



2014 European Medicines Agency / IFAH-Europe Info Day

Upcoming actions for the implementation of Regulation (EC) 470/2009 (MRL-Regulation)

13-14 March 2014, EMA, London

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principles

No medicine can be placed on the market without a marketing authorisation

A Maximum Residue Limit required for pharmacologically active substances in medicines for food-producing animals

Scientific review of an application for a marketing authorisation by independent experts

Benefit-risk analysis

Marketing authorisation process is dynamic: dossier has to be updated to scientific progress and new scientific developments

State of play

- Adopted in 2013: neomycin, prednisolone, monensin, eprinomectin, diclazuril, dsRNA, monepantel, manganese carbonate and diclazuril
- Adopted so far in 2014: chloroform, butafosfan, triptorelin acetate and tildipirosin

Regulation (EC) 470/2009 and Commission Regulation (EU) 37/2010

*What can you expect in 2014
and 2015?*

Report to the Council and EP

- Review the experience gained
- Questionnaire / survey?
- Consultation event?
- MRLs, Reference points of Actions, Biocides

Injectables

- Tildipirosin – Commission Regulation establishing a MRL for muscle
- Also for other injectables MRL is required for controls
- It is necessary to ensure a level playing field
- Consultation on EMA-reflection paper
- Request of EC to EMA for establishing priority list of substances for revision?



MRLs for cascade use

- Commission has to establish detailed rules
- Article 23 of MRL-Regulation
- Agency is preparing advice

Implementing measures – MRL Regulation

- Methodological principles (Art 13)
- Form and content of applications (Art 13, Art. 15)
- Extrapolation (Art 13)
- Principles for assessment of RPAs (Art 19)
- Establishment of RPAs (Art 18)
- MRLs cascade (Art 23)
- Action in case of prohibited substances (Art 24)

Tetracyclines

- Application for an MRL for oxytetracycline – honey
- Challenge to establish MRL and respecting Acceptable Daily Intake



Fees

- Revision of Fee Regulation

Thank you

