INTERNATIONAL MEETING OF WORLD PHARMAPOPOEIAS
29 February to 2 March 2012
WHO, Geneva, Executive Board Room

Answers from pharmacopoeias
1. Name of pharmacopoeia

REAL FARMACOPEA ESPAÑOLA
(ROYAL SPANISH PHARMACOPOEIA)
2. Pharmacopoeia referred to in national/regional legislations

- **REAL FARMACOPEA ESPAÑOLA (ROYAL SPANISH HARMACOPOEIA),**

- **NATIONAL FORMULARY.** Dependent on AEMPS - Department of Inspection
National/regional legislation includes reference to other EUROPEAN PHARMACOPOEIA
4. Publication of latest edition

11\textsuperscript{TH} NOVEMBER 2010
Only on-line
www.boe.es
5. Update frequency

- Up to now, there has been no established frequency.

- In the near future, it is planned to follow the same frequency as the European Pharmacopoeia.

- Plan:
  RFE 5th edition → January 2014
6. For which products does the pharmacopoeia provide specifications?

- APIs
- Excipients
- Herbal products
- Biological products (immunosera, monoclonal antibodies, products of fermentation, products of recombinant DNA technology, vaccines)
- Radiopharmaceutical preparations
- Materials for containers and containers
- Reagents
- Dosage forms
- Sutures
- Homeopathic preparations
7. Number of texts included in the pharmacopoeia

- Monographs for APIs (chemical and biological) and excipients: more than 3000
- Monographs for finished dosage forms: only immunosera, insulin preparations, vaccines and radiopharmaceutical preparations
- General monographs and methods: about 300
- Reagents: about 2400
- Supplementary texts: General information, legal system, responsibilities, National Pharmacopoeia Commission, index, etc.
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

As member of European Pharmacopoeia, we participate in the Pharmacopoeial Discussion Group, together with USP and JP
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

- ICH harmonised texts

- Excipients, General Methods, General Chapters and Methods for Biotechnology Products

- 61 Excipients, 12 General Methods, 20 General Chapters and 6 Methods for Biotechnology Products (included those under on-going harmonization)
10. Interaction with stakeholders, including regulators

- Published by the Spanish Health Ministry through the Spanish Agency of Medicines and Medical Devices (AEMPS)

- AEMPS in charge of marketing authorization of medicines by means of their evaluation and control (regulation, inspection, pharmacovigilance)

- Private, community and hospital pharmacies, pharmaceutical services, distribution of medicines entities and pharmaceutical laboratories must grant that they have an access to the in-force edition of the Royal Spanish Pharmacopoeia.
11. Strategy for the future

-- Follow the timetable of publication of the in-force European Pharmacopoeia successive editions (simultaneous translation)

-- Work with the internal Spanish groups that support the work of Experts and Specialists in European and international Groups

-- Continue our efforts to cooperate with the work of European Pharmacopoeia and international groups (Groups of Experts, Working Parties)