

**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	3	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	0	0	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	21	100%	120.0
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	110	100%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	322	98.8%	30.0
6	Parallel Assessment with EU Procedures	86	100%	-
7	Shared Assessment with International Partners	0	-	-
8	Batch timetable (National) specific Batch Control	18	100%	20.0
9	Autogenous Vaccines. New & Variations	0	0	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)	118	100%
11	Validation	291	94.8%
12	Issue of authorised documentation	517	93.4%

**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)	6	100%
14	New Mutual Recognition (MRP)	0	0
15	MRP Variations (Type IB & II) and Renewals	59	100%

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

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	7	100%
17	Publishing Public Assessment Reports (PuARs)	7	100%
18	Updating PuARs	0	0

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

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	706	98.7%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance
20	Product Defects reports	11	100%
	High risk <5 days	0	-
	Low risk <10 days	11	-

**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	23	100%	15/25
22	Applications for previously imported products	57	100%	15
23	All other urgent applications	45	100.0%	-
	Urgent	0		2
	Non Urgent	45		10
24	Instant Import Certificates	6749	-	-
25	Export	64	100%	10
26	Batch Release	404	100%	10

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	1228	78.9%
28	PSURs	307	100%
29	Inspections	3	100%

**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)	6	100%	-
	Within 5 years (GDP) of last inspection	2	Joint with above	-
31	Inspection Deficiency Reports	13	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	4	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	12	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	80	100%	30.0

Our inspection procedures enable us to extend our GMP inspections beyond 3 years and our GDP inspections beyond 5 years where there are exceptional circumstances, provided a documented risk-assessment is carried out. Risk-assessments have been conducted for all sites where it has not been possible for us to inspect them within 3 years due to covid-19 related restrictions, which were in place until March 2022.

**Published Standard Number 8 – Enforcement**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
35	Quarterly VMR Breaches	0	0
36	Intelligence Activity	7	100%

**Published Standard Number 9 – Residues**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Quarterly Non-Compliance Data	0	0
38	Sample Testing	5289	100%
39	Residue Violation Investigations	3	100%

**Key:**

**100%** Excellent

**>97% - 100%** Excellent, but some targets missed

**92% - 97%** Effective

**< 91%** Ineffective

**Additional information**

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, for example high volume of applications, staff resource, complexity of applications requiring additional input and so on.