



Veterinary Medicines Guidance Note

Marketing Authorisations for Veterinary Medicinal Products - Provisional Marketing Authorisations

No 5



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



VETERINARY MEDICINES GUIDANCE NOTE 5

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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

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INTRODUCTION

1. This is one of a series of guidance notes explaining the requirements under The Veterinary Medicines Regulations 2005. These Regulations came into effect on 30 October 2005 and set out controls on veterinary medicinal products in the UK. Basic information about the scope of the Regulations and the requirements for the marketing authorisations is given in VMG Note 1: *An Introduction to Marketing Controls on Veterinary Medicines*.
2. The purpose of this note is to describe the procedure for applying for a provisional marketing authorisation.

ELIGIBILITY FOR A PROVISIONAL MARKETING AUTHORISATION

3. The Regulations allow a product to be authorised in specific and restricted circumstances, without all the comprehensive data on therapeutic effects, which is normally required. This is when there is no suitable authorised medicine available to treat a particular disease or to treat a new disease in the UK. A new disease could either be one that has not previously been recorded in the UK, or an existing disease whose pattern has changed to such an extent that existing remedies ceased to exert effective control. Anyone who is interested in the possibility of applying for a provisional marketing authorisation is strongly advised to contact the Veterinary Medicines Directorate (VMD) at an early stage.

APPLICATION FOR A PROVISIONAL MARKETING AUTHORISATION

4. A provisional Marketing Authorisation (MA) will only be issued in exceptional circumstances when the issue of a full authorisation is not supported by the available data. As the data dossier is incomplete the applicant is advised to contact the VMD at an early stage to discuss whether it is possible to consider the incomplete data package as a valid application. So far as possible, this should be a normal application supported by all relevant data available to the applicant.
5. Applications will be subject to the normal rules on fees. For further information please refer to the VMD's fees guidance note.

HANDLING THE APPLICATION

6. On receipt, the VMD will assess the application as quickly as possible. We shall need to be sure that the quality is adequate, and that the major safety questions are answered, i.e. that the product will not harm treated animals, that operator and consumer safety are assured, that the environment will not be damaged and, for immunological products, that extraneous pathogens are absent. The active substances of a pharmaceutical product intended for use in food producing animals

must be included in Annexes I, II or III of Regulation 2377/90 before a provisional marketing authorisation may be issued. Although a complete efficacy package may not be necessary, some efficacy data to demonstrate that the product has a positive risk assessment are necessary.

CONDITIONS ATTACHED TO A PROVISIONAL MA

7. The authorisation would be subject to whatever conditions were considered necessary in the circumstances. Possible conditions include:
 - pre-release testing to an agreed protocol of all batches to be marketed;
 - a structured programme for the collection and investigation of suspected adverse reaction reports;
 - an active programme for monitoring safety and/or efficacy in use;
 - the completion and/or conduct of trials needed to rectify deficiencies in the data dossier;
 - particular labelling requirements (for example to indicate that, as the product had a Provisional Marketing Authorisation, efficacy had not been fully evaluated);
 - controlled distribution – Provisional Marketing Authorisation are normally POM–V, but in some circumstances additional controls through the State Veterinary Service or named veterinary surgeons might be appropriate.
8. A provisional marketing authorisation is only valid for one year. Renewal on an annual basis would be dependent on compliance with the conditions of the authorisation, on the results of Suspected Adverse Reaction reports and any additional data submitted, on the extent to which the exceptional circumstances persist, and on whether or not a full marketing authorisation had meanwhile been issued for a product effective against the disease concerned.

FURTHER INFORMATION

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

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