

## Published Standard Number 1 – Applications (National)

Application number	Application type	Number of applications	Performance	Target days
1	Complex timetable  (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives	61	100%	210.0
2	Major timetable  (National) New MRLs. All other MA applications (excl. MAPI and Copycats)	14	100%	180.0
3	Standard timetable  (National Type II variations. New MA - MAPIs and Copycats. New VHRs)	190	98.4%	120.0
4	Shortened timetable  (Type IB variations. New ATC (type B). Out of Scope MRLs)	265	88.7%	60.0
5	Minor timetable  (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations.	1364	88.2%	30.0
6	Parallel Assessment with EU Procedures	830	99.4%	-
7	Shared Assessment with International Partners	1	100%	-
8	Batch timetable (National) specific Batch Control	91	100%	20.0
9	Autogenous Vaccines. New & Variations	8	87.5%	45.0

## Published Standard Number 1 – Applications (Other)

Application number	Application Type	Number of applications	Performance
10	Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources)	937	97.4%
11	Validation	2011	37.5%
12	Issue of authorised documentation	3805	33.2%

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

Application number	Application Type	Number of applications	Performance
13	New Decentralised (DCP)	37	100%
14	New Mutual Recognition (MRP)	12	100%
15	MRP Variations (Type IB & II)	561	99.3%

## Published Standard Number 2 – Public Assessment Reports

Application number	Application type	Total number	Performance
16	Publishing Summary of Product Characteristics (SPCs)	159	97.5%
17	Publishing Public Assessment Reports (PuARs)	101	100%
18	Updating PuARs	13	100%

## Published Standard Number 3 – Quality of Documentation

Application number	Application type	Number of applications	Performance
19	Unreturned Documents	6281	96%

## Published Standard Number 4 – Product Defects

Task number	Task	Number of tasks	Performance
20	Product Defects reports	73	100%
	High risk <5 days	4	-
	Low risk <10 days	69	-

## 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	210	98.6%	15/25
22	Applications for previously imported products	314	99.7%	15
23	All other urgent applications	488	99.6%	-
	Urgent	0		2
	Non Urgent	488		10
24	Instant Import Certificates	41,899	-	-
25	Export	248	100%	10
26	Batch Release	2534	99.3%	10

## Published Standard Number 6 – Pharmacovigilance

Task number	Task	No.	Performance
27	Human, Animal & Environmental AERs	3614	71%
28	PSURs	1781	100%
29	Inspections	19	95%

## Published Standard Number 7– Inspections

Task number	Task	No.	Performance	Target Days
30	Inspections within 3 years (GMP)	30	100%	-
	Within 5 years (GDP) of last inspection	56	Joint with above	-
31	Inspection Deficiency Reports	75	100%	30.0
32	(GMP) Certificates or (GDP) final reports sent	65	100%	90.0
33	Approval of new Feed business operators and SQP retailer sites	42	100%	45.0
34	Final inspection report to Feed business operators and SQP retailers	362	100%	30.0

## Published Standard Number 8 – Enforcement

Task number	Task	No.	Performance
35	Quarterly VMR Breaches	4	100%
36	Intelligence Activity	41	100%

## Published Standard Number 9 – Residues

Task number	Task	No.	Performance
37	Quarterly Non-Compliance Data	3	100%
38	Sample Testing	30,845	93.7%

### **Additional information**

The VMD continuously monitors all targets and puts in place countermeasures, where possible, to ensure targets are met.

#### **[Task 11 and 12] Validation and Issue of authorised documentation**

Keeping GB and NI Marketing Authorisations aligned facilitates shared labelling and is critical to ensuring ongoing availability of veterinary medicines in all UK territories. The consequential increase in application volumes and complexity of work related to parallel submissions and aligned labelling resulted in detrimental impacts on these performance figures in 2024/25. We have acted to address these challenges and anticipate that service levels will return to normal from the end of March 2025.

#### **[Task 27] Human, Animal & Environmental AERs**

The VMD Pharmacovigilance Team validates, assesses, and analyses adverse events reports received from MAHs, veterinary professionals and members of the public. The volume of adverse events received has increased year on year (from 3,000 serious adverse events received in 2016 to over 10,000 in 2024). VMD has developed and continues to develop, IT systems to manage these report volumes.