HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Decentralised and Mutual Recognition Procedures for Veterinary Medicinal Products using Ireland as RMS

AUT-G0059-~~87~~
~~13 SEPTEMBER 2021~~16 FEBRUARY 2022

CONTENTS

1 SCOPE

This guide covers applications for authorisations of veterinary medicinal products using the decentralised procedure (DCP) or the mutual recognition procedure (MRP) with Ireland as the reference member state (RMS).

2 INTRODUCTION

This document aims to provide companies intending to submit applications for marketing authorisation for a veterinary medicinal product, using either the decentralised or mutual recognition procedure, with a description of the services available and the benefits of using Ireland as the RMS.

3 DECENTRALISED PROCEDURE

3.1 Steps in the operation of the decentralised procedure

The applicant should submit an email of intention informing the HPRA that a DCP is proposed with Ireland as RMS. This should be sent to vetinfo@hpra.ie for the attention of the Planning and Authorisations Manager in the Veterinary Sciences Department, at least six months before the intended submission.

It is strongly recommended that the applicant meets with HPRA representatives to discuss the application, the likely date for receipt of the dossier, the proposed Concerned Member States (CMS), the proposed start date, etc. **Any start date agreed at this time is provisional**.

The applicant should confirm their intent to submit an application to the HPRA at least three months prior to the intended start date. The applicant will then be given a procedure number and should inform all CMS of their intention to submit an application. The RMS will also inform the CMS of the proposed start date and timetable.

The applicant should confirm that the application will be submitted on the proposed date at least one month prior to submission.

The applicant simultaneously submits an identical dossier to the HPRA and all CMS in time for the required 145-day validation procedure (note: for generic applications using a European Reference Product, this period may be extended). The cover letter should confirm that the submitted dossier is identical in all Member States. The applicant notifies the HPRA and CMS of the dates of dispatch of the dossier and the HPRA will then start the validation period by sending an email to all CMS and the applicant.

The procedure will begin at the end of the validation period.

Applicants are also referred to the CMDv Best Practice Guide for Veterinary Decentralised Procedure.

3.2 Clock dates

ASSESSMENT STEP I	ACTION
Day -154 to Day 0	Notification of validation problems concerning administration or regulatory issues should be notified by the CMS to the RMS and applicant.
Day 0	RMS informs the applicant and CMS of the start date and timetable of the procedure.
Day 0 to Day 70	RMS assessment.
Day 70	Preliminary Assessment Report (AR) and SPC, labelling and package leaflet sent to CMS and applicant by RMS.
Day 100	CMS comments to RMS and applicant.
Day 100 to Day 105	Preparation of LOQ1 by applicant: applicant may be asked for clarification on some points.
Day 105	Applicant circulates a compiled LOQI to the RMS and CMS.~~RMS sends LOQ1 to applicant and CMS and the clock is stopped for an agreed period.~~
CLOCK STOP (three months with extension if justified)	Applicant prepares responses. If agreed with assessor(s), applicant may send draft responses in advance of the final response. The response, including all attachments, should be sent by email to the RMS and CMS. RMS will check that all questions are answered and all attachments present before restarting the clock.
Day 106	Clock restarted after valid submission of responses from the applicant with a revised timetable.
Day 106 to Day 120	RMS assessment of responses.
Day 120	RMS sends draft AR, draft SPC, draft labelling and package leaflet to CMS and applicant.
Note: Day 120 is a fixed day each month as specified in the CMDv guide, GUI-005 Final 'Clock Start Dates'.	

ASSESSMENT STEP II	ACTION
By Day 145	CMS sends comment (potential serious risk, SPC, labelling and package leaflet) to ~~RMS, RMS forward to~~ applicant.
Day 150	~~RMS~~ Applicant sends compiled LOQ2 to RMS and CMS ~~and applicant~~.
By Day 170	Applicant to send responses to LOQ2 to RMS~~, RMS forwards to~~ and CMS.
Day 190	RMS sends assessment of responses to applicant and CMS.
By Day 195	Pre-meeting comments to be received from CMS.
Day 197/198 (approx.)	Discussion at CMDv/Vitero (teleconference) meeting.
By Day 203~~2~~	Applicant to send revised SPC, labelling and package leaflet to the RMS. RMS forwards these to CMS with revised AR if necessary.
By Day 205	If further modifications are necessary, more revised drafts are sent. Note: each time the SPC is updated, updated labelling and package leaflet should also be submitted. Draft translations in national languages can also be submitted at this time.
Day 210	RMS sends conclusion (agreement or disagreement) email including, if agreement reached: ~~common renewal date,~~ final SPC, labelling and package leaflet~~, final AR,~~ finished product specifications and any agreed commitments. If there is disagreement, RMS prepares for CMDv referral.

NATIONAL STEP	ACTION
Day 215	Applicant to provide mock-ups. Assessors prepare the Public Assessment Report for publication to HPRA website following review by applicant.
By Day 240	Issue authorisation if acceptable mock-ups received (or issue with commitment to provide before marketing).

3.3 Fees

For products entering the DCP where Ireland is acting as the RMS, applicant companies are required to pay the relevant fee, Outgoing Decentralised (code 527 (Complex Dossier – New active substance) / 547 (Reduced Dossier Complex) / 567 (Reduced Dossier Standard)), see the HPRA 'Guide to Fees for Veterinary Products'.

More detailed information on the fees charged by the HPRA can be found in the 'Fee application form (veterinary)'.
The HPRA 'Guide to Fees for Veterinary Products' provides guidance on the fee structure operated by the HPRA; please see the 'Publications and Forms' section of www.hpra.ie.

4 MUTUAL RECOGNITION PROCEDURE

4.1 Steps in the operation of the mutual recognition procedure

The product must first be licensed nationally. If the product is not already authorised in Ireland or any other Member State, the Decentralised Procedure should be used (see section 3 above).

- The applicant marketing authorisation holder (MAH) submits an email of intention to vetinfo@hpra.ie for the attention of the Planning and Authorisations Manager, informing the HPRA that an MRP is proposed with Ireland as RMS. Available slot requests are displayed at the 'Medicines authorisation' section of www.hpra.ie.

- HPRA representatives will be available to meet with the applicant to review the dossier, likely date for receipt of updated dossier, names of Concerned Member States (CMS), provisional start date, etc. Alternatively, where appropriate, these may be decided by correspondence or email. **Any start date agreed at this time is provisional and will not be confirmed until after the dossier is reviewed**.

- The updated dossier is received from the applicant in accordance with Notice to Applicants. Usually a VRA-Complex ~~Type II complex~~V ~~v~~ariation is required to bring it into line with current guidelines.

- As far as possible within 90 days of receipt of the dossier, assessors prepare a draft assessment report, communicating with the applicant regarding any remaining deficiencies in the dossier.

- On completion of the dossier review and agreement regarding the content of the final dossier (including submission of corrected parts where necessary), the HPRA allocates a procedure number and advises this to the applicant.

- ~~The applicant sends the updated dossier to the HPRA at least 30 days~~

- The next available start date for MRP is confirmed by the HPRA, based on HPRA resource availability and published CMDv timetable, and the draft assessment report is sent to the applicant for comment, including checking for accuracy and referencing.

- The applicant sends the updated dossier to the HPRA at least 30 days before the agreed ~~d~~Day -15.

- By Day -154 the HPRA sends out the final assessment report and timetable to CMS and applicant.

- The applicant sends the identical dossier to all CMS in time for the required 145 day validation procedure (see CMDv Best Practice Guides), and sends a Letter of Dispatch to the RMS and all CMS, triggering the validation period.

4.2 Clock dates

Day 0: start of procedure

Day 540: CMS questions

Day ~~77/78~~81/82: CMDv meeting

Day 90: Acceptance or arbitration

4.3 Fees

For authorised products entering the MRP, applicant companies are required to pay an Outgoing Mutual Recognition Supplement fee (code 518 or (Complex Dossier) / code 538 (Reduced Complex Dossier) / code 558 (Reduced Dossier Standard)), see HPRA 'Guide to Fees for Veterinary Products'. This covers not only the production and release of the assessment report, which will be sent to the CMS in the MRP, but also the handling and administration of the MRP.

If the dossier has to be updated ahead of the MRP commencing, (i.e. involving changes to the Expert Reports, Parts II, III or IV), applicants must also pay a ~~n~~National VRA –Complex ~~Type II Complex Variation~~ fee (code 596). Alternatively, where there are only minor changes to Part IB of the dossier (e.g. to bring the SPC and/or labelling into line with current guideline requirements), a ~~n~~National VRA-S ~~Type II Standard Variation fee~~ (code 597) is required. The variation fee payable is in addition to the Outgoing Mutual Recognition Supplement fee. Changes to Part IA of the dossier will be considered as part of the MRP and covered by the Outgoing Mutual Recognition fee.

In the case of a repeat use of the MR procedure, the assessment report is likely to need updating and a second fee (Outgoing Mutual Recognition Supplement, code 558) is payable for handling and administering the new MRP.

In most cases the Veterinary Product Authorisation will have to be varied again at the end of the MRP to incorporate changes required by the CMS. This is done by the HPRA at the end of the procedure. There is no fee for this procedure.

More detailed information on the fees charged by the HPRA can be found in the 'Fee Application Form (Veterinary)'. A further document is also available providing guidance on the

fee structure operated by the HPRA and can be found in HPRA 'Guide to Fees for Veterinary Products', please see the 'Publications and Forms' section of www.hpra.ie.

ANNEX A BENEFITS OF USING IRELAND AS RMS

A1 Experience to date

Over the last number of years, Ireland has gained considerable experience as RMS in both the decentralised and mutual recognition procedures. As recorded in the CMDv/IFAH-Europe survey report on the Mutual Recognition and Decentralised procedures for veterinary medicinal products – available on the HMA website, Ireland, though a small agency, has been one of the leading Member States involved as RMS in European procedures since 2003.

A2 Service commitments

Companies choosing Ireland as RMS can expect the following level of service to be provided in a friendly and efficient manner, based on the HPRA's expert knowledge and experience of acting as RMS:

- Pre-submission meetings will be arranged as required in order to provide guidance and advice on the forthcoming procedure.

- A dedicated personal contact from the administration team will be appointed for the duration of the procedure through whom the company can liaise with the HPRA and queries can be answered.

- Clear communications will be provided via the appointed personal contact. The HPRA will keep the applicant advised of all key deadlines in the procedures and actions to be taken at those times.

- Guidance/advice/feedback will be available from the individual assessors in the HPRA assessment team throughout the procedure.

Note that in performing their role as RMS, the HPRA may on occasion make use of the services of other agencies/external experts.

A3 Department personnel

An organisational chart outlining the department's structure and personnel is available under the Veterinary contact details area on the HPRA's website.

A4 HPRA offices

A4.1 Transport links between the HPRA and Dublin Airport

A coach service is available for transportation between the HPRA and Dublin Airport, the full details of which can be found on the Aircoach website.

A bus service is available for transportation between the HPRA and Dublin Airport, the full details of which can be found on the Dublin Bus website.

A4.2 Transport links between the HPRA and Connolly Railway Station

A bus service is available for transportation between the HPRA and Connolly Railway Station, the full details of which can be found on the Dublin Bus website.
Alternatively you could take any Dublin Area Rapid Transport (DART) train from Connolly Railway Station to Pearse Street Railway Station and walk from Pearse Street Railway Station to the HPRA using the directions given in the following link Directions from Pearse Station to the HPRA.

A4.3 Hotel accommodation

The Camden Court Hotel
Lower Camden Street,
Dublin 2.
Tel: +353 (0) 1 475 9666
Fax: +353 (0) 1 475 9677
Website: www.camdencourthotel.com

The Shelbourne Dublin
27 St Stephen's Green,
Dublin 2.
Tel: +353 (0) 1 663 4500
Fax: +353 (0) 1 661 6006
Sales: +353 (0) 1 663 4500
Website: www.marriott.co.uk

Conrad Dublin
Earlsfort Terrace,
Dublin 2.
Tel: +353 (0) 1 602 8900
Fax: +353 (0) 1 676 5424
Reservations: + 353 (0) 1 602 8900
Website: conradhotels3.hilton.com

The locations of the above hotels in relation to the HPRA are shown in Figure 1 below.

A5 Additional information

Any further information required can be obtained by contacting the Veterinary Sciences Department of the HPRA as follows:

Veterinary Sciences Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6767836
Email: vetinfo@hpra.ie

FIGURE 1. HOTELS IN THE VICINITY OF THE HPRA