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

Answers from pharmacopoeias
1. Name of Pharmacopoeia

Indonesian Pharmacopoeia

- The Indonesian Pharmacopoeia is the official Pharmacopoeia in Indonesia
- Legally binding and mandatory for drugs approved and marketed in Indonesia
- First published in the year of 1962
2. Pharmacopoeia referred to in national/regional legislations

Legal Basis of Indonesian Pharmacopoeia based on:

Act of The Republic of Indonesia Number 36 Year 2009 on Health (Revised of Act of The Republic of Indonesia Number 23 Year 1992)

Article 105

Pharmaceutical dosage form as drug and drug substance have to comply Indonesian Pharmacopoeia or other relevant standards
3. National/regional legislation includes reference to other

- **national pharmacopoeia(s)**: Indonesian Pharmacopoeia
  
  Indonesia has only one pharmacopoeia which is applied in all over the country.

- **regional pharmacopoeia(s)**: not applicable

- **international pharmacopoeia(s)**
  
  Based on our legal basis, we can also refer to other relevant standards such as International Pharmacopoeia, USP, etc as needed.
The latest publication is the third supplement for the fourth edition of the Indonesian Pharmacopoeia. We are in the process of developing the fifth edition and expected to be finished by end of 2012.
5. Update frequency

- Annually by development of supplement and
- Every five years for new edition
6. For which products does the pharmacopoeia provide specifications?

- monograph for active pharmaceutical ingredients,
- monograph for dosage forms,
- monograph for medical devices,
- monograph for biologicals,
- monograph for excipients,
- monograph for radiopharmaceuticals
7. Number of texts included in the pharmacopoeia (4th edition)

- Monographs for Active Pharmaceutical Ingredients: 560
- Monographs for finished dosage forms: 653
- Monographs for biologicals: 29
- Monographs for medical devices: 12
- Monographs for radiopharmaceuticals: 19
- General monographs: 23
- Supplementary texts: general requirement (1)
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

- Indonesia has no collaboration with any other pharmacopoeia, however we have collaboration with ASEAN Countries in developing ASEAN Reference Standard
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

We have no harmonized pharmacopoeia text within the pharmacopoeia but we actively involve in some international activities such as with:

- International Pharmacopoeia
- United States Pharmacopoeia
- Japan Pharmacopoeia
- China Pharmacopoeia
- European Pharmacopoeia
10. Interaction with stakeholders, including regulators

1. Within NADFC, NQCLDF and regional offices
2. Other Government body i.e. Ministry of Health, The National Nuclear Energy Agency of Indonesia
3. Pharmaceutical Industries : as experts
4. University’s Laboratories i.e. Researchers, Students
5. Independent Laboratory
6. School of Pharmacy
11. Strategy for the future

Plan to publish the new edition of Indonesian Pharmacopoeia every five years

Plan to publish the supplement annually for existing pharmacopoeia

Plan to publish the pharmacopoeia in English version
Thank you