European Medicines Agency
Veterinary Medicines and Inspections

Veterinary Scientific Advice Workshop

Introduction

The CVMP scientific advice working party was set up in September 2004. Building on the experience gained to date, the first veterinary scientific advice workshop will be held at the EMEA on 19th June 2008 from 14.00-17.00. The primary objective of the workshop is to provide an in depth view of the scientific advice procedure, its functioning and scope to potential applicants.

A number of members of the CVMP Scientific advice working party (SAWP-V), together with EMEA staff and representatives of industry, including an SME company will give presentations highlighting the opportunities that the procedure offers for different types of veterinary applications. It is an opportunity to engage in dialogue and hear first hand the views of the CVMP scientific advice working party.

Attendees will be provided with:

- an up-to-date view of the current procedure;
- guidance on how to put a scientific advice request together to extract maximum benefit;
- an understanding of how parallel advice with the FDA works;
- details of the incentives available for SME companies.

The workshop will also address scientific advice for products indicated for limited markets, minor use minor species (MUMS) products. The latest MUMS proposals from CVMP, the recently adopted MUMS guidelines on dossier requirements and the link to scientific advice will be presented. The results of a specifically designed questionnaire sent to all scientific advice users in 2005-2006 will be presented with particular emphasis on clinical outcomes. Participants will gain knowledge and understanding of how scientific advice can assist in ensuring a successful outcome for new product development.

For further information, a copy of the agenda and the application form are linked below. Attendance at the workshop is free of charge, however as numbers will be limited, completed registration forms should be returned before the deadline of 12 June 2008.

Agenda

1. Overview of SA procedure and arrangements for parallel advice with FDA - Dr Karen Quigley
2. Results of Industry SA Questionnaire emphasising clinical outcomes - Dr Rory Breathnach
3. Scientific advice for SMEs – experiences of an SME - Irma Middlehof, Dopharma
4. Industry viewpoint of procedure - Ben Buckle, Elanco Animal Health
5. Key considerations for your application - Dr Rory Breathnach
6. MUMS – scientific advice incentives, dossier requirements - Dr Cristina Munoz-Madero

Registration form

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