

**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	21	100%	210.0
2	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	15	100%	180.0
3	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	184	100%	120.0
4	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	404	99.8%	60.0
5	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	1337	93.9%	30.0
6	Parallel Assessment with EU Procedures	596	100%	-
7	Shared Assessment with International Partners	0	-	-
8	Batch timetable (National) specific Batch Control	116	100%	20.0
9	Autogenous Vaccines. New & Variations	4	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)	790	94.4%
11	Validation	1600	80.7%
12	Issue of authorised documentation	2659	71.2%

**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)	32	100%
14	New Mutual Recognition (MRP)	4	100%
15	MRP Variations (Type IB & II) and Renewals	373	100%

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

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	99	100%
17	Publishing Public Assessment Reports (PuARs)	67	100%
18	Updating PuARs	3	100%

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

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	4023	96.6%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance
20	Product Defects reports	86	100%
	High risk <5 days	1	-
	Low risk <10 days	85	-

**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	136	98.5%	15/25
22	Applications for previously imported products	302	99.0%	15
23	All other urgent applications	270	100.0%	-
	Urgent	2		2
	Non Urgent	268		10
24	Instant Import Certificates	37,568	-	-
25	Export	286	100%	10
26	Batch Release	2459	100%	10

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	8406	94.9%
28	PSURs	1456	100%
29	Inspections	21	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)	31	100%	-
	Within 5 years (GDP) of last inspection	39	Joint with above	-
31	Inspection Deficiency Reports	68	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	54	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	66	98.0%	45.0
34	Final inspection report to Feed business operators and SQP retailers	421	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	3	100%
36	Intelligence Activity	63	100%

**Published Standard Number 9 – Residues**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>
37	Quarterly Non-Compliance Data	3	100.0%
38	Sample Testing	31,077	98.6%

**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.