Published Standard Number 1 – Applications (National)

Application number	Application type	Number of applications	Performance	Target days	Average days
1	Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	39	100%	180.0	11
2	Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	114	100%	120.0	15
3	Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs)	318	100%	60.0	12
4	Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals.	1337	99%	30.0	24
5	Parallel Assessment with EU Procedures	559	99.8%	-	13
6	Shared Assessment with International Partners	0	-	-	0
7	Batch timetable (National) specific Batch Control	106	100%	20.0	1
8	Autogenous Vaccines. New & Variations	4	100%	45.0	35

Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
9	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	516	97.9%
10	Validation	1570	100%
11	Issue of authorised documentation	2468	100%

Published Standard Number 1 – Applications (European - NI)

Application number	Application Type	Number of applications	Performance
12	New Decentralised (DCP)	37	100%
13	New Mutual Recognition (MRP)	1	100%
14	MRP Variations (Type IB & II) and Renewals	289	100%

Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
15	Publishing Summary of Product Characteristics (SPCs)	113	100%
16	Publishing Public Assessment Reports (PuARs)	41	100%
17	Updating PuARs	6	100%

Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
18	Unreturned Documents	3836	97.7%

Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance	Target Days	Average Days
19	Product Defects reports	60	100%		
	High risk <5 days	3	-		
	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	Average Days
20	Applications for new products	195	100%	15/25	1.9
21	Applications for previously imported products	206	100%	15	2.3
22	All other urgent applications	432	99.3%	-	2.5
	Urgent	1		2	-
	Non Urgent	431		10	-
23	Instant Import Certificates	34,620	-	-	-
24	Export	391	100%	10	6.6
25	Batch Release	2397	99.8%	10	3.1

Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
26	Human, Animal & Environmental AERs	7025	99.4%
27	PSURs	1214	100%
28	Inspections	19	100%

Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
29	Inspections within 3 years (GMP)	33	100%	-
	Within 5 years (GDP) of last inspection	36	Joint with above	-
30	Inspection Deficiency Reports	71	100%	30.0
31	(GMP) Certificates or (GDP) final reports sent	69	98.6%	90.0
32	Approval of new Feed business operators and SQP retailer sites	44	100%	45.0
33	Final inspection report to Feed business operators and SQP retailers	405	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, 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.