

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	11	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)	45	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	54	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	121	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	280	99.6%

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	83	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	153	99.3%

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>	86	100%		
	• 75 Day Clock	17		75	59.1
	• 90 Day Clock	69		90	89.9
17	New MAs & Variation-Extensions <i>Sign-Off</i>	81	100%		
	• 130 Day Clock	7		130	125.3
	• 180 Day Clock	74		180	161.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	140	100%	30	18.2
20	Type IB / II Variations: <i>Initial Assessment</i>	130	97.7%		
	• Type IB	100		30	23.8
	• Type II	29		60	52.9
	• Renewal	1		60	51.0
21	Type IB / II Variations: <i>Sign-Off</i>	119	100%		
	• Type IB	92		30	9.1
	• Type II	23		60	34.8
	• Renewals	4		60	48.0
22	Admin Variations	38	100%		
	• < 10 Changes	38		30	25.6
	• > 10 Changes	0		60	-
23	ATCs	6	100%		
	• Type A/S	4		30	29.3
	• Type B	1		50	32.0
	• Variations / Renewals	1		30	20.0
24	Batch Release	2934	100%	10	0.7

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	29	100%		
	• No questions asked	24		10	0.9
	• Questions asked	5		20	12.2
26	AVA*	7	71.4%	45	60.4

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	521	99.2%
28	Validation	772	100%
29	Issue of authorisation documentation	1103	99.7%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	2378	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	298	99.7%	15	2.0
32	All other applications	324	100%		
	• Urgent	7		2	1.0
	• Non-Urgent	317		10	2.0
33	Export	360	100%	10	5.0

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	186	99.5%	30	2.0
35	Publish PuAR within 120 days	137	100%	120	50.0
36	Update PuAR within 60 days	90	100%	60	13.0

Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	6482	99.9%
38	Human, Animal & Environmental AERs – Follow Up	3444	99.9%
39	PSURs	1451	99.8%
40	Inspections	15	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection**	32	96.9%	-	-
42	GDP inspections within 5 years of last inspection	32	100%	-	-
43	Send deficiency or post inspections letter	61	98.4%		
	• GMP	31		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	43	97.7%		
46	Product defect reports	35	100%		
	• High risk <5 days	2			
	• Low risk <10 days	33			

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.