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Minor Use Minor species

Evaluation and Authorization of Veterinary medicinal Products

Workshop for OIE national Focal Points for Veterinary Products
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The Problem

- **Reluctance by the veterinary pharmaceutical industry to invest in R&D for small markets.**
 - Costs too high for industry for developing Maximum residue Limit Dossiers and Marketing authorisation dossier
 - Cost too high for maintaining existing dossier


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Consequence

- **A problem for the veterinarian**
 - Veterinarians do not have medicinal products available to treat some minor species and minor uses in major species
- **A problem for public and animal health**
 - Off-label and sometimes illegal use of medicines in food animals may result in problems for:
 - Consumer safety
 - Ecotoxicity
 - Animal safety
 - Efficacy
 - Antimicrobial resistance...

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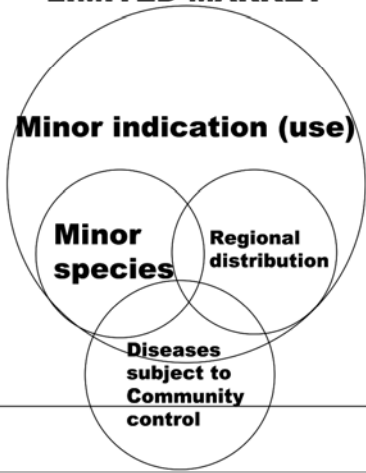
Definitions

- **How to define minor Use minor Species? European example**


All the situations in which the market for a veterinary medicinal product is limited in term of size:

 - ❖ **Minor species**
 - ❖ **Minor indications**
 - ❖ Limited geographical distribution
 - ❖ **IWP classification produced for immunologicals**

LIMITED MARKET



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Definitions

European example

Major species

- Food producing species
 - ❖ **Cattle (dairy and meat animals)**
 - ❖ **Sheep (meat animals)**
 - ❖ **Pigs**
 - ❖ **Chickens (including Laying hens)**
 - ❖ **Salmon**
- Major companion animal species
 - ❖ **Dogs**
 - ❖ **Cats**

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Definitions

European example


Minor use

- ❖ **Low prevalence/incidence**
- ❖ **Limited geographical spread**

Factors to prioritise indication

- ❖ **Lack of availability of alternative, authorised treatment**
- ❖ **Severity of the disease**
- ❖ **Exotic diseases important for reasons of human or animal health**

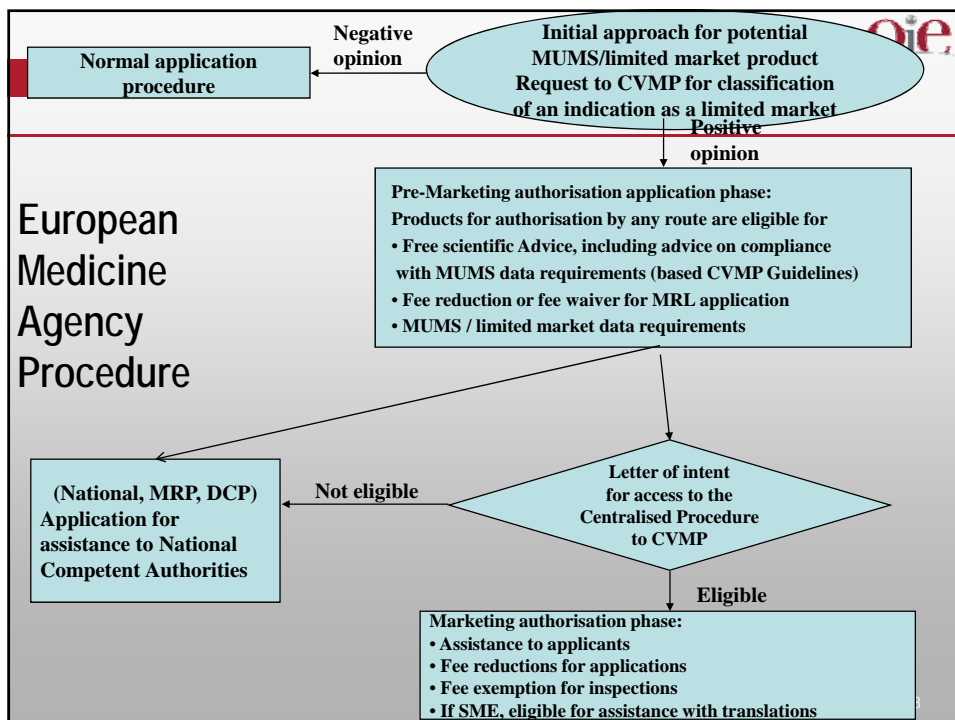
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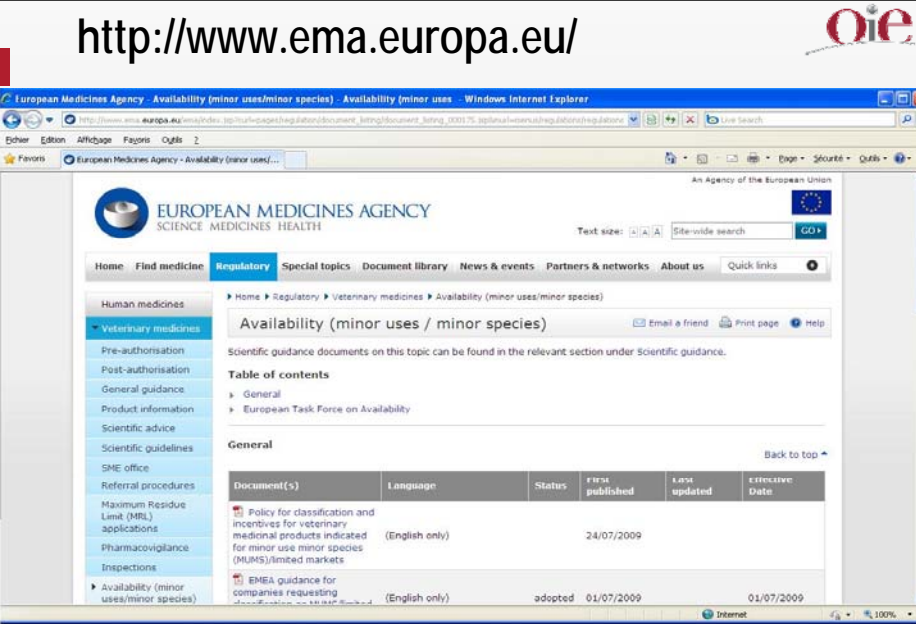
Possible solutions ?

- **Inclusion in the legislation of specific requirements.**
 - Extrapolation of MRLs from major to minor species
 - Reduced data requirements
 - use of provisional authorisation
 - Assistance to applicants
 - Free Scientific advice
 - Fee reductions for MRLs and dossier submission
 - Public support for research funding

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<http://www.ema.europa.eu/>



Other Link: Head of medicines Agencies Task force on availability :
<http://www.hma.eu/204.html>

Thank you for your attention



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