renewals	1		30	20.0
24	Batch Release	**2615**	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	**28**	100%		
	• No questions asked	23		10	1.0
	• Questions asked	5		20	12.2
26	AVA*	**5**	60.0%	45	69.8

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	**472**	99.2%
28	Validation	**724**	100%
29	Issue of authorisation documentation	**1003**	99.7%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2150	98.7%

Published Standard – No. 3 – Import and Export Certificates

	App Type	No of Apps	Performance	Target Days	Average Days
31	Applications for new products	**244**	100%	15	2.0
32	All other applications	**276**	100%		
	• Urgent	5		2	1.0
	• Non-Urgent	271		10	2.0
33	Export	**336**	100%	10	5.3

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	**182**	99.5%	30	2.0
35	Publish PuAR within 120 days	**137**	100%	120	50.0
36	Update PuAR within 60 days	**86**	100%	60	13.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	**5939**	99.9%
38	Human, Animal & Environmental AERs – Follow Up	**3147**	99.9%
39	PSURs	**1300**	99.8%
40	Inspections	**14**	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	**30**	96.7%	-	-
42	GDP inspections within 5 years of last inspection	**29**	100%	-	-
43	Send deficiency or post inspections letter	**59**	98.3%		
	• GMP	29		30	20.0
	• GDP	30			
44	Issue GMP Certificates and final inspection reports	**31**	100%	90	55.0
45	Send final inspection report to wholesaler site	**39**	97.4%		
46	Product defect reports	**29**	100%		
	• High risk <5 days	2			
	• Low risk <10 days	27			

Key:

Dark Green - Excellent 100%

Light Green - Excellent, but some targets missed

Amber - Effective

Red - Ineffective

Additional information about ‘ambers’ and ‘reds’

The VMD continuously monitors all targets and puts in place countermeasures, where possible, to ensure targets are met.

However, sometimes a performance standard may fall into the effective or ineffective category and there are a number of reasons why this may happen, e.g. high volume of applications, staff resource, complexity of applications requiring additional input, etc

*In the case of the AVA application, this one proved to be much more complex than a ‘normal’ application and additional assessment was required. This meant that the application couldn’t be completed in the normal timeframe. Due to the low volume of applications, the overall standard fell into the ineffective category.