EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instrument for Pre-Accession Assistance Programme (IPA)

Introductory Meeting
1-2 February 2010
Centralised Procedure – Veterinary

Presented by: Jill Kieffer
Head of Section/Development and Evaluation of Veterinary Medicines

An agency of the European Union

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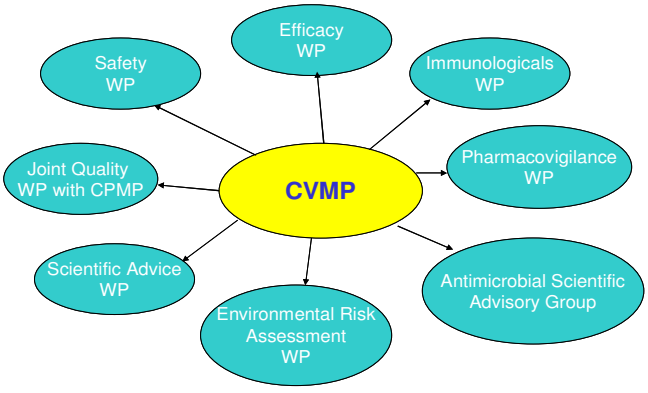
CVMP and its Working Parties



Centralised Procedure – Veterinary Products

EU single market for veterinary pharmaceuticals

- ~ 1.2 million sheep per main producing Member State
- ~ 8.9 million cattle in the EU (France, Germany, UK contribute almost half of the population)

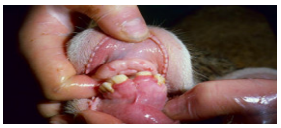
Eurostat 2007 figures

Centralised Procedure – Veterinary Products

Eligibility

- Mandatory for biotechnical products
- Optional for:
  - new active substance
  - products with therapeutic, scientific or technical innovation or 'in the interests of patients or animal health'
  - vaccines for animal diseases subject to community prophylactic measures

Other Agency initiatives to control epizootic diseases


Initiatives to promote the authorisation of vaccines against major epizootic diseases (Avian Influenza, Foot-and-mouth disease, Bluetongue):

- Guidance documents on technical issues (e.g guidelines for minimum requirements for AI, bluetongue vaccines)
- Focus Group meetings involving the Agency and other experts
- Incentives and regulatory and legislative measures to promote and maintain EU authorisation of vaccines (e.g fee waivers)

Centralised Procedure – Veterinary Products

- For food producing target species Maximum Residue Limit (MRL) required for pharmacologically active substances
- Project Manager covers quality, safety and efficacy – no Product Team approach
- No conditional approvals

Centralised Procedure – Veterinary Products

- Co-Rapporteur prepares a critique of Rapporteur's Assessment Report so only one report
- New Scientific Discussion and Benefit Risk Assessment document
  - concise report
  - facilitates CVMP discussion
  - forms the CVMP Assessment Report and then the European Public Assessment Report (EPAR)

Centralised Procedure – Veterinary Products

- Peer Review procedure is specific for veterinary requirements
  - initial pilot procedure currently being revised
  - simple procedure to maximise limited resources
  - objective to raise scientific quality and consistency

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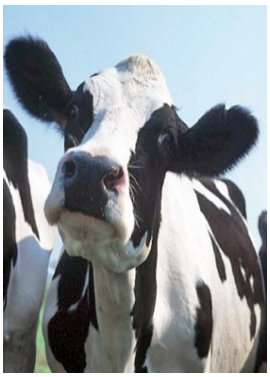
Centralised Procedure – Veterinary Products

Promoting Market Access

Aim: Timely access to safe and effective innovative medicines

Initiatives:

- Provision of Scientific Advice
- Small and Medium Enterprises (SMEs) support
- Provisions for products for limited markets (MUMS)



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