PUBLISHED STANDARDS FOR REGULATORY WORK 2019 / 2020

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

Business Priority 2 - Delivery: A) Facilitate wider availability 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. Import, export and batch release schemes
5. Pharmacovigilance
6. Inspections (GMP and GDP)
7. 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
- Reference to EU procedures will be removed in the event of a 'no deal' scenario

[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 MRLs[3]. All other new MA applications (excl. MAPI[4] and Copycats)	Decision to approve or refuse an application is completed within 180 days of receipt of a valid application.
3	**Standard timetable (National)** Type II variations 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)** Renewals (MA & VHR) Type IB variations 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 variations Administrative Type IB variations New ATC (Type A / S) ATC variations & renewals	Decision to approve or refuse an application is completed within 30 days of receipt of an (valid) application
6	**Batch timetable (National)** Specific Batch Control	Decision to approve or refuse an application is completed within 20 days of receipt of an application
7	**Autogenous Vaccines** New & Variations	Complete scientific assessment by Day 45

[2] Marketing Authorisation (MA)
[3] Maximum Residue Limit (MRL); MRL targets are only applicable in a 'no deal' scenario
[4] Marketing Authorisation for Parallel Import (MAPI)
[5] Veterinary Homeopathic Registrations (VHR)
[6] Animal Test Certificate (ATC)

No.	Procedure	Details of target
8	**Mock-Ups**	Complete assessment of mock-ups within 20 days of receipt. 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
9	**Validation**	Validate all applications within 10 days of receipt except for: • ATCs – within 5 days • European Decentralised – within 14 days • CMS Type IB Variations – within 5 days
10	**Issue of authorisation documentation**	Issue authorisation documentation following conclusion of scientific or mock-up assessment, within 10 days, or: Within 5 days for: • ATCs • Specific Batch Control Within 30 days for: • Grouped Type IA Workshare applications
11	**New Centralised (CAP)**	*UK Role: Comment* Send Day 100 comments in accordance with the timetable
12	**New Decentralised (DCP)**	*UK Role: CMS* Send Day 100 comments in accordance with the phase 1 timetable
13	**New Mutual Recognition (MRP)** **and New DCP**	*UK Role: CMS* Send confirmation of UK position in accordance with the phase 2 timetable
14	**MRP Variations (Type IB & II)** **and Renewals**	*UK Role: CMS* Send UK 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. For centralised applications, it will be available on the EMA website.*		

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. Import, Export and Batch Release Schemes

No.	Procedure	Details of target
19	**Special Import Certificate (SIC) / Wholesale Dealers' Import Certificate (WDIC): Requiring assessment**	**Applications for new* products:** To approve or refuse applications within 15 days of receipt *New products are those not previously assessed for importation into the UK
20		**All other applications:** To approve or refuse applications within 2* or 10 days of receipt ** 2 days for applications where use of the product is urgent.*
21	**Export Certificates**	Accept or reject applications within 10 days of receipt
22	**Batch Release Requests (BRRs)** Immunologicals	Accept or reject requests within 10 days of receipt

5. Pharmacovigilance

No.	Details of target
23	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.

24	Validate, extract and analyse all UK data from Periodic Safety Update Reports within 50 calendar days of receipt
25	Send the final inspection report to inspected Marketing Authorisation Holder (MAH) within 90 calendar days of the closing meeting.

6. Inspections

No.	Procedure	Details of target
26	**Inspections** Good Manufacturing Practice (GMP) Good Distribution Practice (GDP)	Inspections performed at relevant sites on a risk-basis and within 3 years (GMP) or 5 years (GDP) of the last inspection. Under exceptional circumstances the maximum periods above may be extended provided that this is justified by a documented risk assessment, based on formal, defined criteria.
27	**Final Inspection Reports**	Within 90 days of an inspection, issue initial inspection report, assess company's responses of corrective/preventive actions, and issue final inspection report (with GMP certificate for manufacturers)
28	**Product Defects**	Respond to: • **high risk** product defect reports within 5 working days • **other** product defect reports within 10 working days
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.		

7. 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 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:

Level	Outcome of the VPC Evaluation
1	The VMD identified all potentially serious risks to human and animal health or for the environment 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.
2	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.
3	The VMD identified all potentially serious risks to human and animal health and for the environment however generally the questions posed weren't sufficiently clear and easy to understand.
4	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.
5	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 for will be published at the end of the financial year.

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