INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS
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Answers from pharmacopoeias

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1. Name: Czech Pharmacopoeia

- Responsibility for the accuracy of pharmacopoeia texts lies with the **Pharmacopoeia Commission** of the Ministry of Health of the Czech Republic.

- The operation of the Pharmacopoeia Commission of the Ministry of Health of the Czech Republic and its expert sections is organised by the Technical Secretariat of the Pharmacopoeia Commission (Department of Pharmacopoeia, State Institute for Drug Control).
The Czech Pharmacopoeia is drafted by the Czech Pharmacopoeia commission working on the base of the Groups of experts (17 groups and 4 working parties).

Groups of experts (Antibiotics, Biochemistry, Inorganic chemistry, Pharmacology and toxicology, Doses of active substances, Physicochemical methods, Gene and cell therapy, Homeopathy, Immunobiology, Blood and blood substances, Pharmaceutical service, Microbiology, Organic chemistry, Radiopharmaceuticals, Technology of dosage forms, Terminology, Standard terms, Veterinary immunopreparations and medicaments, Medical supplies and packing techniques, …).
2. Pharmacopoeia referred to in national legislations

**YES → in the Act No 378/2007**
(Act on Pharmaceuticals)

- “Czech Pharmacopoeia … helps to ensure safe, effective, and quality of pharmaceuticals. …“

- “… an operator shall be obliged: when handling pharmaceuticals, to adhere to procedures and comply with the requirements of the European Pharmacopoeia and the Czech Pharmacopoeia, …“
Act on Pharmaceuticals

„ Ministry of Health

… publishes the Czech Pharmacopoeia which establishes the procedures and requirements for:

- the manufacture of active substances and excipients,
- the manufacture and preparation of medicinal products,
- testing and storage of active substances, excipients and medicinal products …“
3. National/regional legislation includes reference to other

- national pharmacopoeia(s) → No
- regional pharmacopoeia(s) → No
- international pharmacopoeia(s) → Yes

**European Pharmacopoeia**

Information about implementation of the European texts are regularly published on the websites of the Ministry of Health (http://www.mzcr.cz) and of the State Institute for Drug Control (http://www.sukl.cz).
European Pharmacopoeia in the Czech legislation

Ministry of Health and State Institute for Drug Control

• „… take part in the preparation of the European Pharmacopoeia …“ (arrange for the translations, revisions and expert assessment of Ph.Eur. monographs) …

• … is responsible for the implementation of its issues and publishing in the Czech Republic …“

Translations of these texts are published as the European Part of the Czech Pharmacopoeia.
4. Publication of latest edition

Czech Pharmacopoeia 2009
- Supplement 2011
(PharmacoPOea BOHEmica MMIX
- Addendum MMXI)

valid from 1. 9. 2011
Czech Pharmacopoeia has two parts:

- European part (always includes translations of all current Ph. Eur. texts of the present period of the year).

- National part (includes texts which are necessary for the Czech producers and pharmacies).

5. Update frequency

Annually as Supplements

(a new edition of the Czech Pharmacopoeia is published depending on the number of changes in the texts of both parts).

- Edition 1997 + 3 supplements
- Edition 2002 + 2 supplements
- Edition 2005 + 2 supplements
- Edition 2009 + 3 supplements

(Supplement 2012 is prepared for printing, implementation on 1.9. 2012)
6. For which products does the pharmacopoeia provide specifications?

- **APIs and excipients** - “… for the preparation of medicinal products, only active substances and excipients listed in the Czech Pharmacopoeia may be used (or if they are placed on the list established by the implementing legal regulation or the use of which has been authorised by the Ministry of Health)…“

- **pharmaceutical preparations** „ …products must be prepared in accordance with Czech Pharmacopoeia or a medical prescription for an individual patient …“

- **herbal products** (together with APIs and excipients)
Czech Pharmacopoeia tendency

- decreasing tendency of APIs monographs (replaced with Ph. Eur. monographs) (red columns)

- increasing tendency of monographs for pharmaceutical preparations (blue columns)
7. Number of texts included in the pharmacopoeia

- monographs for APIs and excipients: 36
- monographs for finished dosage forms: 118
- monographs for biologicals: 0
- general monographs: 2 (to be substituted by Ph. Eur. Monographs)
- supplementary texts: 17 (Reagents and References substance used in national monographs; Tables: List of narcotics and psychotropic substances, Venena, Separanda; Recommended therapeutic and maximal doses for adults, for children and for some substances administred to animals; Alcoholimetric tables, Isotonisation of aquaeous solutions of active substances prepared in pharmacies, Molar concentration of actives substances, … , Translation of standard terms of pharmaceutical dosage forms, …)
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

*Traditional collaboration with the Slovak Republic, resulting from our common history:*

- The **Czechoslovak Pharmacopoeia 1st Edition** (this pharmacopoeia was prepared before World War II in 1937 but was published as late as 1947 due to Nazi occupation) with one Supplement published in 1953.

- The **2nd Edition** was published in 1954 with a Supplement issued in 1959.


- The **4th Edition** was published in 1987 as the last authentic and teamwork pharmacopoeia for the Czechoslovak Republic.
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

Convention on the Elaboration of the European Pharmacopoeia was signed by the Czech Republic on 20. June 1998.

The following editions of the Czech Pharmacopeia contain translation of all European Pharmacopoeia monographs into Czech language as a European Part of the Czech Pharmacopoeia

(all texts begining Ph. Eur. 3rd Ed. to Ph. Eur. 7th Ed.).
10. Interaction with stakeholders, including regulators

The Department of Pharmacopoeia of the State Institute for Drug Control cooperates on draftings, revisions and expert assessments of national monographs and on the preparation and distribution of national chemical reference substances with:

- manufacturers and small-scale producers, pharmacists (mainly from hospital pharmacies), universities, analysts, doctors and veterinary surgeons and other pharmacopoeia users

- everybody has a possibility to participate in our pharmacopoeia (everything must be controled and validated by our laboratories)
11. Strategy for the future

Czech pharmacopoeia has several main tasks:

- **Completion of national formularies** (mainly in the field of pediatrics, cooperation with a Chambre of Pediatricians).

- **Assessment of stabilities** in the pharmacopoeia formularies for small scale products and products prepared in pharmacies (establishment of a new group of experts from hospital pharmacies and certified laboratories).