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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CONCEPT PAPER ON THE DEVELOPMENT OF A CVMP NOTE FOR GUIDANCE ON THE STABILITY TEST DATA TO BE SUBMITTED FOR VARIATION APPLICATIONS TO A MARKETING AUTHORISATION

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP)

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Introduction

On 1 October 2003 the revised European Commission Regulations on Variations came into force. Commission Regulation (EC) No 1084/2003 and Commission Regulation (EC) No 1085/2003 cover human and veterinary medicinal products.

Many applications for variations to existing veterinary medicinal product marketing authorisations concern quality aspects. Often, these variations have or may have an impact on the stability of either the active substance or the finished product, and therefore stability data have to be generated.

The guideline is intended to be applicable to chemical active substances and related finished products and not to radiopharmaceuticals, biologicals and products derived from biotechnology.

Problem statement

Variations are now classified into three different categories: Type IA, Type IB and Type II variations. Most of the variations listed in the annexes of the Variation Regulations are related to quality aspects. Although the Notice to Applicants Guideline on Dossier Requirements for Type IA and Type IB Notifications (July 2003) sets out the conditions necessary, and the documentation to be supplied, for each proposed variation and distinguishes whether it should follow a Type IA or a Type IB procedure, some additional specific guidance on stability testing is required, in particular for Type II variations.

Anticipated benefit to Industry & Other Interested Parties and to Regulatory Authorities

There is currently insufficient EU guidance available to either industry or assessors on stability test data for variation applications. Stability studies are very time consuming and it would therefore be beneficial for industry to have clear guidance on the stability studies and data necessary to support applications for variations to veterinary medicinal products before their submission.

Furthermore, in the absence of harmonised specific guidance, conclusions may differ when quality related variations are assessed due to differing policies of the competent authorities concerned. In the case of products authorised via the Mutual Recognition (MR) procedure this might lead to arbitration. Development of a guideline would therefore aim to harmonise interpretation of such variation applications within the Community.

Discussion

In April 1998 a Note for Guidance on Stability Testing for a Type II Variation to a Marketing Authorisation was adopted by the CPMP for human medicinal products. A comparable guideline for veterinary medicinal products has never existed.

At present, this 1998 CPMP (human) guideline is being revised in line with the new Regulations. It is also planned to widen the scope of the existing CPMP guideline to all types of variations (including Type I variations), to include the alternative storage conditions of 30°C/65% RH, and also to be more specific about extrapolation of data. (The title of the CPMP guideline will be changed accordingly.)

Similar guidance is also needed for veterinary medicinal products, which might be in the form of a joint CPMP/CVMP guideline.

Recommendation (points to be addressed)

It is recommended to develop a CVMP guideline on the stability test data to be submitted for applications for variations to marketing authorisations for veterinary medicinal products in line with the draft CPMP Note for guidance on stability testing for variations to a marketing authorisation (CPMP/QWP/576/96, rev 1).

Timetable

December 2003	Adoption of Concept Paper by CVMP
January 2004 – October 2004	Development of draft CVMP guideline
November 2004 – July 2005	Consultation (6 months) and finalisation

Resource requirements for preparation

It is proposed that the CPMP/CVMP Quality Working Party develops the Guideline.

Impact for Industry and other Interested Parties

For industry and other interested parties the development of this guideline will contribute to the clarity and harmonisation of data requirements for variations involving stability issues.

Impact assessment for Regulatory Authorities

For Regulatory Authorities the proposed guideline will be conducive to a uniform assessment of variations throughout the EU Member States and thus will facilitate applications for variations, especially in the Mutual Recognition procedure.

References to literature, guidelines, etc.

Commission Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

Commission Regulation (EC) No 1085/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93.

Notice to Applicants Guideline on Dossier Requirements for Type IA and Type IB Notifications (Final – Revision 0 - July 2003)

Note for Guidance on Stability Testing of New Veterinary Drug Substances and Medicinal Products (CVMP/VICH/900/99)

Note for Guidance on Stability Testing of Existing Active Substances and Related Medicinal Products (CVMP/846/99)

Note for Guidance on Stability Testing for a Type II Variation to a Marketing Authorisation (CPMP/QWP/576/96) respectively Note for Guidance on Stability Testing for Variations to a Marketing Authorisation (CPMP/QWP/576/96, rev 1)