EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accession preparation: The legal framework

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Outline

- Legal implication of accession
- Alignment with the *acquis communautaire*
- Transitional period and upgrading of existing marketing authorisations
- Join the European medicines network
- The new EU pharmaceutical package

The accession process

- EU established by an international treaty
- From Rome to Lisbon
- MSs can amend the Treaty only by unanimous vote
- Need to maintain the right balance (Council, EP, etc.)
- Long negotiations preceding accession
- Numerous chapters (35) addressing different policy issues

Legal requirements and implications

- Alignment with the *acquis communautaire*
- Commission announced that last chapters in the accessions talks can be closed
- Croatia expected to sign the accession treaty this fall (followed by referendum)
- All existing 27 Member States will than have to ratify the Treaty before it takes effect
- This paves the way for Croatia to join the EU as of 1st July 2013

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

The European Medicines Network

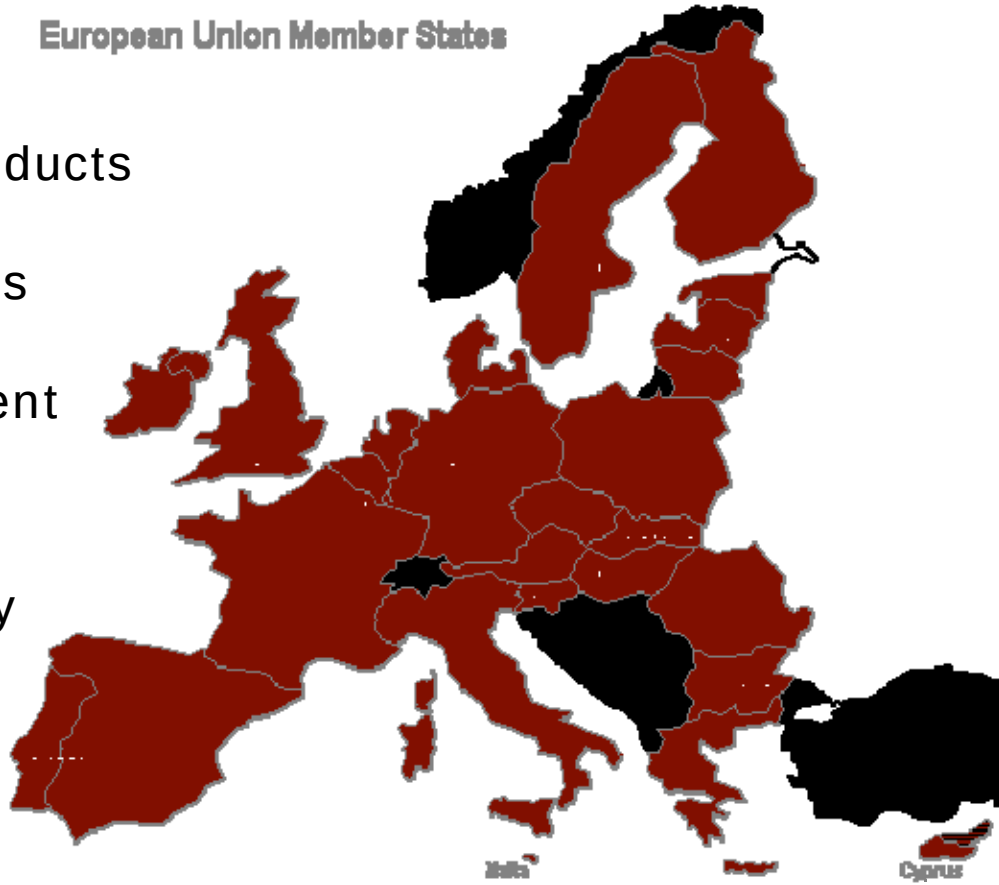
496 million users of medicinal products

30 EU and EEA-EFTA countries

More than 45 national competent authorities

1 European Medicines Agency

CMD(h)- CMD(v) - HMA



A constantly evolving legal environment

- 2000: New legislation on Orphan drugs
- 2001: Codification directives (2001/82 and 83)
- 2004: Regulation (EC) No 726/2004
- 2006: New paediatric legislation
- 2007: New legislation on advanced therapies
- 2008: New legislative package
- 2010: New pharmacovigilance legislation

Upgrading of existing MAs

Croatia has been part of nCADREAC and IPA

It helped to exchange information and prepare for the implementation of European procedures.

There are still some provisions to transpose before actual full membership, and also dossier upgrading, in which the marketing authorisation holder has to harmonise its documentation for products already on the market not previously approved in line with current European legislation.

The centralised procedure

A regulatory assessment process leading to:

- 1 Marketing Authorisation (simultaneously valid in ALL EU MS)
- Identical product information, in all 23 (+1) 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)

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)

A dynamic and constantly changing Agency

Acting Executive Director

New road map 2015

Director designated

Chair of the Management Board

The new EU pharmaceutical package

- Pharmacovigilance: ⇒ Regulation (EU) No 1235/2010 NEW

  ⇒ Directive 2010/84/EU NEW

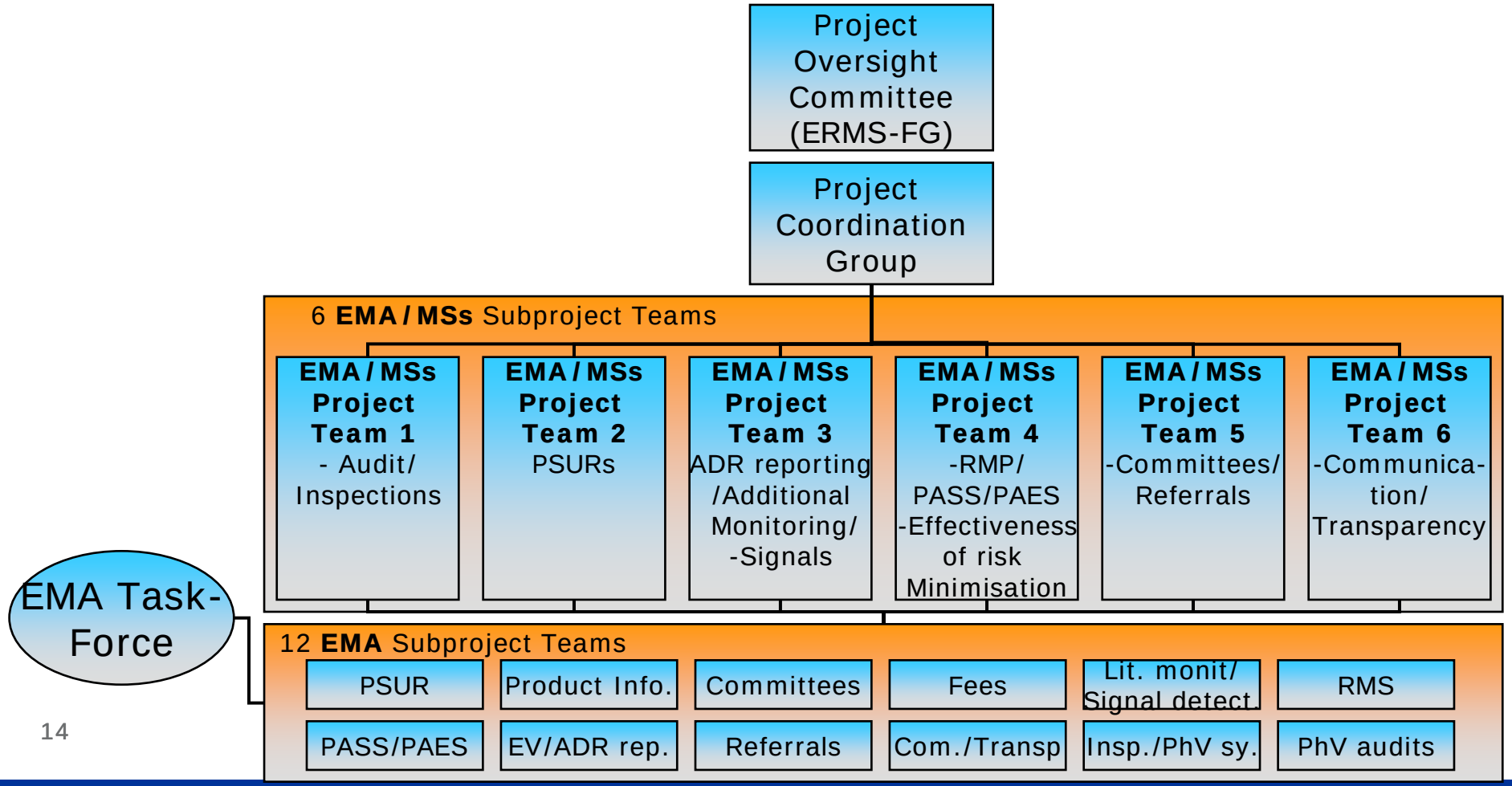
- Falsified medicines: ⇒ Adopted by the Council on 27/5/2011

- Information to patients: ⇒ Modified proposal awaited

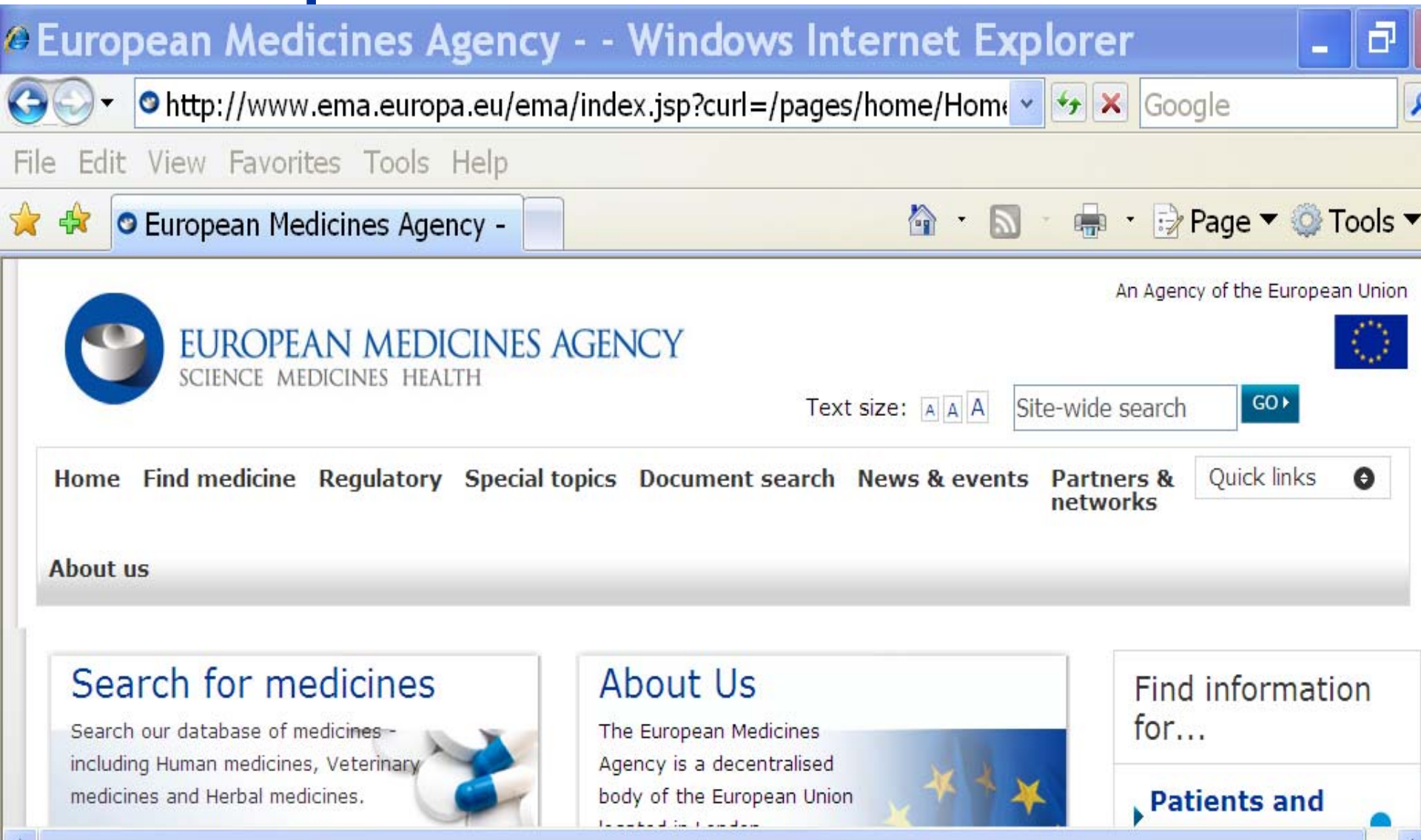
Pharma package objectives

- To better protect patients by strengthening the EU pharmacovigilance system
- To enable citizens to get high-quality information on medicines
- To tackle the growing issues of counterfeiting and illegal distribution of medicine

Implementing the new PhV legislation



To be up-to-date …



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Thank you!

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