

Published Standard – No.1 – Applications (Centralised)

	App Type	No. of Apps	Performance
1	Centralised: New MAs / Extensions	5	100%
2	Centralised – UK as Rapp: Variations / Renewals	2	50% ¹

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)	4	100%
4	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120)	5	100%
5	DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2)	3	100%
6	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1)	12	100%
7	DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2)	18	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)	4	100%
11	MRP – UK as RMS: Type IA Variations	28	100%
12	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1)	41	100%
13	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1)	43	100%

¹ Comments were sent a day late on one application due to IT issues experienced by the VMD on 31st May 2017.

	App Type	No. of Apps	Performance
14	MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2)	22	100%
15	MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2)	70	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>	5	100%		
	• 75 Day Clock	0		75	-
	• 90 Day Clock	5		90	79.6
17	New MAs & Variation-Extensions <i>Sign-Off</i>	6	100%		
	• 130 Day Clock	0		130	-
	• 180 Day Clock	6		180	156.0
18	New Homeopathic	0	-	-	-
19	Type IA Variations	31	96.8%	30	25.8
20	Type IB / II Variations: <i>Initial Assessment</i>	32	100%		
	• Type IB	20		30	12.4
	• Type II	11		60	51.1
	• Renewal	1		60	55.0
21	Type IB / II Variations: <i>Sign-Off</i>	31	96.8%		
	• Type IB	20		30	2.2
	• Type II	7		60	35.9
	• Renewals	4		60	34.8
22	Admin Variations	4	100%		
	• < 10 Changes	4		30	27.5
	• > 10 Changes	0		60	-
23	ATCs	5	100%		
	• Type A/S	2		30	18.0
	• Type B	3		50	33.0
	• Variations / Renewals	0		30	-
24	Batch Release	798	100%	10	0.8

	App Type	No of Apps	Performance	Target Days	Average Days
25	Specific Batch Control	41	100%		
	• No questions asked	26		10	5.2
	• Questions asked	15		20	10.3
26	AVA	1	100%	45	42.0

Published Standard – No. 1 – Applications (Other)

	App Type	No of Apps	Performance
27	Mock-Ups	149	99.3%
28	Validation	282	100%
29	Issue of authorisation documentation	362	100%

Published Standard – No. 2 – Quality of Documentation

	App Type	Total No	Performance
30	Authorisation Documentation	677	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	61	98.4%	15	3.0
32	All other applications	122	100%		
	• Urgent	5		2	1.0
	• Non-Urgent	117		10	2.0
33	Export	184	100%	10	3.9

Published Standard – No. 4 – Public Assessment Reports

	App Type	No of Apps	Performance	Target Days	Average Days
34	Publish link to SPC, or EMA	46	100%	30	2.0
35	Publish PAR within 120 days	10	100%	120	86.0

36	Update PAA within 60 days	0	-	60	0
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Published Standard – No. 5 – Pharmacovigilance

	Task	No.	Performance
37	Human, Animal & Environmental AERs	1688	99.9%
38	Human, Animal & Environmental AERs – Follow Up	782	100%
39	PSURs	549	100%
40	Inspections	3	100%

Published Standard – No. 6 – Inspections

	Task	No.	Performance	Target Days	Average Days
41	GMP Inspections within 3 years of last inspection	11	100%	-	-
42	GDP inspections within 5 years of last inspection	5	100%	-	-
43	Send deficiency or post inspections letter	21	100%		
	• GMP	12		30	23
	• GDP	9			
44	Issue GMP Certificates and final inspection reports	14	100%		
45	Send final inspection report to wholesaler site	20	100%	90	75

Key:

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