European Medicines Agency (EMEA)

Introduction to the EMEA

1st EMEA workshop for micro, small and medium-sized enterprises (SMEs)

2 February 2007, EMEA

40 years of harmonisation

- 1965 – First Directive set out basic principles
- 1975 – First pharmaceutical testing Directive
- 1981 – Specific veterinary legislation adopted
- 1985 – '1992 Single Market' project launched
- 1993 – Council Regulation No 2309/93 adopted
- 1995 – EMEA officially opens
- 2001 – Commission proposes 'Review' package
- 2004 – Part of new legislation comes into force
- 2005 – New legislation came fully into force
- 2005 – SME legislation came into force

The European system – Why?

- Complete single EU market for pharmaceuticals
- Protect and promote public and animal health
- Facilitate access by patients to new & better medicines
- Same product information for professionals and for patients
- Benefit European R&D pharmaceutical industry
- Platform for discussion of public health issues at European level

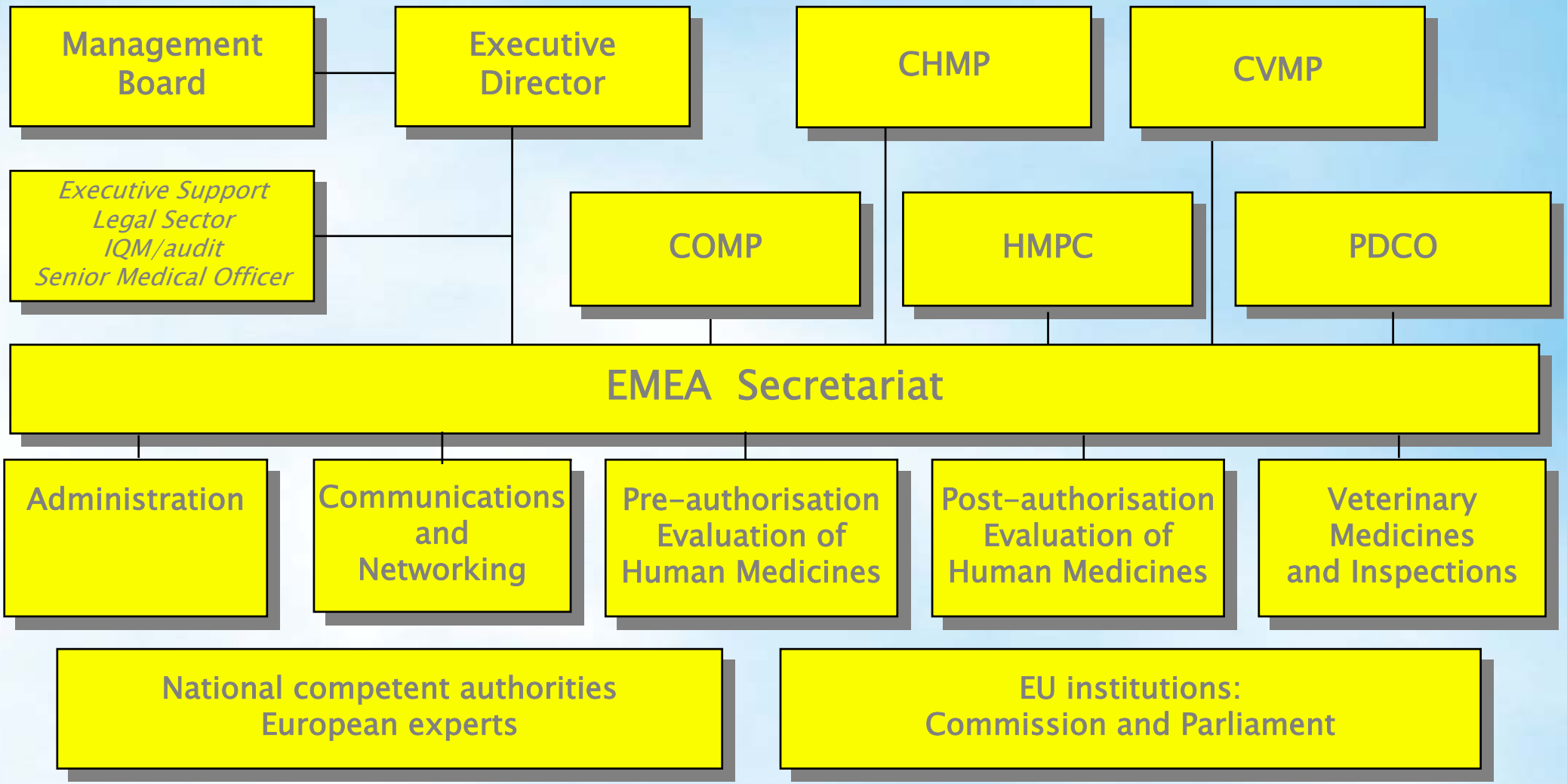
The European system – How?

- "One European system: two procedures"
  - Centralised procedure
  - Mutual recognition and decentralised procedures
- EMEA is focal point of centralised procedure
- Rapid and EU-wide authorisation
- 1 evaluation, 1 authorisation
- No price or reimbursement issues

A networking decentralised agency

- Member States have pooled their sovereignty for authorisation of medicines
- EMEA is designed to coordinate the existing scientific resources of Member States
- EMEA is not intended to replace national authorities, but to be a partner in the system
- A ‘virtual’ agency, providing an interface between all partners
- All parties linked by an IT network (EudraNet)

Structure of the EMEA



EMEA and its Europartners

- Over 40 national authorities in 30 countries dealing with human and veterinary medicines
- Network of over 4,000 European experts

- EU institutions: European Commission, European Parliament, other EU agencies

- European Pharmacopoeia (Council of Europe)
- Medicines Control Laboratories Network

EMEA and national authorities

- European experts' network underpins the work of the scientific committees and working parties
- European experts work for EMEA independently of their nominating authority
- Scientific competence is guaranteed by their nominating authority, independence and integrity assured through public declaration of interests
- Services provided to EMEA on basis of a contract (conditions, quality and payment)

EMEA and EU institutions

- EMEA is a decentralised agency of the EU, not part of the European Commission
- EMEA adopts opinions on basis of scientific criteria, Commission takes decisions based on that opinion
- Commission must fully justify decision when it is not in accordance with EMEA opinion

EMEA and EU institutions

- European Commission (mainly DG Enterprise and DG Health and consumer protection)
- European Parliament (Environment, public health and food safety committee)
- Other EU agencies such as the EMCDDA (narcotics agency), ECDC, EFSA, Translation Centre, etc

EMEA priorities in 2007

- Safety of medicines for human and veterinary use
- Implementation of legislation on medicines for children
- Stimulation of innovation
- Earlier and improved access to medicines
- Transparency, communication and provision of information
- The European medicines network