Covering letters accompanying applications:

Guidance for Applicants

Introduction

You are required to provide a covering letter when submitting an application to the VMD in relation to Marketing Authorisations (MAs), Veterinary Homeopathic Remedies (VHRs), Animal Test Certificates, and Specific Manufacturing Authorisations[1]. The information that should be included in the covering letter is outlined below.

For All Applications

- A brief introduction to the application. It is important to: specify the purpose of the application, highlight any items of relevance specific to your application and to ensure the covering letter does not contradict information held in the application form.

- Anything included in the application that is not typical for an application of the type submitted, e.g. an application for a novel product, or the omission of data that would normally be expected for an application of the type submitted.

- Email address for invoicing; the VMD now sends invoices electronically, so you must provide an email address of where you would like your invoice sent to, if this is not clearly indicated on your application form.

- For Extension applications, state whether the intention is to create a new stand-alone MA ('new extension'), or change an existing MA ('variation extension', i.e. rolled back in).

- For applications for new MAs and ATCs, state whether the product concerned is a pharmaceutical, immunological / vaccine, or a biological veterinary medicinal product (VMP). The VMD uses the following guidance to distinguish an immunological and biological VMP:

    - Immunological: A VMP administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.
    - Biological: The VMD considers that a biological VMP is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source.

  It is anticipated that, because of the novel nature of biological VMPs, these will usually be processed via the centralised procedure. However, it is particularly

[1] Includes Autogenous Vaccines, Non-Food Animal Blood Banks, and Equine Stem Cell Centres

important to highlight that the product concerned is a biological for ATC applications.

For Variations Only

The points below relate specifically to variation applications submitted on both a National and European basis. In addition to the covering letter, you must provide a table of contents listing all the data submitted together with the pages or appendices on which the data can be found. If applicable, you should also specify which documents have been provided in support of the "documents to be supplied" listed under the relevant variation category in the classification guideline. Failure to provide a table of contents will result in additional questions and unnecessary delays during validation assessment.

For Type IA variations there is no validation period and failure to provide the required information will result in refusal of the application. The fee for a Type IA variation is payable regardless of the outcome of the application, i.e. approved or refused.

- If an extension to a MA is to be included as part of a grouped variation, you must provide a declaration confirming that the change(s) is to be retained as part of the original MA, i.e. 'rolled back' into the original MA and treated as a 'variation-extension'.

- For variations that affect the SPC and / or product literature, you should state if the product is joint-labelled with Ireland.

- Please state if the variation is to implement the outcome of a referral, e.g. Article 35.

- Please state if the product(s) involved in the application has ever been subject of an Article 34 referral; in this case, and where the product(s) hasn't been converted to a Mutually Recognised Product it is your responsibility to maintain harmonisation of the SPC. Therefore, if the variation affects the SPC, please confirm that the same variation has been submitted to other relevant member states as well; if not, the VMD will not progress the application until such confirmation is received. NB for these types of applications we strongly recommend that you use the national workshare procedure to help ensure continued harmonisation of the SPC.

- Please state if the variation has been submitted on request of the VMD and whether the fee has been waived; if the fee has been waived you will need to provide evidence of this.

- If the variation is on the list of unforeseen variations that the VMD considers to be classified as Type IB for variations that are dealt with on a national basis only,

this should clearly be stated on the covering letter. The EU application form should also include a clear, concise description of the variation in the 'scope of change' and 'present/proposed' boxes.

- For EU applications, please include the EU procedure number.

- For grouped variations (except variations concerning solely Type IA changes), include an explanation as to how the variations concerned fall into one of the cases listed in Annex III of Commission Regulation 1234/2008. If the grouping has already been agreed with the VMD, reference to this should be provided. This also applies to changes grouped under a worksharing procedure.

- For grouped and workshare variations, state how many variations of each type (Type IA, Type IB, Type II or Extension) are being applied for; e.g. 3 x IA, 2x IB, 1 x Extension, etc. Please note, applications involving extension changes or solely Type IA changes cannot be progressed as workshare variations.

- For grouped and workshare variations, state the number of MAs included in the application.

- In cases where there are multiple variations of the same category included within the same variation, please specify how many variations of each category are being applied for.

- For Type IB (Unforeseen) variations, include reference to discussion and agreement with the CMDv and/or the VMD if applicable. An explanation as to how this falls under a Type IB (Unforeseen) variation should also be provided.

- For worksharing applications, include reference to discussion and agreement with the CMDv and / or the VMD/ Reference authority.

- In the UK an MAH is identifiable by their unique company number, which forms the first part of a product's Vm number. If the products submitted as part of a group or workshare variation have different company numbers, but you believe them to belong to the same MAH, please provide justification for this in your covering letter.