

## **NATIONAL MA APPLICATIONS** **TIMETABLES AND PROCEDURES**

(Please refer to Veterinary Medicines Guidance Note No. 2)

The timetable used for MA applications progressed on a national basis only is set out below. This timetable is used for all MA applications; however, for copycats and MAPIs (where the parent product is mutually recognised) some of the targets are different (highlighted in yellow).

Validation: With 10 days of receipt	Application validated.
Initial Assessment: By 75 / 90 days	Assessment begins; by day 75 / 90 the application will be approved, refused or questions sent to the MAH. <ul style="list-style-type: none"> <li>• If approved – application proceeds into the mock-ups period</li> <li>• If refusal proposed – MAH notified and given opportunity to appeal</li> <li>• If questions asked – application proceeds into company response period</li> </ul>
Company Response: Within 180 days (Clock stops)	The MAH should provide response to questions within 180 days of receiving the 'question letter'.
Sign-Off by assessors: By 130 / 180 days	Assessment continues; by 130 / 180 days the application will be approved or refused. <ul style="list-style-type: none"> <li>• If approved – application proceeds into the mock-ups period</li> <li>• If refusal proposed – MAH notified and given opportunity to appeal</li> </ul> <p>NB. The clock may stop and start several times during the sign-off period in order to allow further discussion between the VMD and MAH to resolve any outstanding issues.</p>
Mock-Ups period: Within 20 days of receipt of correct, revised mock-ups, or confirmation of no mock-ups	Assessment of mock-ups; following approval of correct, revised mock-ups, or confirmation of no mock-ups, the application will proceed into the issue period
Issue: Within 10 days from the end of the mock-ups period	Issue authorisation documentation to the MAH

The timetable used for a renewal of a nationally authorised MA is set out below.

Validation: With 10 days of receipt	Application validated.
Initial Assessment: 0 – 60 days	<p>Assessment begins; by day 60 the application will be approved, refused or questions sent to the MA holder.</p> <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MAH notified and application ends</li> <li>• If questions asked – application proceeds into company response period</li> </ul>
Company Response: Within 60 days (Clock stops)	<p>The MAH should provide response to questions within 60 days of receiving the ‘question letter’. NB. If no response is received within the set deadline, or if the response is unsatisfactory, the application will be considered at an internal meeting to discuss refusal of the application, which will lead to expiry of the MA.</p>
Sign-Off: 60 – 120 days	<p>Assessment of response; within 60 days from receipt of the company response the application will be approved or refused.</p> <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> </ul>
Issue: Within 10 days of approval	Issue authorisation documentation to the MA holder.

The timetables used for variation applications dealt with on a national basis only are set out below.

## TYPE IA

Initial Assessment: Day 0 – 30	Assessment begins; by day 30 the application will be approved or refused. <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> </ul>
Issue: Within 10 / 30* days of approval (*for grouped variations)	Issue authorisation documentation to the MA holder.

## TYPE IB – CLOCK DAYS ARE NOT ACCUMULATIVE

Validation phase: Within 10 days of receipt:	Application validated.
Initial Assessment: Day 0 – 30	Assessment begins; by day 30 the application will be approved, refused or questions sent to the MA holder. <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> <li>• If questions asked – application proceeds into company response period</li> </ul>
Company Response: Within 30 days (Clock stops)	The MA holder should provide response to questions within 30 days of receiving the 'question letter'. Two copies of the responses should be provided if submitting hard copies. NB. If no response is received within the set deadline, or if the response is unsatisfactory, the application will be refused and the MA holder notified accordingly.
Sign-Off: Day 30 – 60	Assessment of response; by day 60 the application will be approved or refused. <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> </ul>
Issue: Within 10 days of approval	Issue authorisation documentation to the MA holder.

## TYPE II – CLOCK DAYS ARE NOT ACCUMULATIVE

In certain circumstances a Type II variation may be run on a reduced timetable, which will reflect the timetable and procedures used for a Type IB variation; otherwise the variation will run on a normal or extended timetable as outlined below. NB. Workshare variation involving nationally authorised products in more than one member state will be run in accordance with an EU Type II timetable. UK Only workshare will run in accordance with a national Type II timetable.

Normal		Extended	
Validation: With 10 days of receipt			Application validated.
Initial Assessment: 0 – 60 days		0 – 90 days	Assessment begins; by day 30 the application will be approved, refused or questions sent to the MA holder. <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> <li>• If questions asked – application proceeds into company response period</li> </ul>
Company Response: Within 60 days (Clock stops)			The MA holder should provide response to questions within 60 days of receiving the 'question letter'. The company response may be extended to a maximum of 120 days upon request. Three copies of the responses should be provided if submitting hard copies. NB. If no response is received within the set deadline, or if the response is unsatisfactory, the application will be refused and the MA holder notified accordingly.
Sign-Off: 60 – 120 days		90 – 180 days	Assessment of response; within 60/90 days from receipt of the company response the application will be approved or refused. <ul style="list-style-type: none"> <li>• If approved – application proceeds into issue period</li> <li>• If refused – MA holder notified and application ends</li> </ul>
Issue: Within 10 / 30* days of approval (* for workshare variations)			Issue authorisation documentation to the MA holder.

## ADMINISTRATIVE VARIATION

Validation phase: Within 10 days of receipt: NB. N/A for single Type IA variations or Type IA led grouped variations)	Application validated.
Sign-Off: Day 0 – 30 / 60*  (* for applications involving 10 or more changes)	By day 30/60 the application will be approved and the authorisation documentation issued to the MA holder, or the application will be refused and the MA holder will be notified accordingly.