PUBLISHED STANDARDS FOR REGULATORY WORK 2025/26

The published standards relate to a number of KPIs in the VMD Deliverables and KPI document.

Business Priority 3 – Delivery of core regulatory services: A) Facilitate optimal availability and safe use of veterinary medicines

In support of the above Business Priority, we commit to:

- Monitor our performance against the **Published standards** which set out the timelines and performance categories for a range of key functions[1]
- Report PhV findings to the Veterinary Products Committee and publish those findings
- To evaluate all Product Defect reports and respond to 'High Risk' ones within 5 working days; and all others within 10 working days

This document sets out the standards to which the VMD will operate. At the end of the year the results against these standards will be published.

Performance Areas Covered:

1. Applications
2. Public Assessment Reports (PuARs)
3. Quality of documentation
4. Product defects
5. Import, export and batch release schemes
6. Pharmacovigilance
7. Inspections (GMP and GDP)
8. Enforcement
9. Residues
10. Evaluation of Applications

Note:

- With the exception of the 'schemes', which run on working days, all other timescales run on calendar days
- Days are 'clock days', i.e. the days when the clock is running and the application is with the VMD for action
- If the VMD fails to meet a deadline due to the actions of a third party this will not count as a missed target
- For procedures on joint-labelled products, the clock may stop at any time to enable communication with Ireland
- For all procedures, the clock may be stopped at any time to enable the VMD to get further information from the applicant, advice from a third party, expert committee, or to ensure a new MA application can be considered by the appropriate peer review committee

[1] *Performances indicators for the main different types of marketing authorisation application work, the recording and assessment of pharmacovigilance data, some inspection work and the publication of summary of product characteristics (SPC) and public assessment reports*

1. Applications

No.	Procedure	Details of target
1	**Complex timetable** **(National)** Complex new MA[2] applications, e.g. novel therapies, new actives.	Decision to approve or refuse an application is completed within 210 days of receipt of a valid application.
2	**Major timetable** **(National)** New MA applications (excl. MAPI[3] and Copycats) Variation-extensions	Decision to approve or refuse an application is completed within 180 days of receipt of a valid application. Will be extended to 210 days where application is deemed to be complex[4]
3	**Standard timetable** **(National)** Type II VRA. New MA – MAPIs and Copycats New VHRs[5]	Decision to approve or refuse an application is completed within 120 days of receipt of a valid application.
4	**Shortened timetable** **(National)** Type IB VRA. New ATC[6] (Type B) Out of scope MRLs.	Decision to approve or refuse an application is completed within 60 days of receipt of a valid application.
5	**Minor timetable** **(National)** Type IA (VNRA). Administrative Type IB (VRA). New ATC (Type A / Type S). ATC variations.	Decision to approve or refuse an application is completed within 30 days of receipt of an (valid) application.
6	**Parallel Assessment** with EU Procedures	Following receipt of a valid application, decision to approve or refuse within: • 210 days for parallel new and variation-extension DCP and centrally authorised procedures • 120 days for parallel MR type 2 (VRA) variations (extended timetable), centrally authorised type 2 variations • 30 days for parallel MR type 2 (VRA) variations (shortened timetable)

[2] Marketing Authorisation (MA)
[3] Marketing Authorisation for Parallel Import (MAPI)
[4] Determined at the validation from set criteria, e.g. novel therapy, new active substances to veterinary medicines in the UK, combination of actives new to veterinary medicines in the UK, applications submitted under partnership / co-assessment arrangements, recombinant DNA applications and monoclonal antibody applications, immunological applications (except informed consent); etc.
[5] Veterinary Homeopathic Registrations (VHR)
[6] Animal Test Certificate (ATC)

		• 60 days for parallel MR type 1B (VRA) variations • 90 days for parallel MR renewals
7	**Batch timetable (National)** Specific Batch Control	Decision to approve or refuse an application is completed within 20 days of receipt of an application.
8	**Autogenous Vaccines** New & Variations	Complete scientific assessment by Day 45.
9	**Mock-Ups**	Complete assessment of mock-ups within 20 days of receipt (or up to 40 days for parallel applications involving different QRD sources). Complete assessment of mock-ups within 20 days of receipt of correct/revised versions following completion of the scientific assessment phase of: • Decentralised procedures • Mutual Recognition procedures • National MA and VHR procedures
10	**Validation**	Validate all applications within 10 days of receipt except for: • ATCs – within 5 days • European Decentralised – within 15 days • CMS Type IB (VRA) Variations – within 5 days
11	**Issue of authorisation documentation**	Issue authorisation documentation following conclusion of scientific or mock-up assessment, within: 5 days for: • ATCs • Specific Batch Control 15 days for: • New MA applications • Variation applications
12	**New Decentralised (DCP)**	*NI Role: CMS* Send Day 100 comments in accordance with the phase 1 timetable.
13	**New Mutual Recognition (MRP)**	*NI Role: CMS* Send confirmation of NI position in accordance with the phase 2 timetable.

14	**MRP Variations (VRA Type IB & II)**	*NI Role: CMS* Send NI comments in accordance with the phase 1 timetable.

2. Public Assessment Reports

No.	Procedure	Details of target
15	**Publishing Summary of Product Characteristics (SPCs)**	Make the Summary of Product Characteristics (SPCs) available via the Product Information Database (PID) within 30 days of issue of a new MA.
16	**Publishing Public Assessment Reports (PuARs)**	Make the public assessment report (PuAR) available via the PID within 120 days of approval or refusal of an application for a new MA or veterinary homeopathic registration (VHR).
17	**Updating PuARs**	If required, update the PuAR following a change to an MA or VHR within 60 days of grant of that change.
• **Following completion of an MRP or DCP application, the PuAR should be available from the RMS.*		

3. Quality of Authorisation Documentation

No.	Details of target
18	To record the numbers of unreturned authorisation documents as a percentage in relation to those issued.

4. Product Defects

No.	Procedure	Details of target
19	**Product Defects**	**Respond to:** • high risk product defect reports within 5 working days • other product defect reports within 10 working days

5. Import, Export and Batch Release Schemes

No.	Procedure	Details of target
20	**Special Import Certificate (SIC) / Wholesale Dealers' Import Certificate (WDIC): Requiring assessment**	**Applications for new* products:** To approve or refuse applications within 15 days (Pharm) and 25 days (Imm) of receipt. *New products are those not previously assessed for importation into the UK.

No.	Procedure	Details of target
21		**Applications for previously imported products:** To approve or refuse applications for New species and new stock use within 15 days of receipt.
22		**All other applications:** To approve or refuse applications within 2 or 10 days of receipt.
23	**Special Import Certificate (SIC): Not requiring assessment**	All instant certificates applied for through the online system.
24	**Export Certificates**	Accept or reject applications within 10 days of receipt.
25	**Batch Release Requests (BRRs)** Immunologicals	Accept or reject requests within 10 days of receipt.

6. Pharmacovigilance

No.	Details of target
26	Validate as required all human, animal and environmental adverse event reports and follow-up messages within 30 calendar days of receipt of the required information.
27	Validate and extract all UK data from Periodic Safety Update Reports within 50 calendar days of receipt of the required information.
28	Periodic Safety Update Report data to be fully validated and the PSUR database closed by December 2025
29	Send the final inspection report to inspected Marketing Authorisation Holder (MAH) within 90 calendar days of the closing meeting.
30	Number of Benefit-Risk reports validated within 60 calendar days of receipt of the required information.
31	Number of Benefit-Risk Reports undergoing full assessment completed within 120 calendar days of receipt of the required information.
32	Number of standard signal notifications fully processed within 60 calendar days of receipt of the required information.
33	Number of urgent signal notifications fully processed within 3 working days of receipt of the required information.

7. Inspections

<table>
<tr><th>No.</th><th>Procedure</th><th>Details of target</th></tr>
<tr><td>34</td><td>Inspections performed at relevant sites on a risk-basis
within 3 years (GMP) or 5 years (GDP) of the last inspection</td><td rowspan="3">Good Manufacturing Practice (GMP)
1. Validate applications for authorisation within 10 days.
2. Inspect new UK veterinary-only manufacturing sites within 90 days of the application being validated.
3. Conduct risk-based inspections of UK veterinary-only manufacturing sites at a frequency not exceeding 3 years[(a)].
4. Conduct risk-based inspections of non-UK veterinary-only manufacturing sites at a frequency not exceeding 3 years unless an arrangement is in place whereby the site is inspected by another Competent Authority with equivalent regulatory controls[(a)].
5. Issue the inspection deficiency report within 30 days of completing the inspection; and issue the GMP certificate (or Statement of Non-Compliance) within 90 days of completing the inspection.

Good Distribution Practice (GDP)
1. Validate applications for authorisation within 10 days.
2. Inspect new UK veterinary-only wholesale dealer sites within 90 days of the application being validated.
3. Conduct risk-based inspections of UK veterinary-only wholesale dealer sites at a frequency not exceeding 5 years[(a)]
4. Issue the inspection deficiency report within 30 days of completing the inspection.

[(a)]in exceptional circumstances these intervals may be extended if a detailed risk assessment is conducted and approved by the Head of Inspections Division/Director.</td></tr>
<tr><td>35</td><td>Within 30 days of the last day on site, send inspection deficiency report
to manufacturers (GMP) or wholesalers (GDP)</td></tr>
<tr><td>36</td><td>Within 90 days of the last day on site, send GMP Certificates to manufacturers</td></tr>
<tr><td>37</td><td>Approval of new Feed business operators and SQP retailer sites within 45 days of application validation</td><td rowspan="2">Feed Business Operators & SQP Retailers
1. Validate applications for approval within 10 days.
2. Approve new Feed business operators and SQP retailer sites within 45 days of the application being validated.
3. Issue the inspection report within 30 days of completing the inspection.</td></tr>
<tr><td>38</td><td>Within 30 days of the last day on site, send final inspection report to Feed business operators and SQP retailers</td></tr>
<tr><td colspan="3">NOTE: Pharmaceutical assessors and / or GMP inspectors will liaise as necessary with inspectors at the Medicines Healthcare and products Regulatory Agency (MHRA) in connection with the inspection of sites producing and / or wholesaling veterinary and human pharmaceutical products where the UK is the Supervisory Authority.</td></tr>
</table>

8. Enforcement

No.	Details of target
39	Investigate and deal with breaches of the VMR: On a quarterly basis publish summary data including the number of allegations received, number of cases closed, internet listings removed, enforcement notices served, and outcomes of prosecutions.

9. Residues

No.	Procedure	Details of target
40	**Publication of results**	Publication of residues non-compliance data once a quarter, as well as publication of each full year's worth of monitoring by the 30 April in any given year.
41	**Sample Testing**	Ensuring the testing laboratory completes testing of samples within 7 calendar days for 'suspect' samples and 28 days for 'routine' samples, over 90% of the time.

10. Evaluation of Applications

Assessments will be conducted by suitably qualified and trained staff who will undertake appropriate Continuing Professional Development (CPD).

The assessment of applications for new MAs will be subject to an internal peer review process, and review by SciSec or Bio, which are meetings that may involve other government departments. In a limited number of cases, where specialist advice is required, applications may also be subject to external review by the Veterinary Products Committee (VPC).

Assessments will take into full account:

- Relevant legislation
- The European Pharmacopoeia (or where relevant another EU Pharmacopoeia)
- Relevant guidelines
- VICH guidelines
- Precedents set during previous procedures
- Any relevant information from the scientific literature which may be known to the assessor.

In reaching decisions on authorisations the benefits associated with the use of the product will be weighed up against the risks.

On an annual basis a sample of assessments performed by the VMD on applications to obtain new MAs, which have been initially assessed by the VMD, will be examined by the VPC and these will be ranked according to the following criteria:

Assurance Level	Outcome of the VPC Evaluation
Substantial The assessment is adequate and effective	The VMD identified all potentially serious risks to human and animal health or for the environment within the context of the existing regulatory framework and put together a comprehensive list of relevant questions for the applicant which were clearly expressed, justified/explained and pivotal to the benefit:risk assessment.

Moderate Some improvements are required to enhance the adequacy and effectiveness of the assessment	The VMD identified all potentially serious risks to human and animal health and for the environment and posed suitable questions which on the whole were easy to understand but in some cases could have been clearer and/or included questions to which the answers were nice to know rather than pivotal to the benefit-risk assessment.
Limited There are significant weaknesses in the assessment	The VMD failed to identify an individual potentially serious risk to human or animal health or for the environment and linked to this failed to send suitable questions to the applicant.
Unsatisfactory There are fundamental weaknesses in the assessment such that it is inadequate and ineffective	The VMD failed to identify a number of potentially serious risks to human or animal health or for the environment and linked to this failed to send suitable questions to the applicant.