Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede, šumarstva i vodoprivrede,
Uprava za veterinu

Republic of Serbia
Ministry of Health
Ministry of Agriculture, Forestry and Water Management,
Veterinary Directorate

alims
Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Acquis communautaire: Perspectives for regulators

General Overview (Human & Vet)

Prof. Vincenzo Salvatore, Head of Legal Service

The “Acquis”

A body of common rights and obligations which binds the European Union and its Members States

It comprises the content principles and political objectives of TEU and TFEU, the legislation adopted in application of the Treaties and the case law of the Court of Justice

Applicants countries have to accept the acquis before joining the EU

Derogations are exceptional and limited in time and scope

Pharmaceutical Industry: a core sector for Europe

- 633.100 employees, often highly skilled
- ~ 195 Billion Euro annual turnover
- ~ 26 Billion Euro invested in R&D each year

Source:
EFPIA, The pharmaceutical industry in figures 2010

45 years of European harmonisation

- 1965: First Directive on medicinal products
- 1993: Regulation (EC) No 2309/93 adopted
- 2000: New legislation on Orphan drugs
- 2001: Codification directives (2001/82 and 83)
- 2004: Regulation (EC) No 726/2004
- 2006: New legislation on paediatrics
- 2007: New legislation on advanced therapies
- 2008: New legislative package
- 2010: New pharmacovigilance legislation

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"
  - 1) Centralised procedure
  - 2) Mutual recognition and decentralised procedures

- EMA is focal point of centralised procedure
- Rapid and EU-wide authorisation
- 1 evaluation, 1 authorisation
- No price or reimbursement issues

The centralised procedure

A regulatory assessment process leading to:

- 1 Marketing Authorisation (simultaneously valid in ALL EU MS)
- 1 Invented Name
- Identical product information, in all 23 EU languages :
  - Summary of Product Characteristics (SPC) which defines the conditions of use of the product – indications, warnings, shelf-life, etc.
  - Package Leaflet (Information for the patient)
  - Package Labelling (Information on the carton)
- Maximum time limit (210 days)

The centralised procedure

The centralised evaluation system is designed to coordinate the existing scientific resources of Member States

EMA is coordinating the scientific evaluation → Scientific Opinion

The European Commission grants the **Commission Decision** (Pan European Marketing Authorisation) on the basis of this Opinion

Legally binding to all MS

A European Medicines Agency

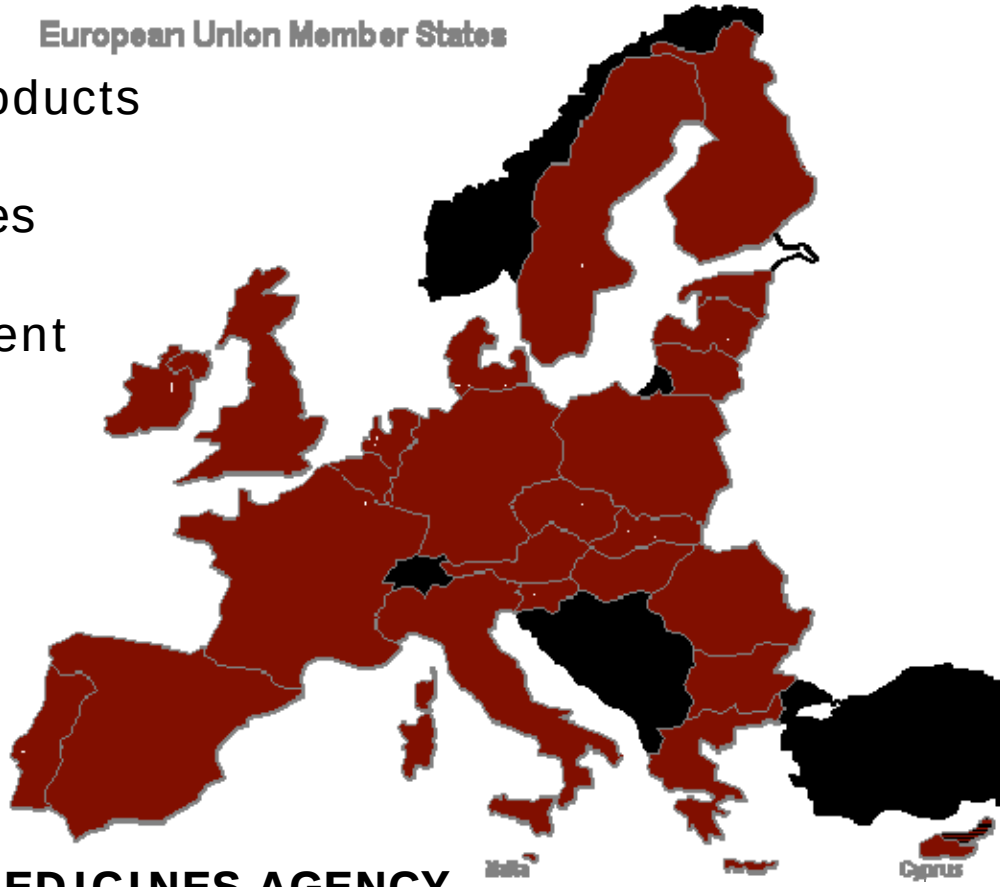
496 million users of medicinal products

30 EU and EEA-EFTA countries

More than 45 national competent authorities

4,500 European experts

6 scientific committees



1 EUROPEAN MEDICINES AGENCY

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

A European Agency

- decentralised body of the European Union
- own legal personality and it is not part of the European Commission
- issues scientific opinions addressed to the European Commission
- Commission issues decisions concerning marketing authorisations
- opinions are not binding but Commission has to provide justification if departing from the opinion

EMA Structure

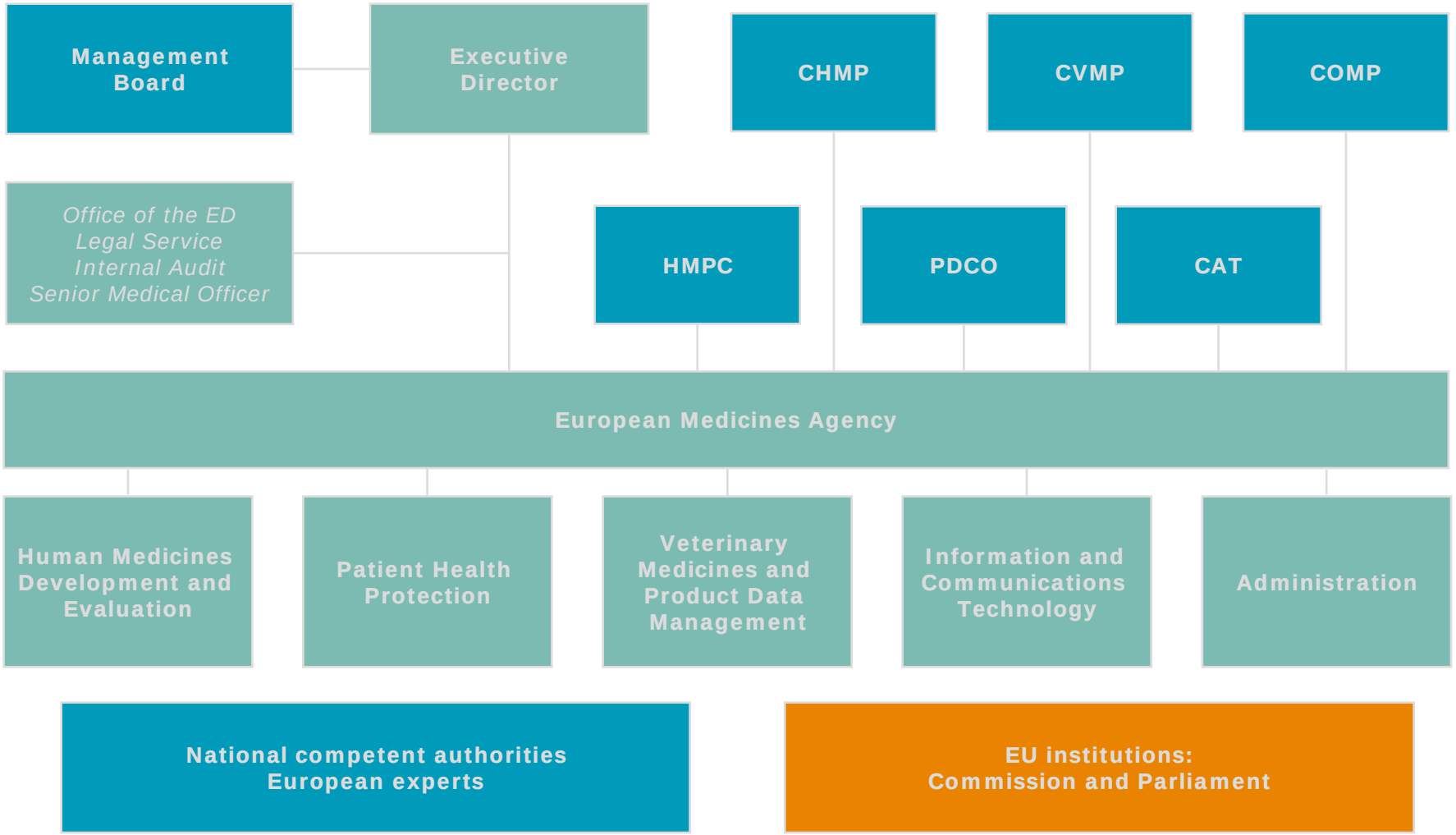
The Executive Director is the Agency's legal representative.

The EMA is supervised by a Management Board and its scientific activities are largely carried out through its six Committees and their Working Parties.

- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)
- Committee for Advanced Therapies (CAT)

Management Board, Committees and their Working Parties are supported by the EMA secretariat.

Structure


Management Board
Executive Director
CHMP
CVMP
COMP
Office of the ED
Legal Service
Internal Audit
Senior Medical Officer
HMPC
PDCO
CAT
European Medicines Agency
Human Medicines Development and Evaluation
Patient Health Protection
Veterinary Medicines and Product Data Management
Information and Communications Technology
Administration
National competent authorities
European experts
EU institutions:
Commission and Parliament

EMA and national competent authorities

EMA = a networking decentralised agency

- Designed to coordinate the existing scientific resources of the MS
- European experts' network underpins the work of the scientific committees and working parties
- European experts work for EMA 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 EMA on basis of a contract (conditions, quality and payment) [approx. €72m in 2010 (€ 67,4m in 2009)]

EMA and national competent authorities

EMA hosts CMD (human and vet) meetings and provides secretariat, which meet in parallel to CHMP and CVMP meetings *(11/year)*

EMA participates at the Heads of Medicines Agencies' meetings *(4/year)*

Regular reports between HMA and Management Board *(4/year)*

EMA and EU institutions

- European Commission (mainly 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

EMA budget

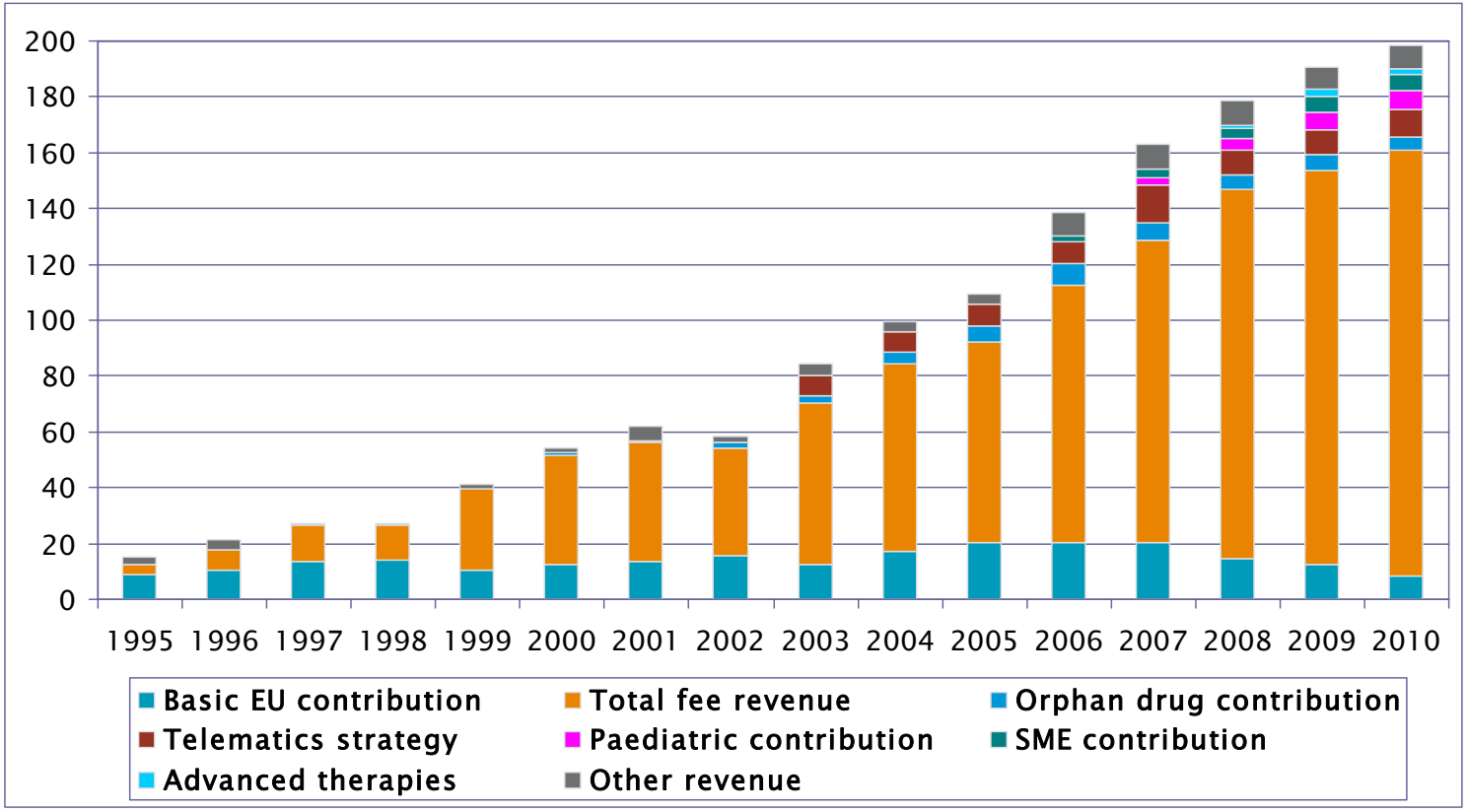
In 2009 total budget of € 194.4 million.

Fees represent 75% of total revenue, amounting to about € 145,8 million. EU subsidies contribute 25% of the budget.

About one-third of budget is paid to national agencies for work done at request of EMA (over € 67.4 million in 2009).

Staff numbers have grown from 67 in 1995, to 210 in 2000 and 567 in 2010.

Budget evolution 1995-2010 (€ million)



A dynamic and constantly changing Agency

- 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)
- 2010: Pharmacovigilance legislation (+ new committee)

Work in progress

- Legal proposal to fight counterfeit medicines
- Legal proposals on information to patients

THANK YOU!

If you want to know more, visit the Agency's website at:

www.ema.europa.eu