HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Guide to
# Renewal of Veterinary Product Authorisations*

**AUT-G0024-5**
**26 JANUARY 2022**
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

***Renewal applications following implementation of Regulation (EU) 2019/6**

As a result of the application on 28 January 2022 of Regulation (EU) 2019/6 on veterinary medicinal products, the requirement for a renewal procedure, after five years, will become obsolete. (A provision for a renewal under exceptional circumstances will be retained after 28 January 2022; however, it is expected that this will occur very infrequently).

*Renewals due before 28 January 2022 (i.e. for* marketing authorisations (*MAs) due to expire by or on 27 July 2022):*

Marketing authorisation (MA) renewals with an expiration date due within six months after the date of application of Regulation (EU) 2019/6 (renewals received before 28 January 2022, i.e. for MAs due to expire by or on 27 July 2022, required to be submitted 6 months in advance of their renewal date), will be assessed in accordance with Directive 2001/82/EC (SI No 786 of 2007), as amended, with the relevant documentation provided.

*Renewals due after 28 January 2022 (i.e. for MAs due to expire on or after 28 July 2022):*

MA renewals due to expire post 28 January 2022 (i.e. on or after 28 July 2022), will be dealt with by the HPRA via an administrative procedure. The HPRA will handle the administrative procedure and issue an unlimited licence.

MAHs **not** wanting to avail of this administrative procedure should notify the HPRA and they will be informed that their licence will lapse on their given renewal date.

Information regarding steps involved in the administrative procedure will become available on the HPRA website.

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# 1 INTRODUCTION

This is a guidance document for holders of Veterinary Product Authorisations (VPAs) for veterinary medicinal products issued by the Health Products Regulatory Authority (HPRA), describing the background to and the procedure for renewing VPAs under European Council Directive 2001/82/EC.

# 2 BACKGROUND

## 2.1 Requirements for renewals

In accordance with Article 28 of European Council Directive 2001/82/EC, a marketing authorisation (MA) is normally granted by the Competent Authority for a five-year period. In Ireland the Health Products Regulatory Authority (HPRA) is the Competent Authority. An MA issued by the HPRA for a veterinary product is known as a Veterinary Product Authorisation (VPA). On receipt of a valid application from the Marketing Authorisation Holder (MAH) the MA can be renewed, based on a re-evaluation of the benefit/risk balance. Once renewed, the MA shall be valid for an unlimited period, unless the Competent Authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

In accordance with Article 12 of European Council Directive 2001/82/EC, a marketing authorisation will not be renewed unless the person responsible for placing the product on the market (i.e. MAH) is established in the Community.

Changes to the authorisation unconnected with the renewal must be requested by way of variation application(s). Variation applications must be submitted and paid for separately.

The requirements for renewals apply to all licensed veterinary medicinal products (see note* above for handling renewals after the application of Regulation (EU) 2019/6).

## 2.2 Manner and timing of renewal application

Renewal applications should be submitted at least six months before the expiry of the current MA (see note* above for pending renewals up to and until 27 July 2022). It is the responsibility of individual companies to make timely applications for renewal of an MA.

The standard EU application form is used for products authorised via the national procedure, the decentralised procedure and the mutual recognition procedure. Forms are available on the 'Publications and Forms' section at www.hpra.ie.

EU legislation requires that the marketing authorisation will expire if a renewal application is not received before the expiry date of the authorisation (see note* above). MAHs will be

notified of expired marketing authorisations for which renewal applications have not been received. Those products will be deemed not authorised in Ireland and the Department of Agriculture, Food and the Marine will be informed of the change in authorisation status.

Once a valid renewal application has been received, the HPRA will endeavour to review the application as quickly as possible. In accordance with the European Communities (Animal Remedies) Regulations, 2007, the marketing authorisation shall remain in force pending the outcome of the renewal assessment/administrative procedure.

## 3 PARTICULARS TO BE CONTAINED IN RENEWAL APPLICATIONS

### 3.1 Documentation required

An application for renewal of a MA must be made using the EU form: Application for Renewal of a Marketing Authorisation (see note* above).

Documentation should be presented as appendices to the EU application form, as detailed in the form. Justification for any documentation omitted from the application must be provided.

Applications which do not include the required documents will not be validated.

Documentation requirements for renewal of national authorisations are the same as those for mutually recognised authorisations. .

Guidance relating to national procedures for submission of the Summary of Product Characteristics and product literature are detailed below.

### 3.2 Summary of Product Characteristics (SPC)

The most recent version of the SPC approved by the HPRA should be submitted with the renewal application (see note* above if processed under Directive 2001/82/EC, as amended). Proposals to change the SPC are generally not acceptable at renewal stage, however the following exceptions apply:

- Changes arising from the review of the Periodic Safety Update Report (PSUR).
- Editorial changes proposed in order to comply with European guidelines (e.g. CMD(v) annotated Quality Review of Documents (QRD) template) or which do not alter the substance of the previously approved SPC.

For standard statements to be included in the SPC, reference should be made to the CMD(v) annotated QRD template, available on the HMA website.

It is strongly recommended that MAHs propose any amendments to the SPC in order to take account of PSUR data or to comply with relevant SPC guidelines at the time of submitting the renewal application, in order to expedite the assessment. Where changes are proposed, these should be highlighted by means of tracked-changes in the SPC provided with the renewal application.

### 3.3 Labels and package leaflet

The submission of actual labels and leaflets or colour mock-ups of the actual sales presentation, as approved by the HPRA, is not required however, the most recently approved versions of the labelling and/or leaflet texts should be provided with the renewal application (see note* above regarding implementation of Regulation (EU) 2019/6).

If changes to the labelling text and/or package leaflet text are proposed in order to reflect proposed changes to the SPC or to comply with relevant guidelines, then these should be highlighted by means of tracked-changes in the corresponding labelling and/or leaflet texts submitted with the renewal application.

On completion of the renewal procedure, it is the MAH's responsibility to incorporate any approved changes into the previously approved mock-ups. Where the product is joint labelled with the UK, and the UK requires a review of mock-ups, the UK will perform an independent assessment of the mock-ups. The MAH will provide the HPRA with a copy of the agreed mock-ups post-UK assessment along with a declaration that no changes have been made, other than those arising from revisions to the QRD texts approved during the renewal assessment. The applicant should note that this does not affect the joint-labelling status of the mock-ups.

Please note that if the product is not marketed in Ireland, and colour mock-ups have not previously been approved by the HPRA, the renewal authorisations will be issued on condition that once the MAH decides to market the product, colour mock ups will be submitted to the HPRA for review and approval. These mock-ups should be submitted by way of variation, with the appropriate fee.

## 4 GENERAL GUIDANCE

### 4.1 Products within the Mutual Recognition procedure (MR) or the Decentralised procedure (DC)

For products for which Ireland is the Reference Member State, a common renewal date will be set on completion of the MR/DC procedure.

For MR/DC renewal applications please consult the CMD(v) Guideline on the Processing of Renewals in the Mutual Recognition Procedure.

### 4.2 Harmonised renewal dates

Requests to bring forward a renewal date in order to synchronise the renewal dates for a range of products or to harmonise renewal dates with the UK or other EU Member States are generally facilitated. Any such proposal should be agreed with the HPRA in advance of the proposed date.

### 4.3 Informed consent authorisations

In order to renew an MA that is authorised via informed consent on another MA, the original MA must still hold a valid authorisation at the time of renewal. If the original authorisation is no longer in existence, the product authorisation cannot be renewed unless it is accompanied by a separate variation application to replace the letter of access with the original Part II data. Alternatively, the informed consent MAH must obtain a letter of access to another MA or must submit Part II data on his own behalf. Whichever of these two options are chosen, the change must be applied for as a new product application.

## 5 ADMINISTRATIVE DETAILS

Please see the HPRA 'Guide to Electronic Submissions – Veterinary Medicines' for details on sending the application to the HPRA.

Applications that do not include the necessary information will be classified at validation as unacceptable and the applicant notified (see note* above regarding implementation of Regulation (EU) 2019/6).

Renewal applications that are unacceptable need to be resubmitted or additional data provided within the time span specified by the competent authority, if it is intended to retain the product on the market.

The HPRA encourages communication with the Veterinary Sciences Department. Should you have specific queries please address them to the Veterinary Sciences Department of the HPRA who will endeavour to be of assistance. Queries in respect of renewal requirements or communication relating to renewal applications (or administrative procedure post 28th July 2022, see note* above) submitted to the HPRA should be made by email.

Email: vetinfo@hpra.ie

## 6 FEES

There is no fee for renewal applications, however a supplement is payable for mutual recognition or decentralised applications where Ireland is the RMS. The fee code is 632 (fee code 632 will be retained for renewals under exceptional circumstances, see note* above) and a single supplement covers the VPA range.