

**Published Standard Number 1 – Applications (National)**

<b>Application number</b>	<b>Application type</b>	<b>Number of applications</b>	<b>Performance</b>	<b>Target days</b>
1	Complex timetable (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives	25	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	8	100%	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	80	100%	120.0
4	Shortened timetable (Type IB variations. New ATC (type B). Out of Scope MRLs)	154	81.2%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	686	87.2%	30.0
6	Parallel Assessment with EU Procedures	377	99.2%	-
7	Shared Assessment with International Partners	1	100%	-
8	Batch timetable (National) specific Batch Control	53	100%	20.0
9	Autogenous Vaccines. New & Variations	5	100%	45.0

**Published Standard Number 1 – Applications (Other)**

<b>Application number</b>	<b>Application Type</b>	<b>Number of applications</b>	<b>Performance</b>
10	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	472	96%
11	Validation	910	40.3%
12	Issue of authorised documentation	1672	22.5%

**Published Standard Number 1 – Applications (European - NI)**

<b>Application number</b>	<b>Application Type</b>	<b>Number of applications</b>	<b>Performance</b>
13	New Decentralised (DCP)	7	100%
14	New Mutual Recognition (MRP)	7	100%
15	MRP Variations (Type IB & II)	268	100%

**Published Standard Number 2 – Public Assessment Reports**

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	84	100%
17	Publishing Public Assessment Reports (PuARs)	28	100%
18	Updating PuARs	5	100%

**Published Standard Number 3 – Quality of Documentation**

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	2611	97.4%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance
20	Product Defects reports	33	100%
	High risk <5 days	2	-
	Low risk <10 days	31	-

**Published Standard Number 5 – Import, Export and Batch Release Schemes**

Application number	Application Type	No of Apps	Performance	Target Days
21	Applications for new products	124	98.4%	15/25
22	Applications for previously imported products	174	99%	15
23	All other urgent applications	232	99.5%	-
	Urgent	0		2
	Non Urgent	232		10
24	Instant Import Certificates	20,960	-	-
25	Export	121	100%	10
26	Batch Release	1260	99.3%	10

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	2299	93.1%
28	PSURs	844	100%
29	Inspections	10	90%

**Published Standard Number 7– Inspections**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>	<b>Target Days</b>
30	Inspections within 3 years (GMP)	15	100%	-
	Within 5 years (GDP) of last inspection	14	Joint with above	-
31	Inspection Deficiency Reports	24	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	27	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	29	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	171	100%	30.0

**Published Standard Number 8 – Enforcement**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
35	Quarterly VMR Breaches	2	100%
36	Intelligence Activity	20	100%

**Published Standard Number 9 – Residues**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Quarterly Non-Compliance Data	1	100%
38	Sample Testing	16,889	99.8%

**Additional information**

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