Veterinary medicines: National authorisation application timetables from 1 April – updated 15 August 2019

From the 1 April 2019 all national applications will be processed on one of six timetables that vary in length depending on the complexity and nature of the application under assessment.

This applies to national Marketing Authorisations (MAs), Animal Test Certificates (ATCs) and Veterinary Homeopathic Registrations (VHR) and variations to or renewals of these. It also covers specific batch control applications for pharmaceutical products.

It does not apply to Autogenous Vaccine Applications or batch release requests; both of which will be processed using current timelines and procedures.

What are the benefits

Having fewer and easier to follow timetables will make national procedures more efficient and transparent, and our published standards will better reflect the work that we do.

The new timetables have more structured clock stops which allow a certain number of rounds of questions and set timescales for assessing responses. This means you should have a better idea of when your application should be completed by.

All timetables will be accumulative in terms of clock days which will ensure consistency across all application types.

Applications that are received after 1 April will run on one of the new timetables.

Applications that have already been received and are either in the validation or initial assessment periods will transfer onto a new timetable.

All other applications will remain on their existing timetables.

Full details of the clock periods and timescales for each timetable are available on the Timetables for national applications page.

Complex

Used for complex new MA applications and will be completed within 210 days of receipt of a valid application. It will be determined at the validation stage based on set criterion, such as whether there are novel therapies or new active substances, whether an application is complex or major. It is likely

that most biological and immunological applications will be processed on a complex timetable.

Major

Used for new MA applications including variation-extensions but excluding MAPIs and Copycats, and will be completed within 180 days of receipt of a valid application.

Standard

Used for MAPIs and Copycats, New VHRs, and Type II variations and will be completed within 120 days of receipt of a valid application.

Shortened

Used for Type IB variations, MA and VHR renewals, new ATCs (Type B) and conditional data. These will be completed within 60 days of receipt of a valid application.

Minor

Used for New ATC (Type A and S), ATC variations and renewals, Type IA variations, and administrative Type IB variations. These will be complete within 30 days of receipt of a valid application.

Batch

Used for Specific Batch Control applications and will be completed within 20 days of receipt of an application.

Additional application process improvements

Multiple products

MA Renewals

You may now include more than one product in a renewal application as long as all products form part of a product range. A product range includes all strengths and pharmaceutical forms of a product, for example:

- VMD 5 mg tablets for cats and ferrets
- VMD 10 mg tablets for small dogs
- VMD 20 mg tablets for medium dogs
- VMD 30 mg tablets for large dogs

A fee will still be charged per product, not per application.

New MAs

If you submit a number of new MA applications for a product range, these will be grouped together for assessment purposes and one application number

assigned. A fee will still be charged per product, not per application.

MA Variations

No change to current position; you can continue to submit grouped or workshare applications for multiple products.

Validation

All MA and VHR applications will be validated within 10 days of receipt. For ATC applications, the validation period remains as 5 days.

Specific batch control applications and Type IB administrative variations will no longer be validated and will go straight into an assessment period upon receipt. Like Type IA variations, these applications will be charged for regardless of the outcome of whether the application is approved or refused.

Clock stops

The clock may be stopped for a number of reasons:

- when we require further information / clarification from you to progress an application
- to ensure an application for a new authorisation can be considered at an appropriate peer review meeting
- during the sign-off period, and in exceptional circumstances, to resolve minor outstanding issues, which is of benefit to you especially when the alternative is to refuse the application
- to get expert advice from a third party, such as Veterinary Products Committee or other Government Department
- to allow communication with Ireland during procedures on joint-labelled products

Questions

You will no longer receive individual question letters from different disciplines during the latter phase of a new MA application.

All questions raised during any part of a procedure will be sent as part of a consolidated list of questions.

Company response

This remains the same, but has been included here to remind you about the importance of submitting full company responses.

The clock will only restart on receipt of a full company response, which is one that addresses all the questions raised.

If, during the assessment of the company response, it is realised that not all questions have been answered therefore making it a partial response, the

clock will be stopped and rewound and you will be asked to submit responses to the outstanding questions.

Mock-Ups

We will be improving this process by applying the ‘2-strike’ system in a more consistent manner. The 2-strike system means that if mock-ups are incorrect upon second submission, the application will be signed-off on condition that mock-ups are submitted for assessment under cover of a separate variation prior to any marketing of the product.

For products that aren’t joint-labelled, there will be one mock-up period and the clock can be stopped only once during this period to allow revised mock-ups to be submitted, if needed. Upon receipt of the revised mock-ups, the clock will restart where it left off; it will not revert to 0.

For joint-labelled products, there may be two mock-up periods. The first is for both countries to assess mock-ups and agree a way forward. If revised mock-ups are needed, these will be requested at the end of the first mock-up period. Once received, the second mock-up period will start.

Issue period

ATCs will continue to be issued within 5 days from the end of the assessment period.

Specific batch control applications will now be issued within 5 days rather than 3 days; however, as they are no longer being validated, the overall timescale is still shorter.

All other applications will be issued within 10 days except where an application includes multiple products. In this case, the issue period may be extended to 20 days.

Refusal

For new MA applications, excluding MAPIs and copycats, you will continue to be notified of our intent to refuse an application and offered a right of appeal before any action is taken.

For further information, please email n.shilling@vmd.defra.gsi.gov.uk