

**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)	5	100%	180.0	19
2	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	16	100%	120.0	12
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	104	100%	60.0	5
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	211	97.2%	30.0	2
5	Parallel Assessment with EU Procedures	234	100%	-	11
6	Shared Assessment with International Partners	0	-	-	0
7	Batch timetable (National) specific Batch Control	15	100%	20.0	-
8	Autogenous Vaccines. New & Variations	2	100%	45.0	44

**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)	222	96.9%
10	Validation	578	100%
11	Issue of authorised documentation	770	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)	16	100%
13	New Mutual Recognition (MRP)	2	100%
14	MRP Variations (Type IB & II) and Renewals	139	100%

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

Application number	Application type	Total number	Performance
15	Publishing Summary of Product Characteristics (SPCs)	29	96.6%
16	Publishing Public Assessment Reports (PuARs)	0	-
17	Updating PuARs	3	100%

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

Application number	Application type	Number of applications	Performance
18	Unreturned Documents	1238	98.4%

**Published Standard Number 4 – Product Defects**

Task number	Task	Number of tasks	Performance	Target Days	Average Days
19	Product Defects reports	17	100%		
	High risk <5 days	0	-		
	Low risk <10 days	17	-		

**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 pharmaceutical products	27	100%	15	-
21	Applications for new Immunological products	4	100%	25	-
22	Applications for previously imported products	83	100%	15	-
23	All other urgent applications	180	100%	2	0
	Urgent	0			
	Non Urgent	180			
24	Instant Import Certificates	11,568	-	-	-
25	Export	111	100%	10	6.5
26	Batch Release	952	100%	10	3.4

**Published Standard Number 6 – Pharmacovigilance**

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	2963	99.8%
28	PSURs	523	100%
29	Inspections	7	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)	11	100%	-
	Within 5 years (GDP) of last inspection	9	Joint with above	-
31	Inspection Deficiency Reports (GMP) Certificates or (GDP)	22	100%	30.0
32	final reports sent	24	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	14	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	132	99.2%	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.

**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, e.g. high volume of applications, staff resource, complexity of applications requiring additional input, etc.