HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Parallel Trade for Veterinary Medicines

AUT-G0081-3
28 JANUARY 2022
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

DEFINITIONS

Parallel trade
The trade, from an EU Member State or a country within the European Economic Area (EEA), of a veterinary medicinal product which shares a common origin to one already authorised on the Irish market, by a wholesaler who is not appointed by the marketing authorisation holder of the product on the Irish market.

Irish-market product
The product marketed in Ireland by the originator marketing authorisation holder.

Source country
The EU/EEA country from which the parallel traded product is imported.

Re-packaging
Re-packaging includes re-labelling and re-boxing.

ABBREVIATIONS

EMA	European Medicines Agency
EU	European Union
EEA	European Economic Area (EU and Norway, Iceland, Liechtenstein)
GMP	Good Manufacturing Practice
HPRA	Health Products Regulatory Authority
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PVPA	Parallel Veterinary Product Authorisation
SPC	Summary of Product Characteristics
UPD	Union Product Database

1 SCOPE

This guide applies to nationally, decentralised, mutual recognition or subsequent recognition-authorised products which are parallel traded from another Member State of the EU or an EEA country and distributed on the Irish market. In order to legally place such a product on the Irish market a parallel trade licence (termed a 'parallel veterinary product authorisation') must be obtained from the HPRA.

The legal basis for the parallel trade in the above veterinary medicinal products is set out in Regulation 2019/6 on veterinary medicinal products (hereafter referred to as 'the Regulation') which is effective from 28 January 2022.

The application forms mentioned in this guide are available on the 'Publications and Forms' section of www.hpra.ie.

Products which are centrally-authorised by the European Commission are **not** covered by this guide; those wishing to parallel distribute these products must notify the EMA of their intention. For details of the notification system, refer to EMA website. Please note that applicants are required to make all related documentation (including approval letters) received from the EMA available to the HPRA during an inspection.

2 PARALLEL TRADE LICENCE – PARALLEL VETERINARY PRODUCT AUTHORISATION

2.1 General provisions

A veterinary medicinal product placed originally on the market in another Member State may be parallel traded to Ireland, provided that a product sharing a common origin is authorised in Ireland, and the wholesale distributor has obtained a parallel trade licence (i.e. parallel veterinary product authorisation) from the HPRA to place the parallel traded product on the Irish market. Approval to parallel trade a veterinary medicinal product is granted in line with the Regulation. The parallel trade licence is termed a Parallel Veterinary Product Authorisation and is identified by the letters 'PVPA' in front of the authorisation number.

Article 102(5) of the Regulation requires the wholesaler to notify his intention to parallel trade the product to the marketing authorisation holder and the competent authority in the source Member State. As per Article 102(6), for parallel trade to Ireland, a declaration and confirmation of obligations in relation to the veterinary medicinal product to be parallel traded should be provided to the HPRA. The declaration and obligations are laid down in section 2.3 of this guide for submission of an application for a PVPA.

In granting a PVPA, the HPRA does not consider, and is not in a position to consider, whether any aspect of the authorisation infringes any private civil rights of third parties. The granting

of a PVPA does not absolve the holder from the need to comply with trademark rights of third parties and, to prevent possible infringements of trademarks; applicants should ensure that they are entitled to use the product name in question.

2.2 Conditions of authorisation

A PVPA is granted only for a product that fulfils the following criteria:

- The veterinary medicinal product obtained from the source Member State must share a common origin with the veterinary medicinal product already authorised in Ireland. All of the following conditions should be fulfilled:
  (a) they have the same qualitative and quantitative composition in terms of active substances and excipients;
  (b) they have the same pharmaceutical form;
  (c) they have the same clinical information and, if applicable, withdrawal period; and
  (d) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.
- The veterinary medicinal product obtained from the source Member State complies with labelling and language requirements in Ireland.
- A declaration has been received stating that the Irish wholesaler distributor will ensure that it is kept informed of any pharmacovigilance issues by the wholesale distributor in the source Member State and take appropriate measures should issues arise.
- The marketing authorisation holder and the competent authority of the source Member State is informed of the intention to place the veterinary medicinal product obtained from the source Member State on the Irish market. A declaration plus a copy of this notification must be submitted to the HPRA.
- The marketing authorisation holder in the destination Member State is informed of the intention to place the veterinary medicinal product obtained from the source Member State on the Irish market, at least one month prior to submitting the parallel trade application to the HPRA. A declaration plus a copy of this notification must be submitted to the HPRA.
- The Irish market and the source Member State veterinary medicinal products must not have been recalled from the market for quality, safety or efficacy reasons.
- The Irish wholesale distributor should collect suspected adverse events for the parallel traded veterinary medicinal product and report them to the marketing authorisation holder.

A PVPA is granted either unlimited validity or, if deemed necessary in exceptional circumstances for a maximum period of five years, at which time the authorisation must be re-examined. After this renewal, the PVPA remains valid indefinitely.

In accordance with the European Court of Justice judgement in C-172/00, a parallel trade licence may be granted, or may remain in force even where the marketing authorisation for the Irish-market product is withdrawn for commercial reasons or is replaced by a new version under the same or a new PVPA number, so long as there are no risks to public health. In cases where the

Irish-market authorisation is withdrawn and the parallel traded product remains authorised, the HPRA may request certain information from the parallel trader in order to adequately monitor adverse reactions occurring in Ireland.

The PVPA ceases to be valid if the parallel traded product ceases to have a valid marketing authorisation in the source Member State.

2.3 Applications

2.3.1 New applications

In order to obtain a PVPA, the wholesale distributor must submit an application as set out below.

An application for a PVPA consists of:

- Completed application form 'Application for a Parallel Veterinary Product Authorisation', available on the HPRA website.
- Covering letter.
- Evidence that the product medicinal product obtained from the source Member State must share a common origin with the veterinary medicinal product already authorised in Ireland.
- Declaration from the wholesale distributor that the Irish wholesaler distributor will ensure that it is kept informed of any pharmacovigilance issues by the wholesale distributor in the source Member State.
- The marketing authorisation holder and the competent authority of the source Member State is informed of the intention to place the veterinary medicinal product obtained from the source Member State on the Irish market. A declaration plus a copy of this notification must be submitted to the HPRA.
- The marketing authorisation holder in the destination Member State is informed of the intention to place the veterinary medicinal product obtained from the source Member State on the Irish market, at least one month prior to submitting the parallel trade application to the HPRA. A declaration plus a copy of this notification must be submitted to the HPRA.
- Proposed Summary of Product Characteristics (SPC). This must be based on the authorised SPC for the veterinary medicinal product authorised in Ireland, as issued by the HPRA only and no other version will be accepted. All SPCs are available on the HPRA website at www.hpra.ie.
- Proposed colour label mock-ups for the immediate container and the outer carton.
- Proposed colour mock-up of the package leaflet.
- Manufacturer's authorisation for the company responsible for re-labelling or re-packaging, issued by the regulatory authority in the appropriate Member State or EEA country (if the manufacturer is not an Irish company).
- Authorisation of the company to distribute wholesale veterinary medicinal products.
- Full colour, high quality scans/photographs of the parallel traded product, clearly showing all sides of the packaging, the product leaflet and the physical appearance of

the product itself. If scans are not of sufficient quality or clarity, a physical sample of the product may be requested.

All organisation details in the application form must be registered in the EMA's Organisation Management Service (OMS) before an application can be made to the HPRA. The applicant should provide the ORG ID and LOC ID received from the OMS. If any of the relevant organisations or sites are not already registered, they will need to be registered with the EMA. Further information is available at https://iris.ema.europa.eu/locations/.

Copies of the application forms and fee forms are available from the HPRA website. Information on the fees and address to send the application to is given in Appendix 1.

Source country
A single source country may be applied for using one application form. In order to parallel trade a product obtained from a number of source countries, a new parallel trade application should be submitted in support of each source country.

Under the Treaties of Accession signed by the EU Member States with the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovakia and Slovenia in 2003, and Bulgaria and Romania in 2005, there is a specific mechanism which entails a temporary derogation to the principle of free movement of pharmaceutical products.

Under the mechanism, the holder, or beneficiary of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the above-mentioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the importation and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection, must give one month's notice to the holder or beneficiary of such protection of their intention, prior to submitting the application, and confirm that they have done so in the application regarding that import. The notification must give the holder or beneficiary sufficient information to adequately identify the product concerned and the country of origin. Upon receipt of the parallel trade authorisation, the parallel trader is again required to give notice to the trademark proprietor by supplying it with a sample of the repackaged product.

This mechanism does not apply to Malta or Cyprus.

Validation
Applications are subject to an administrative check on receipt to ensure that all necessary documentation and samples are submitted with the application. Incomplete applications will not be validated until the missing documentation is provided. In certain cases, the application may be returned to the applicant for re-submission. An administrative fee will be charged in such cases.

Assessment of application
Within 10 working days of validation, the application is assessed to determine if a common origin is confirmed and the obligations of the wholesale distributor in the destination Member State are met in accordance with Regulation (EU) 2019/6 Article 102.

If a common origin is shared and the obligations met, the proposed SPC, labels and package leaflet are assessed and any queries sent to the parallel trader within 15 working days of validation. The 'clock' is then stopped. On receipt of a response, the clock is re-started and the assessment concluded within 45 working days of validation. The decision on the application is then forwarded to the wholesale distributor after completion of processing by the HPRA.

If product common origin and wholesale distributor obligations cannot be demonstrated, the clock is stopped within 10 days of validation in order for the HPRA to request additional information from the wholesale distributor. On receipt of the necessary information, the clock is re-started and the assessment of the application is continued in accordance with the procedure outlined above.

2.3.2 Variations

The parallel trader should ensure that the common origin requirements of products in the source and destination member states remains fulfilled during the lifecycle of the product in order to continue to place the parallel traded product on the Irish market. Changes may require a revision of the product information supplied by the wholesale distributor with the parallel traded product or other amendments to the parallel trade licence. This particularly relates to significant safety variations which must be incorporated into the parallel traded product information.

There should be systems in place for the wholesale distributor to ensure that they have obtained the most recent version of the Irish market product for comparison against the imported product. Records of these checks should be maintained.

The wholesale distributor must also keep informed of any relevant change in the parallel traded product in order to ensure that the PVPA document reflects the current situation at all times. Wholesale distributors are especially reminded to check the labels and leaflets of the parallel traded product as changes made to the texts may have consequences for the product information included with the parallel traded product. Should the parallel traded product's labels

and leaflets not be in English, then the wholesale distributor should be able to show proof of translation on request.

If there is a change in the VPA number of the Irish-market product or in the marketing authorisation number of the parallel-traded product in the destination Member State, the wholesale distributor must notify the change to the HPRA in a variation application using the form 'Application for a Variation to a Parallel Veterinary Product Authorisation' which is available on the HPRA website.

All changes made by the parallel trader to the SPC, label, and leaflet of the parallel-traded product, including changes in line with the source Member State product, must have prior approval from the HPRA. Applications should be made using the variation form, which indicates the variation type for each type of change.

2.3.3 Withdrawal of PVPA

If the PVPA is to be withdrawn, the holder of the authorisation should notify the HPRA using the form 'Notification of withdrawal of authorisations or certificates for veterinary medicines'. Guidance on withdrawals is available in the document 'Guide to Withdrawals of Authorisations or Certificates for Veterinary Medicines'.

2.4 Product information

2.4.1 Labels

Parallel traded products should be labelled with the following information:
- name of the product
- the PVPA holder's name and address
- the PVPA number
- other details as may be necessary to comply with Regulation 2019/6
- the name and address of the manufacturer of the product
- the batch number/packaging code associated with the repackaging/re-labelling operation carried out on behalf of the wholesale distributor

If some of the required label text is already on the parallel traded product in English, these items do not have to be repeated on the PVPA holder's label.

The PVPA holder's label text may be placed over foreign-language text. If the information already printed on the container or carton differs from the information the holder is required to include on the label (e.g. different storage conditions, different product name), the original text must be completely and effectively covered by an over-label.

Full colour mock-ups of the labels are required to accompany each application for a new PVPA or a variation which affects the label. The mock-up should show the placement of the PVPA

holder's label on the source member state product outer packaging and immediate container. The position of the over-label on the carton/container must not be changed without approval from the HPRA.

The HPRA has identified some minor amendments to the labelling and package leaflet which are not considered to require formal assessment. PVPA holders are advised that the following changes do not require notification to the HPRA:

- Moving the location of the batch number/packaging code/expiry date on outer packaging provided that no other details are changed.
- Transfer of the entire text of a carton face to an opposing face, with no change to text, font size, layout, appearance or readability of the text. Please note that a change in the position of an overlabel requires approval from the HPRA.
- The introduction of, or any change to, a barcode, e.g. the number on the barcode, that does not affect any other aspect of the labelling and does not change the location of the barcode, or the position or size of an overlabel if applicable.
- Change to printing key lines on package leaflet or labelling, with no change to text, font size, appearance or readability of information.
- Change in the dimensions of the package leaflet resulting in an increase in the font size of the text.
- Change to the dimensions of a carton with no change in layout or font size of the text.
- Change to a packaging code/internal reference code (not the internal batch number) on the packaging.

In such instances, the revised labels or patient leaflet should be submitted to the HPRA at the next regulatory activity involving a change in the product information. Any and all other changes to product labels or package leaflets will continue to require a formal notification to the HPRA.

2.4.2 Package leaflet

Leaflets should be drawn up in accordance with Quality Review of Documents (QRD) Veterinary Product Information templates.

The product information in the package leaflet must be identical to that on the source country product leaflet.

In the event that the parallel traded products have a different product name to the Irish product, the following statement should be included in the package leaflet: '*The name of this product in <source country> is … '*.

2.5 Manufacture and wholesale

2.5.1 Manufacturers' authorisations

Labelling and re-packaging are defined as manufacturing operations and the wholesale distributor or other company that carries out these operations must hold a manufacturer's authorisation. Manufacturers in Ireland are authorised under the European Communities (Animal Remedies) (No. 2) Regulations 2007. Application forms and information on authorisation requirements may be obtained from the HPRA's website or by contacting the Compliance Department of the HPRA.

If wholesaling the product in Ireland, a parallel trader who holds a manufacturer's authorisation is exempted from the requirement to hold a wholesaler's licence to wholesale parallel traded products, provided that the products are covered by the manufacturer's authorisation (i.e. the manufacturer has carried out manufacturing activities related to those products).

2.5.2 Wholesalers

Where the parallel trader wholesales the product in Ireland and is not the holder of a manufacturer's authorisation, a wholesaler's licence is required under relevant national legislation. An application for an animal remedies wholesaler's licence should be made to the Department of Agriculture, Food and the Marine. Application forms may be obtained from the website of the Department of Agriculture, Food and the Marine.

2.5.3 Batch recalls

Parallel traders are required to ensure that there is a clear audit trail from the supplier (i.e. authorised wholesaler or manufacturer) in the source country. In the event of a recall of a batch of the parallel traded product in the source country, it is imperative that the parallel trader is informed by their supplier so that the parallel trader can take appropriate action on the Irish market, in conjunction with the HPRA. The HPRA requires there to be a contract / technical agreement in place between the supplier and the parallel trader to ensure that information on recalls is passed to the parallel trader; this contract / technical agreement may be requested for review in the course of HPRA inspections at manufacturers and wholesalers.

Should the marketing authorisation on which the PVPA authorisation is based be suspended, revoked or withdrawn for quality, safety or efficacy reasons, a recall of the PVPA product may be required to be executed by the PVPA authorisation holder.

APPENDIX 1 FEES AND SUBMISSION OF THE APPLICATION

A1.1 Fees for applications

Applications must be accompanied by the correct fee - see the '*Guide to Fees for Veterinary Products*' on the 'Publications and Forms' section of www.hpra.ie for details of the fees and the method of fee payment. The fee should be sent on the same day as the application form and data. The application will not be considered until the fee has been paid. All fees must be paid in full and any associated bank charges are for your own account.

A1.2 Submission

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

APPENDIX 2 DOCUMENTATION REQUIREMENTS FOR VARIATIONS TO VETERINARY PARALLEL PRODUCT AUTHORISATIONS

The following general rules apply in every instance:

Articles 61 and 62 of Regulation (EU) 2019/6 foresee two types of variations: Those not requiring assessment and those requiring assessment. Variations classified as variations not requiring assessment, in accordance with Implementing Regulation 2021/17 should be submitted directly on the Union Product database (UPD). Variations classified as variations requiring assessment should be submitted directly to the HPRA with relevant supporting documentation as detailed in *EMA/CMDv/7381/2021 Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations*.

- Each application for a variation to a parallel veterinary product authorisation should be made using the 'Application for a variation to a veterinary product authorisation' available on the 'Publications and Forms' section of www.hpra.ie.
- A brief background explanation for the proposed change should be provided in every instance.
- The precise details of the proposed change should be stated in the present/proposed section of the application form.
- Where changes to the product information (SPC/labels/leaflet) are proposed, these should be clearly highlighted by submitting present and proposed versions of each document.
- There is no requirement to submit documents in duplicate.
- Mock-ups of labels should be an accurate representation of how the product will appear on the market (i.e. all sides of the proposed packaging should be visible and all text, both existing and overlabelled, should be legible).
- Where multiple changes are proposed, each change must be submitted under the appropriate variation category. Multiple variations may be grouped together on one application form provided each category is clearly stated.
- In addition to the background explanation and clearly stating the proposed changes, certain other supporting documentation will be required for various variation categories. These are detailed in the Commission Implementing Regulation 2021/17 (variations not requiring assessment) and Regulation 2019/6 (variations requiring assessment).