MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

SME WORKSHOP

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Safety of Veterinary Medicines

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Agenda

- Main principle
- Purpose
- Annexes
- Legal basis
- Procedure
- Extrapolation

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Ensuring consumer safety during authorisation of veterinary medicines

Main principle

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

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Requirement

In order to obtain 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

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Establishment of Maximum Residue Limits in the **EU**

Community procedure

- **Scientific evaluation/opinion by the EMEA/CVMP;**
- **Legal enforcement by the European Commission**

No national MRLs allowed

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Purpose of establishing Maximum Residue Limits

Consumer safety

Through:

- Establishment of withdrawal periods
- Residue surveillance

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Possible outcome of evaluation

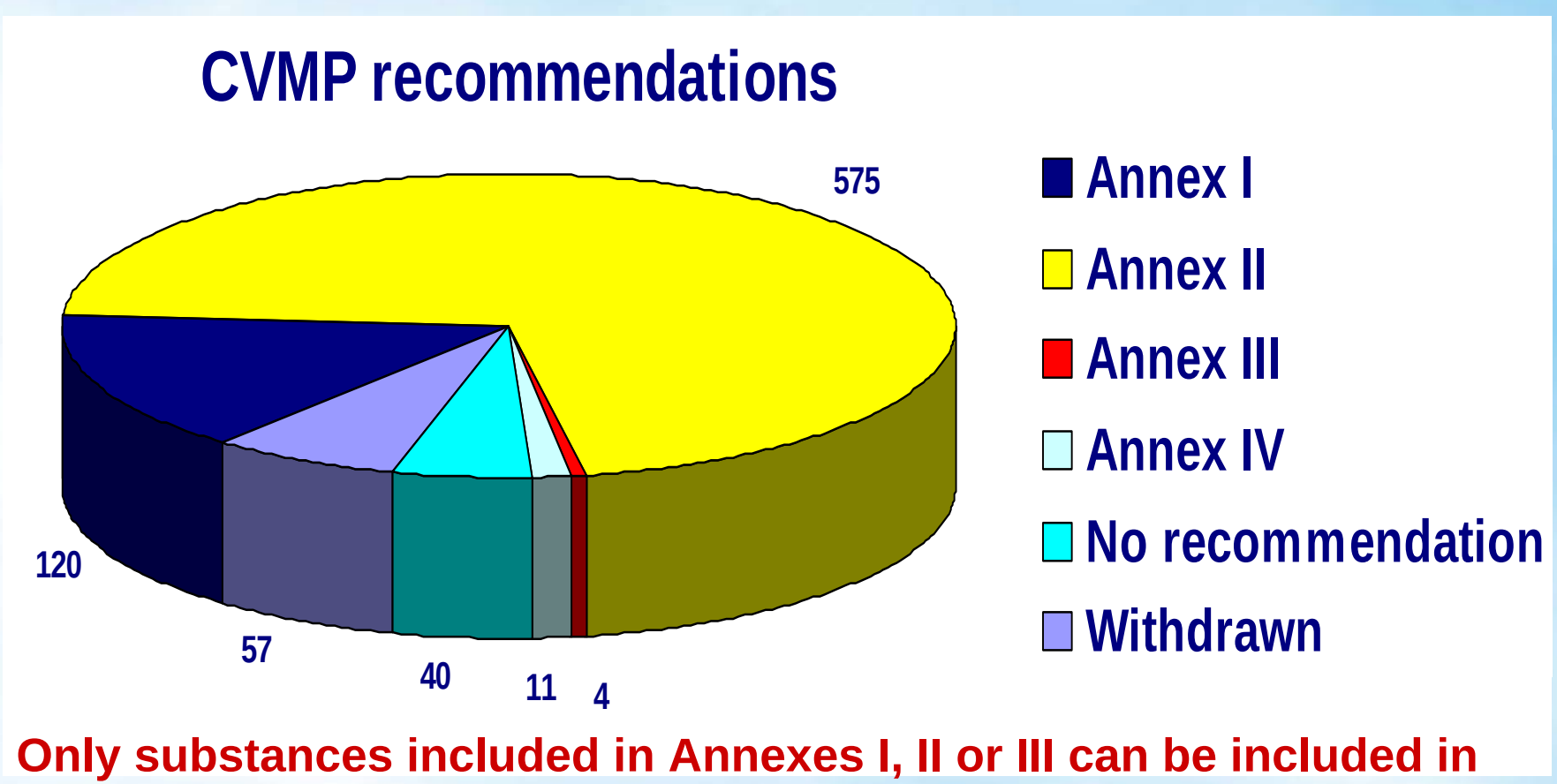
Accepted

- Definitive MRLs : Annex I
- Provisional MRLs : Annex III
- MRLs not required for protection of public health : Annex II
- Residues at whatever concentration constitute health hazard for consumer: Annex IV (= prohibition of substance)

No recommendation for inclusion in any of Annexes possible due to lack of data.

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Over 700 substances have been assessed by the CVMP



Only substances included in Annexes I, II or III can be included in veterinary medicinal products intended for food-producing animals.

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Legal basis

Directive 2001/82/EC on Community Code relating to veterinary medicinal products

- A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annex I, II or II of Council Regulation 2377/90

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Legal basis

- Council Regulation (EEC) **No 2377/90** of 26 June 1990, lays down a Community procedure for the establishment of **maximum residue limits** (**MRLs**) of veterinary medicinal products in foodstuffs of animal origin.

- **Defines the procedure for evaluation and the data requirements for the establishment of MRLs**

Detailed guidance given in Volume 8 of Rules Governing medicinal Products in the European Union

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-8/pdf/vol8_10-2005_.pdf

MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

Pre-submission

- Possibility to request for pre-submission meeting with EMEA secretariat to discuss preparation and submission of dossier and procedural aspects
- Submit letter of intent 3-4 months in advance of intended submission date: Provide identification of the substance, intended use, target animal species
- CVMP appoints a rapporteur and a co-rapporteur
- Applicant informed as well as of Project Manager and ideal submission dates

SOP: http://www.emea.europa.eu/pdfs/vet/sop/081999en.pdf

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Submission and validation

- Submission of dossier to EMEA and rapporteurs
- EMEA checks administrative compliance with legal requirements (within 14 working days)
- In case deficiencies are found, validation can be
  - suspended if needed corrections can be made within the ongoing 14 days or within the following month, or
  - refused if major deficiencies are identified
- Applicant informed of the outcome of the validation procedure; if positive, dossier to be submitted to other CVMP members according to their specific requirements

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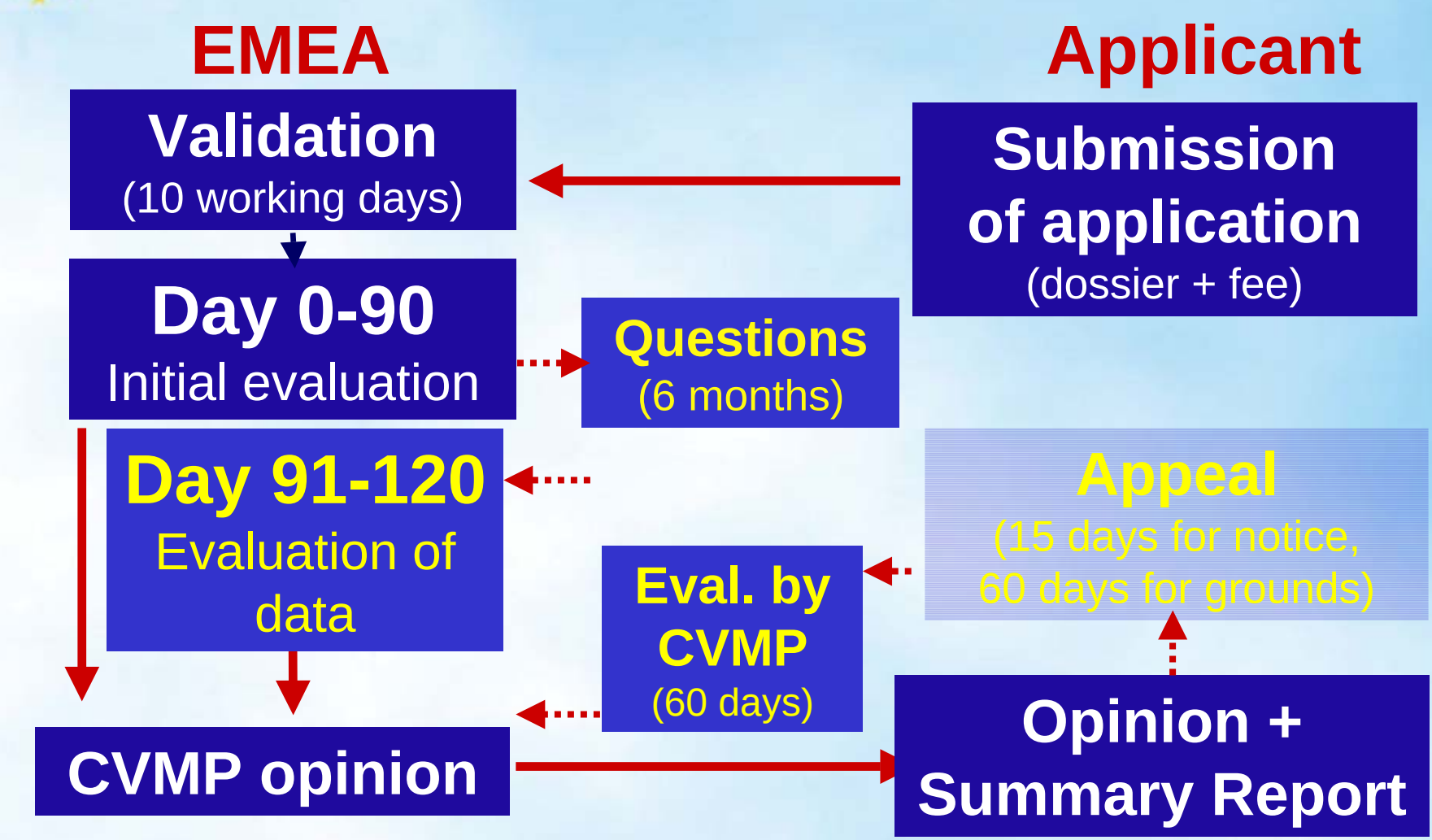
Evaluation procedure

- Clock start – day after validation
- Applicant and CVMP members informed
- CVMP agrees time table for evaluation
- Rapporteur's assessment report and Co-rapporteur's critique sent to applicant for info
- Adoption of list of questions/opinion
- Possibility of notification of appeal within 15 days of adoption of opinion; submission of grounds for appeal within 60 days

emea SOP: http://www.emea.europa.eu/pdfs/vet/sop/093100en.pdf


EMEA
Applicant
Validation
(10 working days)
Submission of application
(dossier + fee)
Day 0-90
Initial evaluation
Questions
(6 months)
Day 91-120
Evaluation of data
Appeal
(15 days for notice, 60 days for grounds)
Eval. by CVMP
(60 days)
CVMP opinion
Opinion + Summary Report

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Post opinion: Commission's decision making procedure

- CVMP opinion transmitted to the Commission within 30 days of adoption together with summary report and analytical method (in case of Annex I or III recommendations)
- Interservice consultation within European Commission (DG Health and Consumer Protection) and Member States consultation (Standing Committee by written procedure)
- Adoption of Regulation by the Commission, publication in the Official Journal of the European Communities
- EMEA publishes MRL summary report on the Website and submits analytical method to national competent authorities and European Reference Laboratories (in case of Annex I or III)

CVMP recommendations

EMEA

Opinion + Summary Report + Analytical method
to European Commission

Adoption of Regulation after agreement of Member States
Publication of MRLs in OJ (Official Journal):
MRLs established applicable in all Member States of the European Union

Extrapolation of MRLs

- **Approach as CVMP Note for Guidance on risk analysis approach for residues of veterinary medicinal products in food of animal origin – EMEA/CVMP/187/00 Summary reports**

Species for which MRLs have been set	Extrapolations to:
Major ruminant (meat)	All ruminants (meat)
Major ruminant milk	All ruminant milk
Major monogastric mammal	Extrapolation to all monogastric mammals
Chicken and eggs	Poultry and poultry eggs
Salmonidae	All fin fish
Either a major ruminant or a major monogastric mammal	Horses

Information available on MRLs on EMEA website

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

- **Summary opinions**
- **Summary reports**
- **General information**
  (status of MRLs procedures, policy documents)
- **Guidelines**

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