EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MRLs for active substances and excipients

Presented by: Isaura Duarte
Head of Animal and Public Health

Overview

- MRLs and marketing authorisations
- MRLs for active substances
- How to consider excipients
- Contacts and references

MRLs and marketing authorisations

If the product is intended for a food producing species:

Prior to submitting a marketing authorisation application the MRL status for all constituents of the product has to be addressed.

These include:

- Active substance(s)
- Excipients

MRLs for the active substances (1)

The active substance has to be included in table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 for the relevant animal species and/or food commodity.

The entry in table 1 of the Regulation may include:

- MRL values, or
- "No MRL required" classification.

Exemption: Active principles of biological origin used in immunological veterinary medicines

(for complete provision see Article 1(2) of Regulation 470/2009)

MRLs for active substances (2)

Examples:

- Medicinal product for dairy cattle:
  - MRLs need to be established for edible tissues of bovine species and milk
  - “No MRL required” classification referring to or including bovine species without restrictions to animals producing milk for human consumption
- Medicinal product for bees:
  - MRLs need to be established in honey
  - “No MRL required” classification referring to or including bees

How to consider excipients (1)

The requirements for the establishment of MRLs is applicable to all pharmacologically active substances included in the veterinary medicinal product

Unless it can be proven that the excipients are not pharmacologically active and do not raise specific safety concerns an MRL classification is required.

The exemption for immunological products concerns the active principles only; all other constituents such as adjuvants and preservatives need to have their MRL status clarified

How to consider excipients (2)

Options:

- The excipient is included in table 1 of the Annex to the Regulation (normally with a “No MRL required” classification) relevant for the target animal species and for the intended us of the product
- The excipient is included in the list of substances not falling within the scope of Regulation (EC) No 470/2010 (EMA/CVMP/519714/2009)

  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004958.pdf

How to consider excipients (3)

What to do if one of the constituents of the veterinary medicinal is not in table 1 of the Regulation nor in the out of scope list?

Two possibilities:

- Submit a MRL application in order to have the substance included in table 1 of Regulation (EU) No 37/2010;
- Submit a request for inclusion of the substance in the list of substances not falling into the scope of Regulation 470/2009

Relevant guideline: CVMP guideline on data to be provided in support of a request to include a substance on the list of substances not falling within the scope of Regulation (EC) No 470/2009

Contacts and references

Email: vet.applications@ema.europa.eu

EMA website www.ema.europa.eu