

**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	48	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	10	100%	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	147	98.6%	120.0
4	Shortened timetable (Type IB variations. New ATC (type B). Out of Scope MRLs)	211	86.3%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations.	1094	86.2%	30.0
6	Parallel Assessment with EU Procedures	690	99.6%	-
7	Shared Assessment with International Partners	1	100%	-
8	Batch timetable (National) specific Batch Control	77	100%	20.0
9	Autogenous Vaccines. New & Variations	8	87.5%	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)	743	96.5%
11	Validation	1502	39.4%
12	Issue of authorised documentation	3174	19.9%

**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)	30	100%
14	New Mutual Recognition (MRP)	9	100%
15	MRP Variations (Type IB & II)	448	99.3%

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

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	128	100%
17	Publishing Public Assessment Reports (PuARs)	80	100%
18	Updating PuARs	8	100%

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

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	5133	96.6%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance
20	Product Defects reports	61	100%
	High risk <5 days	4	-
	Low risk <10 days	57	-

**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	174	98.3%	15/25
22	Applications for previously imported products	279	99.6%	15
23	All other urgent applications	392	99.4%	-
	Urgent	0		2
	Non Urgent	392		10
24	Instant Import Certificates	34,242	-	-
25	Export	190	100%	10
26	Batch Release	2036	99.5%	10

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	3367	73.5%
28	PSURs	1453	100%
29	Inspections	17	94%

**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)	26	100%	-
	Within 5 years (GDP) of last inspection	40	Joint with above	-
31	Inspection Deficiency Reports	57	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	43	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	36	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	266	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	3	100%
36	Intelligence Activity	35	100%

**Published Standard Number 9 – Residues**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Quarterly Non-Compliance Data	2	100%
38	Sample Testing	25,216	92.4%

**Additional information**

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