EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Consumer safety and MRLs

Introductory meeting for candidate and potential candidate countries

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An agency of the European Union

Overview

- Consumer safety/marketing authorisations
- Legal basis and guidance for the establishment of MRLs
- Procedure for the establishment of MRLs in the EU
- Implementation and residue control
- Information on MRLs made publicly available by the Agency

Consumer safety/marketing authorisations

Main principle

- Foodstuffs obtained from animals treated with veterinary medicinal products must not contain residues which might constitute a health hazard to the consumer

Consumer safety/marketing authorisations

Requirement

- In order to obtain a marketing authorisation, all pharmacologically active substances included in the product intended for food-producing animals must undergo an evaluation of the safety of residues

  No marketing authorisation if no MRL established

Purpose of establishing MRLs

Ensure consumer safety

- Withdrawal periods
- Residue surveillance

Facilitate trade

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

Legal basis regarding the establishment of maximum residue limits (MRLs)

Regulation (EC) No 470/2009 of 6 May 2009
(repealing Regulation (EEC) No 2377/90)

- Defines the procedure for establishment of residues of pharmacologically active substances in foodstuffs of animal origin

Regulation (EU) 37/2010 of 22 December 2009
(replacing Annexes I, II, III and IV of Regulation 2377/90)

- Alphabetic list of allowed (table 1) and forbidden (table 2) substances

Further guidance on the establishment of maximum residue limits (1)

Volume 8 of the Notice to Applicants and Guideline: establishment of maximum residue limits – currently under review to take into account the new MRL Regulation

- Provides detailed explanation on:
  - the data requirements
  - how to prepare/present the dossier
  - the procedure for the evaluation of the applications

Further guidance on the establishment of maximum residue limits (2)

CVMP Guidelines on how to carry out the studies on pre-clinical safety and residue depletion

- Available on the Agency's website:

http://www.ema.europa.eu/htms/vet/vetguidelines/background.htm

Establishment of MRLs in the EU

Community procedure: One single assessment, valid for all member States

- Scientific evaluation/opinion by the EMA/CVMP;
- Legislative measures by the European Commission

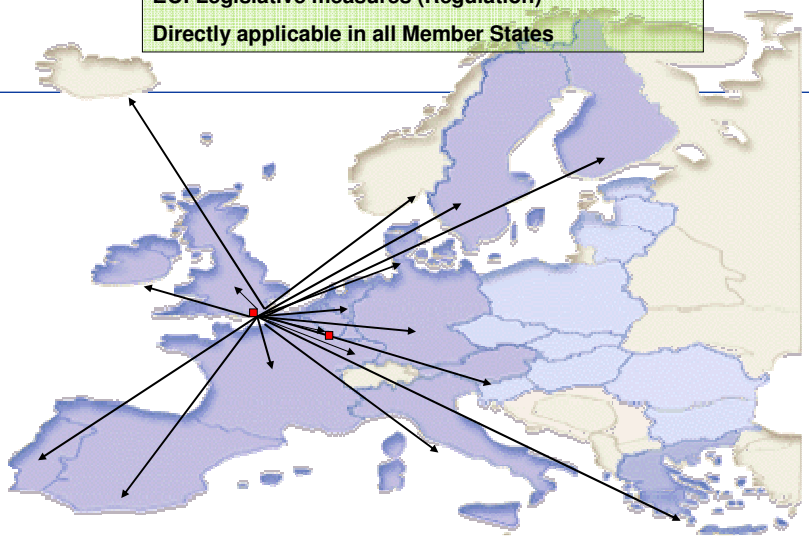
No national MRLs allowed

Establishment of MRLs in the EU

EMA: scientific evaluation and recommendation

EC: Legislative measures (Regulation)

Directly applicable in all Member States



European Procedure

European Medicines Agency

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Opinion + Analytical method (if relevant)

European Commission

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Adoption of Regulation after agreement of MSs
Publication of MRLs in EU Official Journal
MRLs established are applicable in all Member States

European Medicines Agency role

- To provide the European Commission a scientific opinion with regard to the establishment of MRLs
- The opinion follows the evaluation of the safety of residues carried out by the CVMP upon receipt of a valid application

Possible outcome of the evaluation(1)

Positive

- MRLs established (old Annex I)
- Provisional MRLs established with deadline to resolve outstanding issues (old Annex III)
- MRLs not required for protection of public health (old Annex II)

Possible outcome of the evaluation(2)

Negative

- No MRLs established as no safe limit can be identified (old Annex IV)
- No MRLs established as no final conclusion concerning the effect on human health can be drawn

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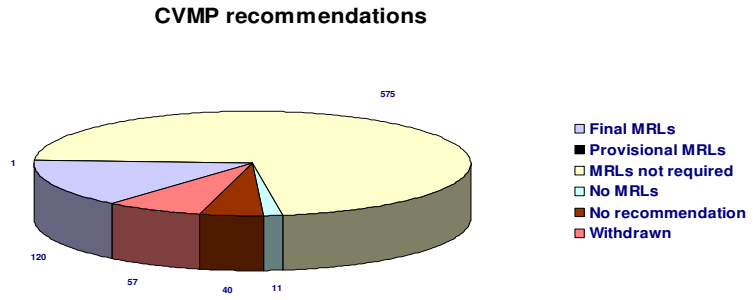
Overview of MRLs established in the EU

Over 800 substances assessed by CVMP



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Analytical methods (1)

- With the application for the establishment of MRLs the company must submit an analytical method for monitoring of residues;
- The suitability of the analytical method is one of the evaluation criteria;
- The relevant community reference laboratory is consulted on the adequacy of the method for control purposes

Analytical methods (2)

- The analytical method is submitted to the European Commission together with the CVMP opinion
- Following publication of the MRLs in the Official Journal of the European Communities (OJ) the analytical method is submitted (if relevant) to the Community and National Reference laboratories

Implementation and residue control

- The responsibility for monitoring residues of veterinary medicinal products in foodstuffs of animal origin lies with the competent authorities of the EU Member States

Information publicly available on MRLs on the Agency website

http://www.ema.europa.eu/index/indexv1.htm

- Summary opinions
- European Public MRL Assessment Reports (EPMARs)
- General information (status of MRLs procedures, policy documents)
- Guidelines

SUMMARY(1)

- No MRLs: no marketing authorisation for medicines intended for food producing species
- MRLs are established at Union level only and are directly applicable in all Member States
- Agency: scientific evaluation ⇨ recommendation to the European Commission
- European Commission: Legislative measures
- Member States: Monitoring (EC coordination)

SUMMARY(2)

- Information is available on the Agency's website
  http://www.ema.europa.eu/
- Queries on MRLs: mrl@ema.europa.eu