EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines for bees

Establishment of maximum residue limits

Principles for marketing authorisations

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An agency of the European Union

Overview

- Role of the European Medicines Agency
- Establishment of maximum residue limits
- Authorisation of veterinary medicines in the EU


The European Medicines Agency

The Agency's principal activities

- Scientific evaluation of applications (centralised procedure)
- Continuous supervision authorised medicines (Pharmacovigilance)
- Scientific advice and incentives to stimulate the development new medicines
- Recommendation of safe limits for residues of veterinary medicines used in food producing animals
- Development of guidance for medicines evaluation
- Arbitration on divergent opinions/decisions from Member States
- Incentives for products intended for Minor Uses/Minor Species

Authorisation of veterinary medicines for food producing species in the EU

2 Steps:

- Establishment of maximum residue limits
- Granting of a marketing authorisation

Authorisation of veterinary medicines and establishment of maximum residue limits

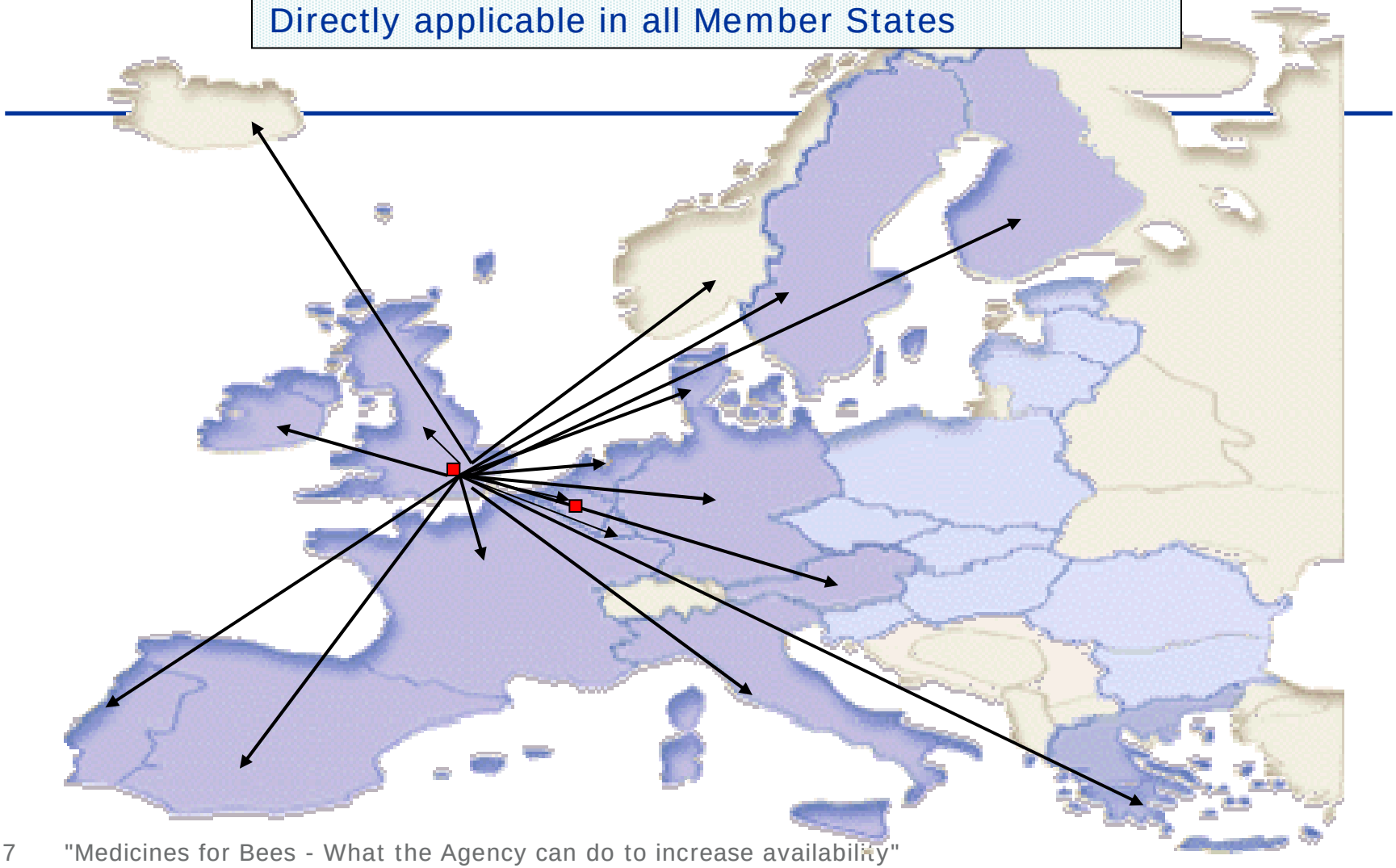
Before obtaining a marketing authorisation, all pharmacological active substances, included in the product intended for food-producing animals must undergo an evaluation of the safety of residues, i.e.:

- Establishment of maximum residues limits (MRLs)

EMA: scientific evaluation and recommendation

EC: Legislative measures (Regulation)

Directly applicable in all Member States



Establishment of maximum residue limits

Objectives

Ensure consumer safety

Through the establishment of withdrawal periods and residue surveillance

Facilitate trade

Avoid barriers to the free movement of veterinary medicines or of foodstuffs of animal origin within the EU

Requirements for the establishment of maximum residue limits

A MRL application for a new substance comprises safety and residues data

- Safety data:
  - Pharmacological and pharmacodynamics studies
  - Toxicity studies
  - Antimicrobial studies, if appropriate (depending on the nature of the substance)

Aim: To establish an acceptable daily intake (ADI)

Requirements for the establishment of maximum residue limits

- Residue data:
  - The evaluation of residues in honey is more complex – There is no time dependent depletion/elimination of residues – Residues once in honey, largely remain there
  - If it is not possible to assess metabolism and depletion of the substance the risk assessment can consider monitoring or exposure data – particularly relevant for honey
  - Studies should cover a reasonable range of commercial treatment conditions showing with reasonable statistical certainty that residues will not be above the proposed MRL

Requirements for the establishment of maximum residue limits in honey

For substances which have already MRLs in other species only the residue part of the dossier will be required as the safety of the substance has already been established

Establishment of maximum residue limits

Outcome of evaluation

- MRLs established (previously Annex I of Regulation 2377/90)
- Provisional MRLs established (previously Annex III)
- No need to establish MRLs in order to ensure consumer safety (previously II)
- No MRLs can be established: Forbidden substances (previously included in Annex IV)
  - Residues at whatever level might constitute a health hazard to the consumer
  - The data available is not sufficient to conclude on the establishment of MRLs

Maximum residue limits established for honey

- Amitraz (MRL established)
- Coumafos (MRL established)
- Flumethrin (no MRL necessary)
- Tau fluvalinate (no MRL necessary)
- Oxalic acid (no MRL necessary)

Other substances such as formic acid, camphor, menthol, thymol, essential oils (e.g eucalyptus oil) are included in Annex II of the Regulation (no MRL necessary) for all food producing species which therefore applies to bees and honey

Requirements for marketing authorisations

- Data required:
  - Pharmaceutical (physico-chemical, biological or microbiological) tests
  - Safety and residue tests
  - Pre-clinical and clinical tests
  - Test assessing the potential risk to the environment

Authorisation of veterinary medicines in the EU

- A veterinary medicinal product can only be marketed or used it in the EU if a marketing authorisation has been granted
- Procedures for authorisation of veterinary medicinal products in the EU
  - National procedure
  - Mutual recognition/decentralised procedure
  - Centralised procedure


Thank you for your attention