EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# The European Medicines Agency: Overview and structure

Introductory meeting on the participation of candidate and potential candidate countries in European Medicines Agency activities, London 1-2 February 2010

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An agency of the European Union



## Science. Medicines. Health.

The mission of the
European Medicines Agency
is to foster scientific excellence in
the evaluation and supervision of
medicines, for the benefit of
public and animal health.

## Where does the Agency come from? A quick history

From 45 years of European harmonisation

- 1965: First Directive on key principles of approval
- 1975: Directive on testing of human medicines
- 1981: First specific veterinary medicines Directive
- 1985: '1992 Single Market' project includes Agency
- 1993: Regulation (EC) No 2309/93 adopted
- 1995: Agency officially opens for business
- 2004/5: Revised legislation comes into force
- 2010: Celebration of 15 years of the Agency



## A European agency and medicines system: Why?

- Protect and promote public and animal health
- Pooling of best scientific expertise from across Europe for evaluation of medicines
- Facilitate availability of new medicines to patients
- Same product information to patients and healthcare professionals
- Single market for pharmaceuticals
- Benefits R&D industry
- Platform for discussion of public health issues

## A European agency and medicines system: How?

'One system, two routes for approval'

- Centralised European route
- Mutual recognition + decentralised national routes

Agency is the focal point of centralised procedure

One application, one evaluation, one rapid and EU-wide authorisation

No pricing or reimbursement issues



## Our partners in Europe

More than 45 national competent authorities dealing with human and veterinary medicines

Network of more than 4,900 European experts

EU institutions: European Commission, European Parliament, other EU agencies (EMCDDA, EFSA, ECDC, Translations Centre)

European Pharmacopoeia (Council of Europe)

Medicines Control Laboratories Network

## A networking Agency

Member States have pooled their sovereignty for authorisation of medicines

The Agency is designed to coordinate the existing scientific resources of Member States

It is not intended to replace national authorities, but to be a partner in the system

It is a 'virtual' agency, providing an interface between all partners

All parties linked by an IT network (EudraNet)



## National competent authorities: Our national partners

European experts' network underpins the work of the scientific committees and working parties

Scientific competence is guaranteed by their nominating authority, independence and integrity assured by public declaration of interests

Services are provided to the Agency on basis of a contract (conditions, quality and payment)
➲ €72m in 2010 (€ 67.4m in 2009)

## European institutions

The European Medicines Agency is an agency of the EU, not part of the European Commission

It 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 the Agency's opinion

Oversight by European Parliament and European Court of Auditors



## A dynamic and constantly changing Agency

The Agency new tasks and responsibilities:

- 2001: Orphan medicines (+ new committee)
- 2005 & 2008: Extended mandatory scope
- 2005: 'Biosimilar' and generic medicines
- 2005: Herbal medicines (+ new committee)
- 2007: Paediatric medicines (+ new committee)
- 2008/2009: Advanced therapies (+ new committee)
- Soon: pharmacovigilance (+ new committee) and counterfeit medicines legislation

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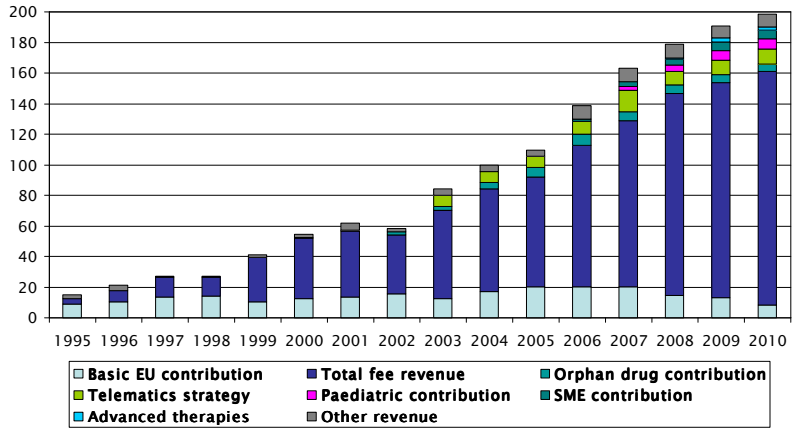
# Budget evolution 1995-2010 (€ million)

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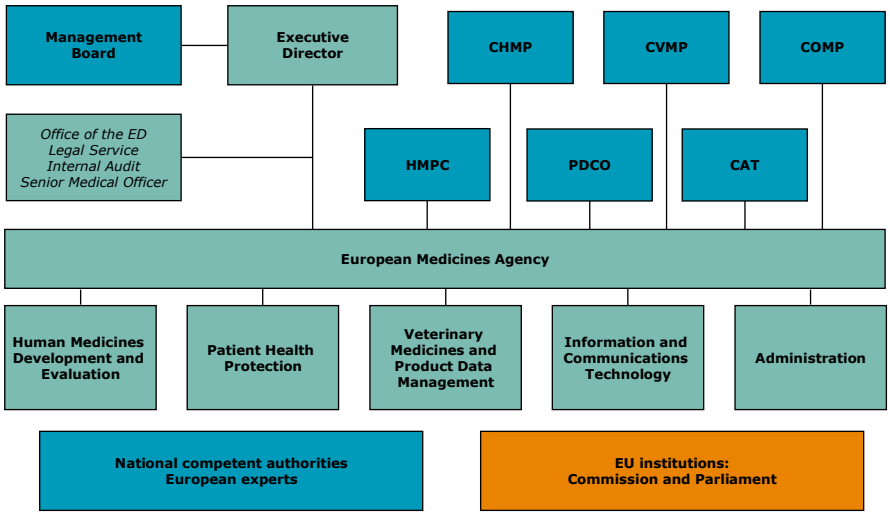


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## Priority areas for 2010

- Deliver on our core business
- Implement new legislative tasks
- Strengthen the European medicines network
- Continue to improve safety-monitoring of medicines
- International partners and international activities
- Communication, provision of information and increasing transparency
- Contribute to an environment that stimulates innovation and improved availability of medicines



## Review

This has been an overview of

- The history and background of the European medicines system and the Agency
- The European network of partners
- Changes to the Agency over the years
- Budget evolution from 1995 – 2010
- Priority areas for 2010
- High-level organisational structure of the Agency

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## Website

Our new website will be operational later in 2010

**www.ema.europa.eu**