



Veterinary Medicines Guidance Note

Marketing Authorisations For Veterinary Medicinal Products - Parallel Imports

No 6

Last updated September 2009



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE

VETERINARY MEDICINES DIRECTORATE

WOODHAM LANE, NEW HAW, ADDLESTONE, SURREY KT15 3LS
Telephone: (+44) (01932) 336911 Fax (+44) (01932) 336618
E-mail VMGNotes@vmd.defra.gsi.gov.uk www.vmd.gov.uk



INVESTOR IN PEOPLE

TABLE OF CONTENTS

CONTENTS	PARAGRAPH	PAGE
INTRODUCTION	1	3
What is a Parallel Import	3	3
Exemption for Dual Labelled Products	4	3
REQUIREMENTS FOR A MAPI	6	4
WHO SHOULD APPLY	9	4
WHERE TO APPLY	11	4
HOW TO APPLY	13	5
Supporting Documentation and Application Form	16	5
SPC and Product Literature	26	6
HOW THE VMD HANDLES APPLICATIONS	29	7
The Vm Symbol	35	8
OBLIGATIONS PLACED ON THE HOLDER OF A MAPI		
Specific Obligations	36	8
General Obligations	40	9
Application of the General Law	43	9
RENEWALS AND VARIATIONS OF MAPIs	44	9
Variations	48	10
FEES	50	10
FURTHER INFORMATION	51	10

INTRODUCTION

1. This is one of a series of Veterinary Medicine Guidance VMG Notes explaining the requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not included in this VMG Note. The VMG Notes will be updated as necessary and the date of the most recent update is shown on the front cover. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. The purpose of this VMG Note is to provide guidance on the UK's Marketing Authorisation for Parallel Import (MAPI) scheme.

WHAT IS A PARALLEL IMPORT

3. A parallel import arises when
 - a veterinary medicine is authorised in the UK and a product, that is identical or therapeutically the same, is authorised in at least one other Member State of the European Community; and
 - the product is bought from wholesalers in one Member State, and imported into the UK for distribution.

EXEMPTION FOR DUAL LABELLED PRODUCTS

4. A product is considered to be dual labelled when it is authorised and marketed in the UK and in one or more other Member States, and the labels and package leaflets contain all the wording (including the marketing authorisation number), in English, that is required by the UK. A dual labelled product may be imported into the UK without the need for re-labelling, or for the identical nature of the products to be verified. In such circumstances no further authorisation of the product is necessary.
5. It should be noted that:
 - (i) Importers of dual labelled products must hold a current UK Wholesale Dealer's Authorisation (WDA) if they intend to market the product;
 - (ii) Importers must also follow specific batch release procedures for Immunological veterinary medicinal products, and
 - (iii) The duties and responsibilities of the marketing authorisation holder, and in particular those relating to pharmacovigilance, remain the same as if they had initially placed the product on the market.

REQUIREMENTS FOR A MAPI

6. The Regulations require that before a veterinary medicinal product is placed on the market in the UK, it must have a Marketing Authorisation (MA). Therefore, parallel imports may only be marketed in the UK if an MA already exists in the UK.
7. Applications for MAs must be made in accordance with the relevant provisions of the Regulations. The application for a MAPI does not need to be a full application; i.e. it does not need to meet all the requirements of the Regulations.
8. The product to be imported into the UK must be a veterinary medicinal product authorised in accordance with Directive 2001/82/EC as amended by Directive 2004/28/EC in the Member State from which it is to be imported. Products authorised in EEA states will also be eligible for this scheme since they too are authorised in accordance with Directive 2001/82/EC as amended.

WHO SHOULD APPLY

9. The proposed MAPI holder must:
 - (i) be established within the European Community. For companies this means they must be formed in accordance with the law of a Member State, and have their registered office, central administration or principle place of business within the Community. The “Community” includes other countries in the European Economic Area (EEA): Iceland, Liechtenstein and Norway;
 - (ii) be the holder, or have a contract with a holder, of a suitable UK WDA, and
 - (iii) be the holder, or have a contract with a holder, of a suitable Manufacturer’s Authorisation.
10. Proposed MAPI holders should satisfy themselves that they can fully discharge the obligation set out in VMG Notes 1 and No. 13.

WHERE TO APPLY

11. Applications for MAs for parallel imports (MAPIs) for veterinary medicinal products should be sent to:

Information Management Section
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

12. It would help the VMD to process your application more efficiently and speedily if, in addition to paper copies, you could provide an electronic copy of the application or any parts of it that are available electronically. All word processing formats are acceptable, but Word for Windows held on a CD-ROM is preferred.

HOW TO APPLY

13. Applicants may apply to obtain a MAPI for a nationally authorised product and/or mutually recognised product. There are some differences between the two procedures but, unless otherwise stated, the requirements are the same.
14. Please note that a MAPI, for a nationally authorised product, only covers one member state. However, a MAPI for a mutually recognised product can cover more than one member state.
15. It is not necessary for the original and MAPI product to be manufactured by the same company, although the products should be therapeutically the same unless justification can be provided for any possible differences. In cases where the information is not readily known to the importer, the VMD will assess the application on the basis of the details supplied. However, in order to ensure that the withdrawal period is appropriate it is necessary to establish the identical nature of the formulation for pharmaceutical products authorised for food producing animals. It should also be noted that in some cases the VMD may have to rely on information from Licensing Authorities in other Member States to verify the identical nature or therapeutic equivalence of the products. This can take some time to obtain and the application clock will be stopped during this period.

SUPPORTING DOCUMENTATION AND APPLICATION FORM

16. Applicants must complete all parts of the application form, which is available on the VMD website (www.vmd.gov.uk) under Industry Information > Applications Page.
17. For nationally authorised products, separate applications should be made for each individual product/member state in order to permit the necessary identical nature checks.
18. For mutually recognised products, the name of each member state should be included on the application form and, if granted, all named member states will be included on one authorisation. Each member state will incur a separate fee. Additional member states may be added to the MAPI, following grant of the original authorisation, by way of a variation application.
19. Each application should be in writing, in English and be signed by the applicant. Four copies of the complete application should be submitted to the VMD. An electronic version of the draft Summary of Product Characteristics should also accompany the application.

20. Applications may be submitted by, or on behalf of, a prospective MAPI holder, but the proposed MAPI holder must always accept responsibility for the contents of the application and should sign the declaration accordingly. If any matters stated in the application are false or incomplete in any way that might influence the decision-making process, we may refuse your application or revoke any MAPI that has been granted. However, so long as the application is signed in good faith and there is no deliberate or fraudulent intention to mislead, no criminal charges will arise.
21. When you sign the declaration you are confirming that you have:
 - a) read and understood the criteria set out in paragraphs 8, 9 and 15, and that your application is made in accordance with those criteria; and
 - b) included all information known and available to you, which is relevant to the evaluation of the application, whether favourable or unfavourable, and included all relevant details required in the application form and paragraphs 22-28.
22. A MAPI can be held by an individual or by a legal body such as a company. If a company, the full legal title, registration number and registered address should be stated. If some other title is to be shown on the authorisation (e.g. a division of the company) this should be clearly stated in the application.
23. The proposed name of the product may be either the name of the product in the UK or the name of the product in the Member State from which it is being imported (so long as this would not risk confusion with another product marketed in the UK), or a "generic" description. It is the applicant's responsibility to ensure that the proposed name is not protected by trademark or other legislation.
24. The applicant should provide a detailed description of the Pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place.
25. All information submitted in support of an application must be securely presented in a way which allows each page to be read easily. Applicants are asked to ensure that copies or reproductions, of text and/or relevant drawings or illustrations with their captions, are legible. A4 size should be used. Pages should be numbered consecutively, and an index to the dossier should be provided.

SPCs AND PRODUCT LITERATURE

26. The application should include (a) a mock-up of the pack with the importers label as it will appear when placed on the market, and (b) any package leaflets to be used when marketing the parallel import in the UK. This must include the proposed name and conform to the labelling provisions in the Regulations. The MAPI holder's own name and address and the marketing authorisation number must appear. Otherwise the wording of the labels and any package leaflet should be closely based on the labels and package leaflet of the UK authorised product

and include all claims and warnings appearing there. The original manufacturer's batch number and expiry date must be shown. Further information about the requirements for product literature and SPCs is available in VMG Note 18.

27. A detailed description of the arrangements to be adopted for re-labelling the imported product will be required. This information will need to include:
 - the site of operations
 - the name and qualifications of the person responsible for supervising the operations;
 - where re-labelling is to take place in the UK, particulars of the UK manufacturer's authorisation, must be included;
 - where re-labelling is to take place outside the UK then a copy of the Manufacturing Authorisation(s) for each site concerned.
28. The application must also provide a draft Summary of Product Characteristics (SPC) for the MAPI based on the SPC of the UK authorised product. Where the SPC of the UK authorised product is not available to the applicant, the VMD will provide a copy. This should be obtained before submission of an application, as it will be needed by the applicant to use as a basis for his SPC.

HOW THE VMD HANDLES APPLICATIONS

29. Your application will be validated within 10 days of receipt by the VMD. This process ensures that the application form is complete, legible and in the required form, and that all other required information has been provided. In all cases you will be informed whether the application is considered valid or not. If one or more of the above requirements have not been met then the application will fail validation and you will be asked to either rectify the problem, or the application will be returned to you.
30. MAPI applications are subject to the same procedures/timetables as applications for other new (national) marketing authorisations. However, the initial assessment period for a MAPI application for a mutually recognised product is 75 days rather than 90 days.
31. VMD assessors will evaluate the application according to set procedures, and within the required timescales. If the product meets the required criteria then an authorisation will be granted. It is rare for an authorisation to be granted outright. It is more usual for the assessor(s) to conclude that an authorisation could be granted if satisfactory further information were provided, or if certain changes were made, e.g. to the label. In this event, the VMD will explain to you what is required, and why. The "clock" will be suspended until a reply is received from you, or from a licensing authority in another Member State who has been asked to provide additional information.

32. The speed with which you receive a decision on your application will depend on the quality of the application and the speed with which you, or the other Member State, responds to questions. Such questions may relate to the manufacture of the products in order to satisfy ourselves that the products are the same.
33. Sometimes the conclusion of the assessment is that an authorisation should not be granted. In these circumstances your rights of appeal will be explained to you. For further information please refer to VMG Note 11.
34. When a MAPI is granted the VMD will inform the holder of the existing UK marketing authorisation for the product concerned. The issue of a MAPI will be announced in MAVIS.

The Vm Symbol

35. If, following assessment, it is concluded that a UK authorisation should be issued, the MA holder will be required to include the Vm symbol as part of the MA number on product labelling and packaging. The Vm symbol was developed in June 1996 following liaison between the VMD and the National Office of Animal Health (NOAH) and offers users a clear guarantee that the medicine has been assessed and approved for use in accordance with the instructions on the label.

OBLIGATIONS PLACED ON THE HOLDER OF A MAPI

SPECIFIC OBLIGATIONS

36. The MAPI holder must:
 - keep a record of the origin, quantity and batch number of all parallel imports;
 - retain it at least until a period of two years has elapsed after the expiry date of the import consignment; and
 - make it available to the VMD on request.
37. The MAPI holder must ensure that the authorised product is labelled with the version approved by the VMD in accordance with the UK labelling requirements set out in the Regulations.
38. Where this involves re-labelling, the approved label must be securely affixed to the product container and any outer package, and must completely obscure all parts of the original which are NOT to be retained. Labels appearing elsewhere on the product must be similarly obscured using a label approved by the VMD. A package leaflet will be required if all the necessary particulars cannot be incorporated on the labels of the container and outer package.
39. In the majority of cases where the UK product has a package leaflet then one will also be required for the MAPI. Re-labelling may take place before or after import, but must occur before the product is placed on the UK market. A UK Manufacturing Authorisation will be required if the product is to be relabelled in the

UK. If re-labelling is to take place outside the UK then a copy of the Manufacturing Authorisation(s) for each site concerned will be required.

GENERAL OBLIGATIONS

40. Although a MAPI is granted in response to a special abbreviated application, it is a marketing authorisation with the full force of law, and thus the MAPI holder must comply with other relevant duties and obligations placed on authorisation holders.
41. This means the holder of a MAPI must:
 - make no changes to the items provided with the application, including the approved labels and the SPC, without previously applying for a variation (please refer to the VMG Note 4)
 - notify the VMD immediately of any events or developments in the country or countries from which the product is imported which come to his attention and which may affect the safety, quality or efficacy of the product, or the terms of the marketing authorisation. Such developments include:
 - any variations to the authorisation in that country;
 - any revocation or suspension of the authorisation; and
 - any information available to the importer concerning suspected adverse reactions or other factors which could affect safety in use;
 - comply with the normal advertising controls, and
 - appoint an appropriately qualified person to monitor and assess reports of suspected adverse reactions in accordance with the Regulations.
42. Please note that, if there is an impact on your authorisation from a suspected adverse reaction to a similar product, the VMD may inform you of any risk to human or animal health or the environment which has come to their attention. Likewise, the VMD may inform other MA Holders of any risk to human or animal health or the environment which has been identified through a suspected adverse reaction involving your product. The VMD may notify the parent company of a suspected adverse reaction involving a MAPI product., and

APPLICATION OF THE GENERAL LAW

43. The granting of a MAPI does not absolve the holder from complying with the general law which may apply as a consequence of the authorisation. In particular, any private law rights, such as trademark and patent rights, are not affected by the grant of a MAPI, and are a matter between the companies concerned.

RENEWALS AND VARIATIONS OF MAPIS

44. Once a MAPI has been granted, it will initially be valid for five years. After five years, for the product to continue to be authorised, a renewal application must be submitted and the MA re-assessed on the basis of the risk/benefit balance.

MAs FOR VETERINARY MEDICINAL PRODUCTS - PARALLEL IMPORTS

45. The renewal application must be submitted at least six months before the end of the five year period, and no earlier than nine months before. If a renewal application is not received the MA will expire, and the product must not be marketed. Whilst the VMD will normally inform you that the MA is due to expire this is a courtesy. It remains the responsibility of the MAPI holder to ensure that renewal applications are submitted in a timely manner.
46. An MA will only be renewed in its existing form. For any changes to be made, a variation application must be submitted and paid for separately.
47. Once renewed the MA will remain valid indefinitely unless the VMD considers a single, additional renewal is justified on grounds of pharmacovigilance (surveillance of suspected adverse reactions to the product) five years after the first renewal, or unless the MA is revoked or expired.

VARIATIONS

48. If you wish to make a change to the formal documentation, or underlying data, submitted in support of the MAPI you should submit a variation application to the VMD. For example, if you wish to add an additional member state to your MAPI in respect of a mutually recognised product this would constitute a variation. However, you cannot add another member state to a MAPI for a nationally authorised product, so you would need to apply for a new MA to import the same product from another Member state.
49. In order to make changes to the SPC and/or product literature as a direct consequence of the approval of a variation to the SPC and/or product literature of the UK authorised product you should submit a national Type IB(J) variation to the VMD. Further information about variations is available in VMG Note 4.

FEES

50. Details on the relevant fees can be found in the Regulations, which are available on the VMD website (www.vmd.gov.uk/). The fee should not accompany the MAPI application. MAPI holders will also be subject to the normal variation, renewal and annual fees as appropriate.

FURTHER INFORMATION

51. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: (+44) (01932) 336911; Fax: (+44) (01932) 336618 or E-mail: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.gov.uk/).

VETERINARY MEDICINES GUIDANCE NOTE

VETERINARY MEDICINES DIRECTORATE

WOODHAM LANE, NEW HAW, ADDLESTONE, SURREY KT15 3LS

Telephone: (+44) (01932) 336911 Fax (+44) (01932) 336618

E-mail VMGNotes@vmd.defra.gsi.gov.uk www.vmd.gov.uk



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES