Published standards for regulatory work 2023/24 - GOV.UK (www.gov.uk)

# PUBLISHED STANDARDS FOR REGULATORY WORK 2023/24

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]
- Achieve an overall performance of ≥92%, which is effective
- 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. The VMD will monitor progress against these targets on a monthly basis. At the end of the year the results against these standards will be published. The way in which this information will be presented is detailed at the end of this document.

## PERFORMANCE LEVELS

| Ineffective | Effective | Excellent |
|---|---|---|
| < 92% | ≥92 – 97% | ≥ 97% |

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

[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*

- 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. Applications

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

[2] Maximum Residue Limit (MRL)
[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<br>• 90 days for parallel MR renewals |
| **6** | **Shared Assessment**<br>with International Partners | For shared assessment or workshare with international partners to reach a decision to approve or refuse within:<br>210 days or as per the agreed contract / arrangement |
| **7** | **Batch timetable (National)**<br>Specific Batch Control | Decision to approve or refuse an application is completed within 20 days of receipt of an application. |
| **8** | **Autogenous Vaccines**<br>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).<br>Complete assessment of mock-ups within 20 days of receipt of correct/revised versions following completion of the scientific assessment phase of:<br>• Decentralised procedures<br>• Mutual Recognition procedures<br>• National MA and VHR procedures |
| **10** | **Validation** | Validate all applications within 10 days of receipt except for:<br>• ATCs – within 5 days<br>• European Decentralised – within 15 days<br>• 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 10 days, or:<br>Within 5 days for:<br>• ATCs<br>• Specific Batch Control<br>Within 10 days for:<br>• new MA applications<br>• variation applications involving <9 products/ changes<br>Within 30 days for:<br>• Variation applications >9 products/ changes<br>• Workshare applications |
| **12** | **New Decentralised (DCP)** | *NI Role: CMS*<br>Send Day 100 comments in accordance with the phase 1 timetable. |
| **13** | **New Mutual Recognition (MRP)** | *NI Role: CMS*<br>Send confirmation of NI position in accordance with the phase 2 timetable. |

| | | |
|---|---|---|
| **14** | **MRP Variations (VRA Type IB & II) and Renewals** | *NI Role: CMS*<br>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:**<br>• high risk product defect reports within 5 working days<br>• 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:**<br>To approve or refuse applications within 15 days (Pharm) and 25 days (Imm) of receipt.<br>*New products are those not previously assessed for importation into the UK. |

| No. | Procedure | Details of target |
|---|---|---|
| **21** | | **Applications for previously imported products:**<br>To approve or refuse applications for New species and new stock use within 15 days of receipt. |
| **22** | | **All other applications:**<br>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)**<br>Immunologicals | Accept or reject requests within 10 days of receipt. |

## 6. Pharmacovigilance

| No. | Details of target |
|---|---|
| **26** | Input, assess and transmit as required to interested parties all human, animal and environmental adverse event reports and follow-up messages within 15 calendar days of receipt of the required information. |
| **27** | Validate, extract and analyse all UK data from Periodic Safety Update Reports within 50 calendar days of receipt. |
| **28** | Send the final inspection report to inspected Marketing Authorisation Holder (MAH) within 90 calendar days of the closing meeting. |

## 7. Inspections

<table>
<tr><th>No.</th><th>Procedure</th><th>Details of target</th></tr>
<tr><td>29</td><td>Inspections performed at relevant sites on a risk-basis<br>within 3 years (GMP) or 5 years (GDP) of the last inspection</td><td rowspan="3"><u>Good Manufacturing Practice (GMP)</u><br>1. Validate applications for authorisation within 10 days.<br>2. Inspect new UK veterinary-only manufacturing sites within 90 days of the application being validated.<br>3. Conduct risk-based inspections of UK veterinary-only manufacturing sites at a frequency not exceeding 3 years[(a)].<br>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)].<br>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.<br><br><u>Good Distribution Practice (GDP)</u><br>1. Validate applications for authorisation within 10 days.<br>2. Inspect new UK veterinary-only wholesale dealer sites within 90 days of the application being validated.<br>3. Conduct risk-based inspections of UK veterinary-only wholesale dealer sites at a frequency not exceeding 5 years[(a)]<br>4. Issue the inspection deficiency report within 30 days of completing the inspection.<br><br>[(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>30</td><td>Within 30 days of the last day on site, send inspection deficiency report<br>to manufacturers (GMP) or wholesalers (GDP)</td></tr>
<tr><td>31</td><td>Within 90 days of the last day on site, send GMP Certificates to manufacturers</td></tr>
<tr><td>32</td><td>Approval of new Feed business operators and SQP retailer sites within 45 days of application validation</td><td rowspan="2"><u>Feed Business Operators & SQP Retailers</u><br>1. Validate applications for approval within 10 days.<br>2. Approve new Feed business operators and SQP retailer sites within 45 days of the application being validated.<br>3. Issue the inspection report within 30 days of completing the inspection.</td></tr>
<tr><td>33</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 |
|---|---|
| **34** | 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. |
| **35** | Log, analyse, develop and disseminate intelligence internally, and if applicable to relevant enforcement partners, within 5 working days of receipt, whilst ensuring compliance with GDPR principles. |

## 9. Residues

| No. | Procedure | Details of target |
|---|---|---|
| **36** | **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. |
| **37** | **Testing of samples** | 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. |
| **38** | **Investigations into findings** | Ensuring over 80% of investigations into residue violations are completed within 4 weeks of receipt of non-compliance sample paperwork from the laboratory. |

## 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<br>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<br>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<br>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<br>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. |

**PUBLICATION OF RESULTS**

Individual Results

Our performance against each target will be published at the end of the year for each category / application type involving at least 12 items / applications.

Overall Results

The following system will be used to obtain a score as an overall measure of the performance.

**Excellent – 6 points**
**Effective – 4 points**
**Ineffective – 0 points**

A total score will then be calculated and this will be judged against the following overall criteria:

**Total point score of more than Y (Y calculated as maximum possible score[7] x 0.97) = Excellent**

**Total point score of X to Y = Effective**

**Total point score of less than X (X calculated as maximum possible score x 0.92) = Ineffective**

The overall score will be published at the end of the financial year.

[7] 6 x the number of category / application types that qualify for inclusion in the overall score i.e. involving 12 or more data points)