HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Parallel Imports for Veterinary Medicines

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

DEFINITIONS

Parallel-importation
The importation, from an EU Member State or a country within the European Economic Area (EEA), of a medicinal product which is equivalent to one already authorised on the Irish market, by an importer who is someone other than the importer appointed by the marketing authorisation holder of the product on the Irish market.

Parallel-distribution
The marketing of a centrally-authorised product, placed originally on the market in one Member State by the marketing authorisation holder (MAH), in any other part of the Community by a 'parallel distributor', independent of the MAH.

Irish-market product
The product marketed in Ireland by the originator company.

Source country
The EU/EEA country from which the parallel 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

1 SCOPE

This guide applies to nationally-authorised products which are parallel-imported 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 import licence (termed a 'parallel veterinary product authorisation') must be obtained from the HPRA – see section 2 below.

The framework for these schemes is that set out in Commission Communication *Parallel Imports of Proprietary Medicinal Products for which Marketing Authorisations have already been granted* (COM(2003)839). The simplified procedures in this guide are in accordance with the procedure in the Communication in terms of the information required to be submitted by applicants and the administrative steps to be taken by the HPRA.

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

Products which are centrally-authorised by the European Commission are **not** covered by this guide; importers 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 IMPORT 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 imported to Ireland, provided that the originator's equivalent product is already on the market here or has been withdrawn for commercial reasons only, and the importer has obtained a parallel import licence (i.e. parallel veterinary product authorisation) from the HPRA to place the parallel imported product on the Irish market. Authorisation is granted under the European Communities (Animal Remedies) (No. 2) Regulations 2007. The parallel import licence is termed a Parallel Veterinary Product Authorisation and is identified by the letters 'PVPA' in front of the authorisation number.

Article 65.5 of Directive 2001/82/EC, as amended by Directive 2004/28/EC, requires the distributor of a product imported from another Member State to notify his intention to import the product to the marketing authorisation holder and the competent authority in the Member State to which the product is to be imported. For parallel importation to Ireland, this means informing the HPRA and the MA holder of the Irish-market product. The obligation to

inform the HPRA is met by the procedure laid down in this section 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 name in question.

2.2 Conditions of authorisation

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

- The Irish-market product must have a current, full marketing authorisation at the time of submission or, if not still authorised, it must have been withdrawn for commercial reasons only. Where there is no longer a marketing authorisation on the Irish market (withdrawn for commercial reasons), the product information published on the VMRI Product Index at http://mri.medagencies.org/veterinary/ which is current and available, should be used by the PVPA holder.
- The parallel-imported product must have the same active substance(s), the same pharmaceutical form and be identical to, or have no significant therapeutic difference from, the Irish-market product.
- The parallel-imported product must be imported from an EU or EEA country and it must have a current, full marketing authorisation in that country.

A PVPA may be granted for parallel imported product from one or more source countries. Where particulars concerning the product (such as appearance or excipients) differ between source countries, the differences are stated in the authorisation document.

A PVPA is granted either unlimited validity or, if deemed necessary for pharmacovigilance reasons, for a maximum period of five years, at which time the authorisation must be renewed. After the renewal, the PVPA remains valid indefinitely.

In accordance with the European Court of Justice judgement in C-172/00, a parallel import 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 import product remains authorised, the HPRA may request certain information from the parallel importer in order to adequately monitor adverse reactions occurring in Ireland.

The PVPA ceases to be valid if the parallel-imported product ceases to have a valid marketing authorisation in the EU or EEA country from which it is imported.

2.3 Applications

2.3.1 New applications

In order to obtain a PVPA, the proposed authorisation holder, or another person acting on his behalf, 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*~~Authorisation', available on the HPRA website.
- 'Fee application form (Veterinary~~),~~)', available on the HPRA website.
- Covering letter.
- Where a company is proposed as the PVPA holder, a certificate of incorporation for the company (for the first application only).
- Proposed Summary of Product Characteristics (SPC). This must be based on the authorised SPC for the reference product 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.~~www.hpra.ie.
- Proposed colour label mock-ups for the immediate container and the outer carton.
- Proposed colour mock-up of the package leaflet.
- ~~Samples of the parallel-imported product from each Member State from which importation is required, including copies of the package leaflet in the parallel-imported product.~~
- 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).
- ~~Information on the manufacturers and excipients~~Full colour, high quality scans/photographs of the parallel imported product~~. This information is available from the package leaflet of~~, clearly showing all sides of the packaging, the product ~~on~~leaflet and the physical appearance of the ~~market in~~product itself. If scans are not of sufficient quality or clarity, to request a physical sample of the ~~source country. Applications may be invalidated if this information is not provided~~product.

Applicants should note the requirements outlined in the Commission Communication, particularly the need to give advance notice to the VPA holder prior to placing the repackaged product on the market. The European Court of Justice, in C-143/00, suggested a period of 15 working days as a reasonable time for the parallel importer to give notice to the trade mark proprietor by supplying it simultaneously with a sample of the repackaged pharmaceutical product. According to the Commission Communication, in all circumstances, repackaging is permitted only if it is necessary. Any alleged infringement of intellectual property arising from the repackaging is a matter for the parallel importer and the trademark holder only.

Copies of the application forms and fee forms are available from the HPRA's website. Information on the fees and address to send the application to is given in appendix 1 and further details on completing the application forms is given in appendix 2.

Source countries
A number of source countries may be applied for using one application form. Additional countries may be applied for by variation at a later stage (see below for further details).

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 product authorisation, the parallel importer is again required to give notice to the trade mark 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 ten working days of validation, the application is assessed to determine if a presumption of identity is reasonable and if therapeutic equivalence between the imported and Irish product can be reasonably presumed.

If these assumptions can be made, the proposed SPC, labels and package leaflet are assessed and any queries sent to the parallel-importer 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 parallel-importer after completion of processing by the HPRA.

If presumptions of identity and therapeutic equivalence cannot be made, the clock is stopped within 10 days of validation in order for the HPRA to seek information from the regulatory authority in the Member State from which the product is to be imported. At the same time, provided the applicant agrees, the MA holder that supplies the Irish-market product is contacted and asked to indicate whether or not the product(s) are therapeutically equivalent. 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-importer should regularly check the product information of the Irish-market product, as changes may require a revision of the product information supplied by the importer with the parallel imported product or other amendments to the parallel import licence. This particularly relates to significant safety variations which must be incorporated into the parallel imported product information.

There should be systems in place for the parallel importer 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 parallel importer must also keep informed of any relevant change in the parallel-imported product in order to ensure that the PVPA document reflects the current situation at all times. Importers are especially reminded to check the labels and leaflets of the parallel-imported product as changes made to the texts may have consequences for the product information included with the parallel imported product. Should the parallel imported product's labels and leaflets not be in English, then the importer should be able to show proof of translation.

If there is a change in the VPA number of the Irish-market product or in the marketing authorisation number of the parallel-imported product (in the Member State where it was originally placed on the market), the importer 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. Deletions of source countries must also be applied for by variation using the same form.

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

2.3.3 Additional source countries

Additional source countries may be added to the PVPA. Applications for additional countries should be made using the form 'Application for addition of a source country to a parallel veterinary product authorisation'.

Applications for additional source countries are processed according to the same procedure and timelines as new PVPA applications. Applicants should ensure that the product information (SPC, labels and package leaflet) are correct and in line with the reference product prior to submission of the additional source country variation.

2.3.4 Renewals

The initial PVPA remains in force either indefinitely or for a maximum of five years (see section 2.2). If a five-year authorisation is given, it must be renewed at least once if the holder wishes to continue parallel importation of the product. An application for renewal must be made not later than six months before the date of expiry of the authorisation, using the form 'Application for addition of a source country to a parallel veterinary product authorisation'. The PVPA holder should consult the HPRA's 'Guide to renewal of veterinary product authorisations' for general guidance on updating the SPC, label and leaflet at renewal. In addition, the holder should ensure that the clinical particulars in the SPC and package leaflet are in accordance with the currently-marketed SPC and package leaflet of the originator product. Where changes are needed to bring the SPC into line with the originator's, this should be done prior to the renewal by submitting a type II standard variation for the changes.

After the renewal, the PVPA remains valid indefinitely.

2.3.5 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 Summary of Product Characteristics (SPC)

An SPC should be provided for each pharmaceutical form and strength in a parallel-imported product range. The proposed SPC should be drawn up in accordance with the current Notice to Applicants Guideline on Summary of Product Characteristics for Veterinary Medicinal Products. Additional guidance on specific sections of the SPC is given below, using the numbering of the SPC.

1 Name of the medicinal product

The name should be given in the order: (invented) name, strength, pharmaceutical form, target species; the same name must also be used in the leaflet and on the labels.

In order to minimise confusion on the market, the name of the Irish market product should be used as the name for the parallel-imported product. However, in cases where this is not possible (e.g. for trade mark reasons), the PVPA holder may propose to use either the trade name of the source-country product or a generic name provided that the proposed name is in line with the HPRA's 'Guide to invented names of veterinary medicinal products'. For example, the use of the trade name of the source-country product will only be accepted if the HPRA is satisfied that that name is appropriate with respect to the general principles outlined in the above guideline. The use of a generic name for a parallel-imported product will not be accepted for modified-release products and will only be accepted where the HPRA is satisfied that the parallel-imported product is therapeutically equivalent with the Irish reference product.

2 Qualitative and quantitative composition

The qualitative and quantitative declaration of the active substance should be included, along with the standard statement 'For a full list of excipients, see section 6.1'.

Where a product contains excipients, knowledge of which is essential for the proper administration of the veterinary medicinal product, a statement that the product contains these excipients should be included in this section, followed by the standard statement 'For a full list of excipients, see section 6.1'.

3 Pharmaceutical form

Product parallel imported from more than one Member State may differ in appearance; any differences in the appearance should be described, with reference to the Member State from which the product is to be parallel imported.

4 Clinical particulars

The following particulars should be in accordance with the marketing authorisation for the Irish-market product:

- Target species
- Indications for use, specifying the target species
- Posology
- Contraindications
- Special warnings
- Special precautions for use
- Withdrawal period(s)

6.1 List of excipients

The list of excipients is usually available from the SPC of the product on the market in the source country.

Where a product is imported from more than one Member State, a single list of excipients should be given if the excipients in the product parallel-imported from all Member States concerned are the same. If there are differences in one or more excipients, separate lists should be given, related to the Member State from which the product is to be parallel-imported. Each excipient list should have the header 'Product as sourced from <source country>'.

For clarity, it is recommended that each excipient be listed on a separate line.

6.2 Incompatibilities

One of the following standard statements should be used where appropriate:

- Not applicable. (*e.g., for solid oral pharmaceutical forms*)
- In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. (*e.g., for parenterals*)
- Do not mix with any other vaccine or immunological product.
- None known.

6.3 Shelf life

Batches of parallel-imported product placed on the market in Ireland must keep the same expiry date as they had in the country from which they are imported; the importer is not permitted to change the expiry date.

The statement that should be included in this section is 'The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin'.

(Where the parallel-imported product is re-packaged into another container, the importer must justify retaining the same shelf life.)

A reference to the in-use shelf-life should be included if appropriate. In cases where the in-use shelf-life of the Irish-market product is different than that on the container of the parallel-imported product, the in-use shelf-life proposed by the applicant should be the more conservative of the two.

6.4 Special precautions for storage

The storage statements on the label of the Irish-market product may be different from those on the container of the parallel-imported product. The storage statements proposed by the applicant should be the more conservative of the two.

6.5 Nature and contents of container

All pack sizes to be imported should be included.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste materials derived from the use of such products

One of the following standard statements should be used when appropriate:

- No special requirements. (*e.g., for solid oral dose forms*)
- Any unused product or waste material should be disposed of in accordance with local requirements. (*e.g., for cytotoxics*)

2.4.2 Labels

Parallel-imported 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 Directive 2001/82/EC, as amended
- 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 parallel importer.

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

If the parallel imported product is known to contain any excipient that has a recognised action or effect, the PVPA holder is required to label the parallel-imported product with this information. The label statement should use the wording 'Also includes…' and not 'Also contains…,' to avoid giving the impression that the named excipient is the only other ingredient in the product. Country-specific label text may be needed if the excipients to be declared on the label differ depending on the Member State from which the product is imported or if excipients are known for product imported from some Member States but not from others.

The label must also identify the manufacturer of the product in the relevant source country.

Full colour mock-ups of the labels are required to accompany each application for a new PVPA, an additional source country, a variation which affects the label or renewal. The mock-up should show the placement of the PVPA holder's label on the originator's 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 labeling 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.

2.4.3 Package leaflet

Leaflets should be drawn up in accordance with Directive 2001/82/EC, as amended. Additional guidance for leaflets for parallel-imported products is given below.

Product name
To overcome potential confusion for users when parallel imports 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 …* Please also refer to section 2.4.1 above.

Clinical details
The leaflet of the parallel product should use the same wording as that contained within the PL of the originator product.

Excipients
The excipients of known effect in the parallel-imported product are usually given in the package leaflet of the product on the market in the source country.

Manufacturer
The manufacturer(s) of the product intended to be parallel-imported (as defined by Directive 2001/82/EC, as amended) is/are normally named in the package leaflet of the product on the market in the source country. Where the manufacturer does not appear in the source country package leaflet, the parallel importer can source this information from the source country regulatory authority.

The manufacturer(s), as listed in the package leaflet on the market in the source country, must be listed in the package leaflet to be supplied with the parallel-imported product when placed on the market in Ireland. Where a number of source countries are involved and the manufacturing sites are different, the name and address of each manufacturer should be listed in the package leaflet.

Number of leaflets
One leaflet may be sufficient for a parallel-imported product sourced from a number of Member States if there are only minor differences in the information to be included in the leaflet. However, it may be necessary to provide more than one leaflet if the information differs between the parallel-imported products on the market in different Member States to an extent which could be confusing to users. The applicant should prepare the leaflet(s)

carefully, bearing in mind the requirement of Directive 2001/82/EC, as amended, that 'the package leaflet shall be written in terms that are comprehensible to the general public…'

Where more than one leaflet is necessary, it is the responsibility of the PVPA holder to ensure that the correct leaflet is included with each batch, in accordance with the requirements of Good Manufacturing Practice.

Full colour mock-ups of the leaflet are required to accompany each application for a new PVPA, an additional source country, a variation which affects the leaflet, or a renewal.

2.5 Manufacture, batch control and wholesale

2.5.1 Batch control and batch testing

In regard to the necessary batch control documentation that must accompany products moved from one Member State to another, it is intended that, wherever possible, a presumption of conformity with the specifications of the parallel-imported product will be made.

In instances where it is impractical to make this presumption, or where special problems exist, the parallel importer may be required to provide proof of conformity by means other than by documents to which he has no access. This may involve testing of each batch of the parallel-imported product by the parallel importer.

Where the HPRA requires the parallel-imported product to be tested by the parallel importer, details will be required on the following:

- the test methods and specification limits,
- analytical method validation data where appropriate,
- the name and address of the manufacturer responsible for testing and for batch release, and documentary evidence that the manufacturer is appropriately licensed,
- the name and address of the testing laboratory (if not part of the manufacturer responsible for batch release) and documentary evidence that the laboratory is approved by the relevant competent authority.

2.5.2 Manufacturers' authorisations

Labelling and re-packaging are defined as manufacturing operations and the parallel importer 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-importer who holds a manufacturer's authorisation is exempted from the requirement to hold a wholesaler's licence to wholesale parallel-imported 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).

2.5.3 Wholesalers

Where the parallel importer wholesales the product in Ireland and is not the holder of a manufacturer's authorisation, a wholesaler's licence is required under Regulation 30 of the European Communities (Animal Remedies) (No. 2) Regulations 2007. 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.

2.5.4 Batch recalls

Parallel-importers 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-imported product in the source country, it is imperative that the importer is informed by their supplier so that the importer 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 importer to ensure that information on recalls is passed to the parallel-importer; 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 ADDRESSES FOR THE APPLICATION

A1.1 Fees for applications:

The HPRA '*Guide to fees for veterinary products*', the fee application form (veterinary) and details on payment are available from the HPRA website. Payment is to be made with the application. Fees are payable to the account of the Health Products Regulatory Authority.
Account no.: 33712185; sort code 93-10-12
Allied Irish Bank,
1-3 Baggot Street Lower,
Dublin 2

~~Applications can be submitted in hard copy or electronically by e-mail.~~

A1.2 Address for ~~hard copy~~ applications submitted on CD/DVD

Receipts and Validation,
Health Products Regulatory Authority,
Kevin O'Malley House
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

A1.3 E-mail address for electronic applications

Scanned signed versions of the application form can be e-mailed to:
~~submit@hpra.ie~~

submissions@hpra.ie.

APPENDIX 2 GUIDANCE ON COMPLETING THE PARALLEL VETERINARY PRODUCT AUTHORISATION APPLICATION FORMS

Application form types

There are four forms designed for applications relating to applications for parallel veterinary product authorisations.

1 'Application for a veterinary parallel product authorisation': for applications for authorisation to import and distribute a product
2 'Application for addition of a source country to a veterinary parallel product authorisation': for applications to add further source countries after a veterinary parallel product authorisation has been granted
3 'Application for a variation to a veterinary parallel product authorisation': for applications to make changes to the veterinary parallel product authorisation other than additional source countries
4 'Application for renewal of a veterinary parallel product authorisation': for applications for renewal of a veterinary parallel product authorisation.

Using the application forms

The application forms are designed as templates and can be used as such or used in hard-copy format. They are available in electronic form on the 'Publications and Forms' section of ~~www.hpra.ie.~~www.hpra.ie.

General guidance

1 Where an electronic SPC is submitted on a CD-ROM, it should be sent on a PC-compatible CD, in a Word-compatible format.
2 Package leaflets in the imported product may be submitted as originals or as photocopies.
3 Columns for HPRA Use Only should be left blank.

Comparative product details

In the application forms for a new veterinary parallel product authorisation, to add a source country and to renew an authorisation, details of the Irish and imported product are required to be submitted in a tabular format. The details for the Irish product should be taken from the label and leaflet of the product marketed in Ireland and the details for the imported product from the label and leaflet of the imported product. The details may also be available from the SPC of the Irish and/or imported product, if these are publicly-available documents.

The line listing of excipients is used in the determination as to whether or not it is reasonable to presume that the Irish and imported products are therapeutically equivalent. Therefore it is important to present the list in a manner which facilitates this determination. Each excipient

should be listed on a separate line; where the same excipient is present in both the Irish and imported product, they should be listed on the same line in the relevant columns, as in the following examples.

COMPARATIVE PRODUCT DETAILS	IRELAND	MEMBER STATE OR EEA COUNTRY *Insert name*
Line list of excipients	Lactose Magnesium stearate Microcrystalline cellulose	Lactose Magnesium stearate Microcrystalline

Where the same excipient is given a different name in the Irish product and the imported product they should still be listed on the same line. This also applies where different salt or hydrate forms are used, as in the following example:

COMPARATIVE PRODUCT DETAILS	IRELAND	MEMBER STATE OR EEA COUNTRY **Insert name**
Line list of excipients	Lactose Methylhydroxypropylcellulose Polyvidone Silicon dioxide	Lactose monohydrate Hypromellose Povidone Colloidal anhydrous silica

Where different excipients are present, they should be presented on different lines:

COMPARATIVE PRODUCT DETAILS	IRELAND	MEMBER STATE OR EEA COUNTRY *Insert name*
Line list of excipients	Propylene glycol Cellulose acetate Hypromellose Polyethylene glycol - - -	- - Methylhydroxypropylcellulose - Crospovidone Maize starch Lactose

APPENDIX 3 DOCUMENTATION REQUIREMENTS FOR VARIATIONS TO VETERINARY PARALLEL PRODUCT AUTHORISATIONS

The following general rules apply in every instance:

- 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.~~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).
- Applicants are encouraged to submit applications in electronic format wherever possible.
- 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 Guideline on Variations.