

**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>	<b>Average days</b>
1	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	49	100%	180.0	12
2	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	127	100%	120.0	15
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	363	100%	60.0	13
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	1501	99.1%	30.0	24
5	Parallel Assessment with EU Procedures	628	99.8%	-	13
6	Shared Assessment with International Partners	0	-	-	0
7	Batch timetable (National) specific Batch Control	123	100%	20.0	1
8	Autogenous Vaccines. New & Variations	5	100%	45.0	37

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

<b>Application number</b>	<b>Application Type</b>	<b>Number of applications</b>	<b>Performance</b>
9	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	565	98.1%
10	Validation	1750	100%
11	Issue of authorised documentation	2798	100%

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

<b>Application number</b>	<b>Application Type</b>	<b>Number of applications</b>	<b>Performance</b>
12	New Decentralised (DCP)	47	100%
13	New Mutual Recognition (MRP)	1	100%
14	MRP Variations (Type IB & II) and Renewals	328	100%

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

Application number	Application type	Total number	Performance
15	Publishing Summary of Product Characteristics (SPCs)	122	100%
16	Publishing Public Assessment Reports (PuARs)	42	100%
17	Updating PuARs	6	100%

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

Application number	Application type	Number of applications	Performance
18	Unreturned Documents	4293	97.7%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance	Target Days	Average Days
19	Product Defects reports	61	100%		
	High risk <5 days	3	-		
	Low risk <10 days	58	-		

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

Application number	Application Type	No of Apps	Performance	Target Days	Average Days
20	Applications for new products	201	100%	15/25	1.9
21	Applications for previously imported products	229	100%	15	2.4
22	All other urgent applications	453	99.3%	-	2.7
	Urgent	1		2	-
	Non Urgent	453		10	-
23	Instant Import Certificates	38,693	-	-	-
24	Export	424	100%	10	6.7
25	Batch Release	2579	99.8%	10	3.0

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
26	Human, Animal & Environmental AERs	8525	99.2%
27	PSURs	1540	100%
28	Inspections	20	100%

**Published Standard Number 7– Inspections**

<b>Task number</b>	<b>Task</b>	<b>No.</b>	<b>Performance</b>	<b>Target Days</b>
29	Inspections within 3 years (GMP)	39	100%	-
	Within 5 years (GDP) of last inspection	44	Joint with above	-
30	Inspection Deficiency Reports (GMP) Certificates or (GDP)	83	100%	30.0
31	final reports sent	75	98.8%	90.0
32	Approval of new Feed business operators and SQP retailer sites	49	98.0%	45.0
33	Final inspection report to Feed business operators and SQP retailers	456	99.1%	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.

**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.