European Directorate for the Quality of Medicines (EDQM)

Isabelle Mercier
The Council of Europe

46 member states
Ph.Eur. membership

• 36 member states incl. the EU
  (Poland 21.12.2006)

• 20 observers incl. USA/FDA
  (Blood Products) + WHO
Ph. Eur. Members & Observers

Observers countries non-members of the Council of Europe

- Algeria
- Australia
- Brazil
- Canada
- China
- Israel
- Kazakhstan
- Madagascar
- Malaysia
- Morocco
- Senegal
- Syria
- Tunisia
- USA

Member states
Observer states
Role of the Ph. Eur.

• Harmonised quality standards for use by health professionals
• Mandatory in European MA dossiers in 36 Member States (Ph.Eur.Convention)
• Recognised as the only official Pharmacopoeia in Europe, to be used for international trade
Groups of experts

- Composed of experts from Member States
- Proposed by the national authorities, appointed by Ph.Eur. Commission
- Chaired by a member of the Ph.Eur. Commission
- 3-year term of office, renewable once
Working methods

- Work programme: decided by the Ph.Eur. Commission
- Proposals from: delegations, groups of experts, EDQM secretariat
- Elaboration of monographs allocated to a group of experts or working party
- Final adoption by Ph.Eur. Commission
The European Pharmacopoeia

- 6th Edition (1.01.2008)
- International harmonisation with JP, Ph.Eur., USP
- Functionality-related characteristics in excipient monographs
- Control of impurities in API’s
- Certification scheme
- Electronic communication: Helpdesk