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

CROATIAN PHARMACOPOEIA
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- Croatian Pharmacopoeia implements European Pharmacopoeia on the Croatian territory
- According to our law Croatian Pharmacopoeia was published in the Official Gazette No. 33/07
- Croatian Pharmacopoeia with Comments as a book:
Pharmacopoeia referred to in national/regional legislations

- Medicinal Products Act (Official Gazette No 71/07), Act on Amendments to the Medicinal Products Act (Official Gazette No 45/09), Act on Amendments to the Medicinal Products Act (Official Gazette No 124/11)

- Ordinance on the Procedure and Method for Granting Marketing Authorisation for Medicinal Products (Official Gazette No 113/08)

- Ordinance on Special Conditions for Placing Medicinal Products Authorized in the Member States of the European Union on the Market of Republic of Croatia (Official Gazette No 10/08)

- Ordinance on the quality control of medicinal products (Official Gazette No 56/05)
National/regional legislation includes reference to

- national pharmacopoeia(s)

  *Croatian Pharmacopoeia*

- international pharmacopoeia(s)

  *European Pharmacopoeia, Supplements*
Publication of latest edition

- CROATIAN PHARMACOPOEIA WITH COMMENTS 2007
Update frequency

- Translation of the European Pharmacopoeia does not follow the frequency of publication of European Pharmacopoeia and its Supplements
Content od Croatian Pharmacopoeia 2007

- Section A: Introductory provisions
- Section B: Quality norms
- Section C: Links to the European Pharmacopoeia
- Section D: Standard terms
- Section E: Information chapter
For which products does the pharmacopoeia provide specifications?

European Pharmacopoeia Monographs are all summarized in the Croatian Pharmacopoeia 2007, their titles included:

- **APIs and excipients**
- **Dosage forms,**
- **Herbal drug preparations,**
- **Biologics (Blood and plasma derived substances, Vaccines for human and veterinary use, Antitoxins)**
- **Radiopharmaceutical preparations**
- **Homeopathic preparations**
- **Bandage and surgical materials**
Number of texts included in the pharmacopoeia

- 2,000 monographs in 10 groups

- List of monographs with necessary data (name of API on croatian, latin, english, and french language, ID number in Ph. Eur.)

  + formula (API, excipients, radiopharmaceuticals)

  + description text (herbal preparations, dosage forms)
Number of texts included in the pharmacopoeia

- **monographs for APIs**: all monographs included in European Pharmacopoeia 5 as reference + 47 complete translated monographs (API, excipients, herbals) based on texts of European Pharmacopoeia monographs

- **monographs for finished dosage forms/ general monographs**: all monographs included in European Pharmacopoeia 5 + 8 complete translated Dosage forms + 3 General monographs

- supplementary texts: **Comments** (Section E. Information chapter) such as Reference substances, Validation of analytical procedures, Statistical analysis
Collaboration with and/or being part of a (different) national/regional pharmacopoeia
Interaction with stakeholders, including regulators

- between Pharmacopoeia and Regulatory affairs within Agency
- with industry (domestic industry)
- occasionally with pharmacies
Strategy for the future

Preparation and publication of new edition of Croatian Pharmacopoeia