Dr. Anja Holm
Chair of CVMP, EMA

Danish Medicines Agency
Copenhagen, DK - Denmark
anh@dkma.dk

Overview of existing structures relevant for Veterinary Products

Regional Structures: Europe

European Medicine Agency (EMA)

Workshop for OIE national Focal Points for Veterinary Products
23 – 26 November 2010, Johannesburg, South Africa

1

Presentation

- Legislative framework
- Structures
- Overview of regulatories activities

Legislative Framework

- Harmonised legal framework covering pharmaceutical products as part of the *Acquis Communautaire*
- Key legal instruments
  - Directive **2001/82/EC** of the European Parliament and of the Council of 6 November 2001 on the **Community code relating to veterinary medicinal products** (Official Journal L 311, 28/11/2001 p. 1 – 66)
  - Amended by Directive **2004/28/EC** of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (Official Journal L 136, 30/4/2004 p. 58 - 84).

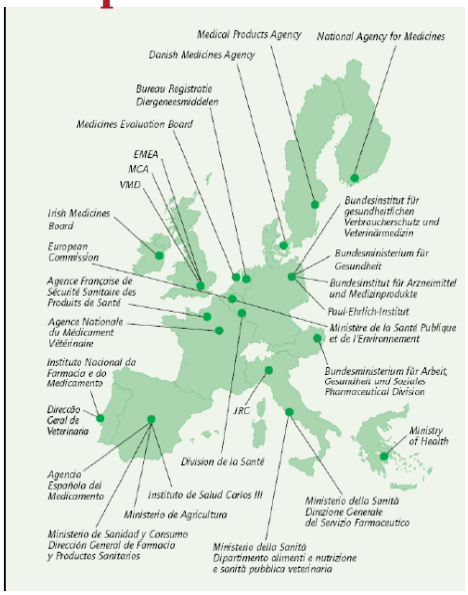
3

Legislative Framework

- Key legal instruments
  - Commission Directive **91/412/EEC** of 23 July 1991 laying down the principles and guidelines of **good manufacturing practice** for veterinary medicinal products (Official Journal L 228, 17/8/1991 p. 70 – 73).
  - Council Regulation Regulation (EC) No **470/2009** replacing Regulation (EEC) No **2377/90** of 26 June 1990 laying down a Community procedure for the establishment of **maximum residue limits** for veterinary medicinal products in foodstuffs of animal origin. (Official Journal L 224 , 18/08/1990 p. 1 – 8).
  - Regulation (EC) No **726/2004** of the European Parliament and of the Council of 31 March 2004 laying down **Community procedures for the authorisation** and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Official Journal L 136, 30/4/2004 p. 1 - 33).

4

STRUCTURES
European Medicines Network



network of over 4 500 European experts

The European Medicines Regulatory Networking Model

- **Elements of the network**
  - **National Competent Authorities coordinated by Heads of Medicines Agencies (HMA)**
    - **Joint human/vet Agencies/Authorities**
    - **Veterinary Agencies/Authorities**
    - **Inspection Agencies/Authorities**
      - **42 agencies, including EEA**
  - **European Medicines Agency (EMA)**
  - **European Commission**
  - **European Directorate for the Quality of Medicines & Healthcare (EDQM)**
  - **Network of Official Medicines Control Laboratories**
  - **Mutual Recognition Agreement partners**

6

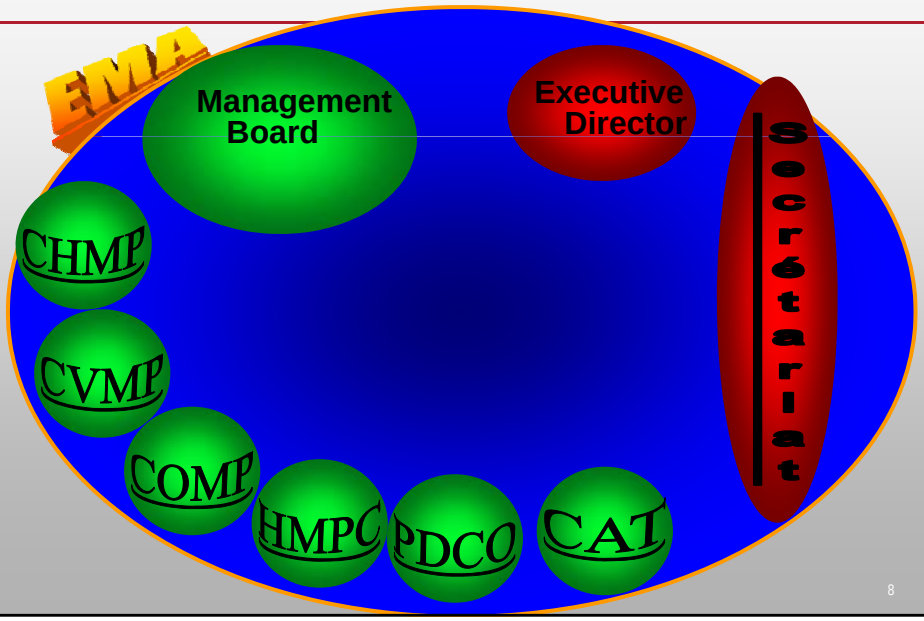
European Medicines Agency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Created in 1995
- Based in LONDON
- Regulation CE 726/2004
- Concerning Human and Veterinary Medicinal products
- Advisory role
  (Member States – EU Commission)

7

European Medicines Agency



8

European Medicines Agency

- Committee for Medicinal Products for Human use (CHMP)
- Committee for Medicinal Products for Veterinary use (CVMP)
- Committee on Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)
- Committee for advanced therapies (CAT)

9

EMA Secretariat

- 440 Staffs

Veterinary Unit

41 staffs

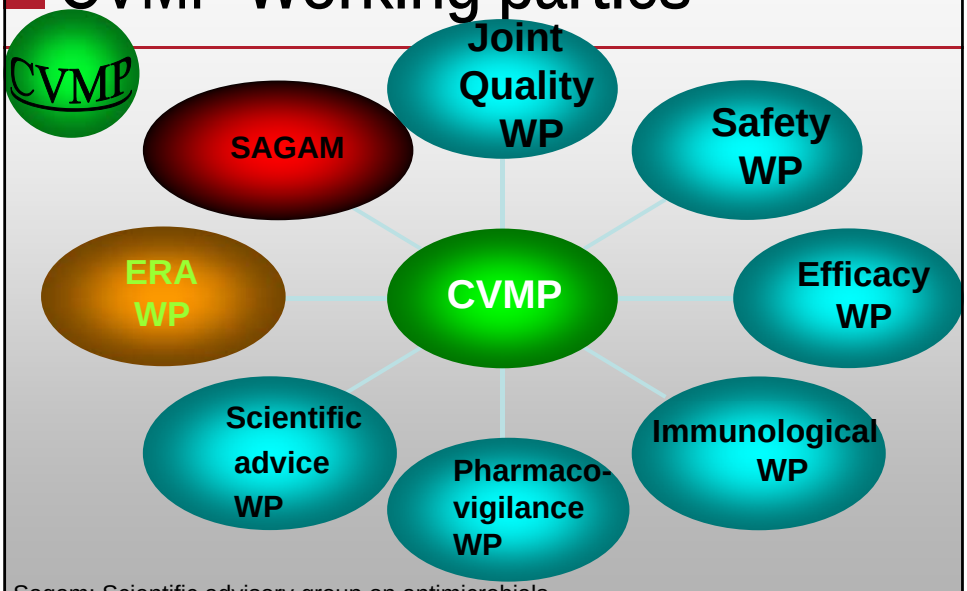
10

CVMP organisation

- One Chairperson (Dr. Holm, DK)
- One Vicechair (Dr. Schefferlie, NL)
- One member for each EU Member State (27) and one member for each EEA Country (3)
  - Each member has an alternate who can attend and vote in the absence of the member
- Five co-opted Members in order to complement CVMP expertise
- Decisions taken by consensus or qualified majority

11

CVMP Working parties



Sagam: Scientific advisory group on antimicrobials
ERA: Environmental Risk Assessment Working Party

12

The European Medicines Regulatory Networking Model

Activities of the CVMP

- Establishment of Maximum Residue Limits (MRLs)
- Authorisation of products (Biotech, GMO, Innovative)
- Referral and arbitration (eg. disagreements in MSs)
- Production of guidance documents
- Production of scientific strategy documents
- Comment on legislative proposals from COM
- Post-authorisation activities
  - Pharmacovigilance
  - Sampling and testing
- Inspection of manufacture

Overview of regulatories activities

Authorisation

Any veterinary medicinal product placed on the EU market must have a marketing authorisation ('Product Licence')

- Four routes to authorisation
  - National
  - Mutual Recognition
  - Decentralised Procedure
  - Centralised Procedure
- Same technical requirements for all procedures defined in Annex 1 to Directive 2001/82/EC, as amended

14

Routes to Authorisation

Type of Authorisation	National	Mutual Recognition	Decentralised	Centralised
Issued by	National Authority	National Authority through CMDv	National Authority through CMDv	European Commission through EMEA/CVMP
Validity	**One** Member State	**Several** Member States	**Several** Member States	**All** Member States
Legal Base	Directive 2001/82/EC	Directive 2001/82/EC	Directive 2001/82/EC	Regulation 726/2004
Time to authorisation (standard)	210 days	210 days	210 days	210 days
Appeal &/or arbitration	National appeal systems	Appeal to CMDv then arbitration by CVMP	Appeal to CMDv then arbitration by CVMP	Re-examination by CVMP
Types of product	Conventional, novel actives and generics	Conventional, novel actives and generics	Conventional, novel actives and generics	Novel, biotech, GMO and generics of CAPs

15

Coordination group for Mutual recognition and Decentralised procedures (CMDv)

- The CMD(v) is made up of a representative from each Member State
- EMA provides the secretariat.
- The Group meets monthly and provides a forum where procedural issues can be discussed, and problems regarding individual applications for veterinary product authorisation can be resolved.
- Scientific discussions related to individual applications are organised and chaired by the specific Reference Member State (the RMS).
- An electronic tracking database allows the Member States to follow the progress of individual applications and their subsequent variations.

16

Overview of regulatories activities

- Control of **manufacture**
  - Manufacturing authorisation
    - Compliance with Good manufacturing Practices (GMP) requirements Directive 91/412/EEC
    - Facility inspection, product related inspection, Qualified Person
- **Monitoring of products** on the market
  - Pharmacovigilance
    - Urgent reporting of serious **S**uspected **A**dverse **R**eactions (SARs), Periodic Safety Update Reports (PSURs), PV inspections
  - Sampling and testing
    - Coordinated by EDQM Network (European Directorate for Quality of Medicines)
  - Inspection of facilities
    - to maintain GMP accreditation of manufacturers

17

Key websites

- **European Commission DG Enterprise**
  - EudraLex: The Rules Governing Medicinal Products in the EU
  - http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm
- **EMA Veterinary Medicines Webpage**
  - http://www.ema.europa.eu/index/indexv1.htm
- **Heads of Medicines Agencies (EU)**
  - http://www.hma.eu/
- **European Directorate for the Quality of Medicines**
  - Home of the European Pharmacopoeia
  - http://www.edqm.eu/site/Homepage-628.html
- **VICH – International Cooperation on Harmonisation of the Technical Requirements for Registration of Veterinary Products**
  - http://www.vichsec.org/

18

The End

- **Thank you for your attention**

19