



HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to **Parallel ~~Imports~~ Trade 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	3
ABBREVIATIONS	3
1 SCOPE	5
2 PARALLEL IMPORT LICENCE – PARALLEL VETERINARY PRODUCT AUTHORISATION	5
2.1 General provisions	5
2.2 Conditions of authorisation	6
2.3 Applications	7
2.4 Product information	12
2.5 Manufacture, batch control and wholesale	17
APPENDIX 1 FEES AND ADDRESSES FOR THE APPLICATION	20
APPENDIX 2 GUIDANCE ON COMPLETING THE PARALLEL VETERINARY PRODUCT AUTHORISATION APPLICATION FORMS	21
APPENDIX 3 DOCUMENTATION REQUIREMENTS FOR VARIATIONS TO VETERINARY PARALLEL PRODUCT AUTHORISATIONS	23
DEFINITIONS	3
ABBREVIATIONS	3
1 SCOPE	5
2 PARALLEL TRADE LICENCE – PARALLEL VETERINARY PRODUCT AUTHORISATION	5
2.1 General provisions	5
2.2 Conditions of authorisation	6
2.3 Applications	7
2.4 Product information	12
2.5 Manufacture and wholesale	17
APPENDIX 1 FEES AND SUBMISSION OF THE APPLICATION	20
APPENDIX 2 DOCUMENTATION REQUIREMENTS FOR VARIATIONS TO VETERINARY PARALLEL PRODUCT AUTHORISATIONS	24

DEFINITIONS

Parallel-~~importation~~ trade

The ~~importation~~trade, from an EU Member State or a country within the European Economic Area (EEA), of a ~~veterinary~~ medicinal product which ~~is equivalent~~shares a common origin to one already authorised on the Irish market, by ~~an importer~~a wholesaler who is ~~someone other than the importer~~not 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~~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-~~imported~~ ~~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 ~~import~~trade 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 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; ~~importersthose~~ 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~~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 ~~imported~~traded to Ireland, provided that ~~the originator's equivalent a product sharing a common origin is already on the market here or has been withdrawn for commercial reasons only~~authorised in Ireland, and the ~~importer~~wholesale distributor has obtained a parallel ~~import~~trade licence (i.e. parallel veterinary product authorisation) from the HPRA to place the parallel ~~imported~~traded product on the Irish market.

~~Authorisation~~Approval to parallel trade a veterinary medicinal product is granted ~~under the European Communities (Animal Remedies) (No. 2) Regulations 2007 in line with the Regulation~~. The parallel ~~import~~trade licence is termed a Parallel Veterinary Product Authorisation and is identified by the letters 'PVPA' in front of the authorisation number.

Article ~~65~~102(5) of ~~Directive 2001/82/EC, as amended by Directive 2004/28/EC,~~the Regulation requires the ~~distributor of a product imported from another Member State~~wholesaler to notify his intention to ~~import~~parallel trade the product to the marketing authorisation holder and the competent authority in the ~~source~~ Member State ~~to which the product is to be imported.~~ As per Article 102(6), for parallel ~~importation~~trade to Ireland, ~~this means informing a declaration and confirmation of obligations in relation to the veterinary medicinal product to be parallel traded should be provided to~~ the HPRAs and the MA holder of the Irish market product. ~~The obligation to inform the HPRAs is met by the procedure~~declaration and obligations are laid down in ~~this~~section 2.3 of this guide for submission of an application for a PVPA.

In granting a PVPA, the HPRAs 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 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~~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 substance(s), substances and excipients;
 - (b) ~~they have the same pharmaceutical form and be identical;~~
 - (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, or have no significant therapeutic difference from, the Irish~~ 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 product 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-imported traded veterinary medicinal product must be imported from an EU or EEA country and it must have a current, full report them to the marketing authorisation in that country-holder.~~

~~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, in exceptional circumstances~~ for a maximum period of five years, at which time the authorisation must be ~~renewed~~re-examined. After ~~the~~this renewal, the PVPA remains valid indefinitely.

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

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

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,~~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.

- ~~— 'Fee application form (Veterinary)', available on the HPRAs website.~~
- Covering letter.
- ~~Where~~Evidence that the product medicinal product obtained from the source Member State must share a ~~company~~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 proposed as the PVPAs~~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 certificate~~copy of incorporation ~~for this notification must be submitted to the company (for HPRAs~~
- ~~The marketing authorisation holder in the first 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 only) to the HPRAs. A declaration plus a copy of this notification must be submitted to the HPRAs.~~
- Proposed Summary of Product Characteristics (SPC). This must be based on the authorised SPC for the ~~reference~~veterinary medicinal product authorised in Ireland, as issued by the HPRAs only and no other version will be accepted. All SPCs are available on the HPRAs 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 ~~imported~~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, ~~to request~~ a physical sample of the product ~~may be requested~~.

~~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.~~

~~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 HPRAs. 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's HPRA](#) 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~~[country](#)

A ~~number of single~~ source ~~countries~~[country](#) 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).~~[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 ~~product~~[trade](#) authorisation, the parallel ~~importer~~[trader](#) is again required to give notice to the ~~trade mark~~[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 ~~ten~~10 working days of validation, the application is assessed to determine if a ~~presumption of identity~~common origin is ~~reasonable~~confirmed and ~~if therapeutic equivalence between the imported~~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 Irish product can be reasonably presumed.~~

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

If ~~presumptions of identity~~product common origin and ~~therapeutic equivalence~~wholesale distributor obligations cannot be ~~made~~demonstrated, the clock is stopped within 10 days of validation in order for the HPRA to ~~seek~~request additional 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 equivalentwholesale 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-~~importer~~ trader should ~~regularly check~~ensure that the ~~product information~~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~~ product, as. Changes may require a revision of the product information supplied by the ~~importer~~wholesale distributor with the parallel ~~imported~~traded product or other amendments to the parallel ~~import~~trade licence. This particularly relates to significant safety variations which must be incorporated into the parallel ~~imported~~traded product information.

There should be systems in place for the ~~parallel-importer~~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 ~~parallel importer~~wholesale distributor must also keep informed of any relevant change in the parallel-~~imported~~ ~~traded~~ product in order to ensure that the PVPA document reflects the current situation at all times. ~~Importers~~Wholesale distributors are especially reminded to check the labels and leaflets of the parallel-~~imported~~ ~~traded~~ product as changes made to the texts may have consequences for the product information included with the parallel ~~imported~~~~traded~~ product. Should the parallel ~~imported~~~~traded~~ product's labels and leaflets not be in English, then the ~~importer~~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-~~imported~~~~traded~~ product (in the ~~destination~~ Member State ~~where it was originally placed on~~, the market), the ~~importer~~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. ~~Deletions of source countries must also be applied for by variation using the same form.~~

All changes made by the ~~importer~~parallel trader to the SPC, label, and leaflet of the parallel-~~imported~~~~traded~~ product, including changes in line with the ~~reference~~source Member State product, must have prior approval from the HPRA. Applications should be made using the ~~variations~~variation 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.~~

~~2.3.5.2.3~~ 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~~ 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.~~

~~2~~ 2 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~~ 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'.~~

~~2—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.~~

~~2—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)~~

2.4.772.4.1 Labels

Parallel-~~imported~~ ~~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 [Directive 2001/82/EC, as amended/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 [parallel importer/wholesale distributor](#)

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

~~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, or~~ 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 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 [labeling/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.

[2.4.782.4.2](#) 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.](#) [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 Product name

~~To overcome potential confusion for users when the event that the parallel import/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 ... 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.

2.262.5 Manufacture, batch control and wholesale

2.26.1 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.~~

~~2.26.2.5.1~~ Manufacturers' authorisations

Labelling and re-packaging are defined as manufacturing operations and the ~~parallel importer~~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-~~importer~~ trader who holds a manufacturer's authorisation is exempted from the requirement to hold a wholesaler's licence to wholesale parallel-~~imported~~ traded products, provided that the products are covered by the manufacturer's authorisation (i.e. ~~the~~ the manufacturer has carried out manufacturing activities related to those products).

~~2.26.3.2.5.2~~ Wholesalers

Where the parallel ~~importer~~trader 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.~~ 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.

[2.26.42.5.3](#) Batch recalls

Parallel ~~importers~~ [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 ~~imported~~ [traded](#) product in the source country, it is imperative that the ~~importer~~ [parallel trader](#) is informed by their supplier so that the ~~importer~~ [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 ~~importer~~ [parallel trader](#) to ensure that information on recalls is passed to the parallel ~~importer~~ [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 ADDRESSES FOR SUBMISSION OF THE APPLICATION

A1.1 Fees for applications:

~~The HPRA Applications must be accompanied by the correct fee - see the '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~~

A1.2—~~Address for 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:
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.~~

General guidance

- ~~5 — Where an electronic SPC is submitted on a CD-ROM, it [for details of the fees and the method of fee payment](#). The fee should be sent on a PC-compatible CD, in a Word-compatible format.~~
- ~~6 — Package leaflets in the imported product may be submitted as originals or as photocopies.~~
- ~~7 — 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 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.

COMPARATIVE PRODUCT DETAILS	IRELAND	MEMBER STATE OR EEA COUNTRY <i>Insert name</i>
Line list of excipients	Lactose	Lactose
	Magnesium stearate	Magnesium stearate
	Microcrystalline cellulose	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 <i>Insert name</i>
Line list of excipients	Lactose	Lactose monohydrate
	Methylhydroxypropylcellulose	Hypromellose
	Polyvidone	Povidone
	Silicon dioxide	Colloidal anhydrous silica

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

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

[A1.2 Submission](#)

[Please see the HPRAs 'Guide to Electronic Submissions – Veterinary Medicines' for details on sending the application to the HPRAs.](#)

APPENDIX 32 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 overlabeled, 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 Implementing Regulation 2021/17 \(variations not requiring assessment\)](#) and [Regulation 2019/6 \(variations requiring assessment\)](#).