State Pharmacopoeia of Ukraine

WHO INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS
29.02 – 2.03 2012
Geneva, Executive Board Room

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1. State Pharmacopoeia of Ukraine (SPU)

SPU is being developed by the Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines; established by the order of the Ministry of Healthcare March 19, 1992. Pharmacopoeial Center is a public self-financing enterprise in the structure of the State Service of Ukraine on Medicinal Products (SSUMP), that endorsed the SPU.

**Principal tasks:**

- elaboration and distribution of the SPU;
- establishment and distribution of Pharmacopoeial Reference Standards;
- implementation of the Professional Testing Scheme for medicine control laboratories;
- quality control of medicines;
- related scientific issues.

The Pharmacopoeial Center is the largest scientific center for standardization and quality control of medicines in Ukraine.
Status of SPU in Ukraine is defined by the law “About medicinal products”; Article 2 “Definition of the terms” thereof states:

“The State Pharmacopoeia of Ukraine (SPU) is a legal act that contains general requirements for medicinal products, pharmacopoeial chapters as well as medicine quality control procedures”.
3. National/regional legislation includes reference to other

Status of other Pharmacopoeias in Ukraine is not defined by *law/de jure*. When registering medicines in Ukraine, in case when related monographs are missing in the SPU, an application of standards of the *European Pharmacopoeia* is permitted *firstly*, and those of other pharmacopoeias *secondarily* (the BP, USP, JP). Available other Pharmacopoeias are used as textbooks/reference manuals.
4. Publication of latest edition

The SPU is being developed in conformity with the Decree of the President of Ukraine within the
*Strategy of Integration of Ukraine into the European Community*

- **2001** – First edition
- **2004** – Supplement 1
- **2008** – Supplement 2
- **2009** – Supplement 3
- **2011** – Supplement 4

- The SPU is published in Ukrainian and Russian languages.
5. Update frequency

- It was planned to update SPU biannually but update frequency depends on availability of finances

- Last 2 Supplements were published biannually

- Now we are preparing the Second edition of the SPU. Planned date of publication 2013
6. For which products does the pharmacopoeia provide specifications?

**APIs and excipients** - widely used as ingredients, raw materials for drugs largely represented on the local pharmaceutical market - 326

**Dosage forms** from national and WHO List of vital drugs – 74

**Herbal products** - traditionally used by local manufacturers - 104

**Biologicals** (immunoseras, insulins, interferons, etc) - 24

**Monovaccines** – included in the National scheme of vaccination – 26

**Traditional preparations**, prepared ex temporo - 5
7. Number of texts included in the pharmacopoeia

- **Methods of Analysis (physical, phisicochemical, biological, pharmaceutical technical procedures)** - 211
- **Reagents** – more then 2500
- **Materials for Containers and Containers** – 24
- **General texts** – 37
- **General monographs** - 16
- **General monographs on dosage forms** - 26
- **Homeopathy** - 4
8.1. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

According to the national concept of integration into the European Community the SPU is harmonized with the European Pharmacopoeia (Eur.Ph.)

Since 1998 the Ukrainian Pharmacopoeial Center is an observer in the Eur. Ph. and received from it an approval to use the Eur. Ph. monographs for SPU development.
8.2. Collaboration with the USP

- Since 2010 the Pharmacopoeial Center has got status of the voting delegate in the USP.

- Grant of Rights to Copy and Adapt the USP-NF (the Adopt/Adapt Agreement) between the administration of USP and the Pharmacopoeial Center (signed on June 2, 2010) – permits usage of the monographs of USP-NF for elaboration of national monographs for finished dosage forms.

- Memorandum (signed on October 27, 2011) between the USP and the State Service of Ukraine on Medicinal Products

- Visiting scientist program
8.3. Collaboration with the State Pharmacopoeia of the Republic of Kazakhstan (SPRK)

- A number of the Ukrainian Pharmacopoeial Center (UPhC) staff are members of the Editorial Board of the SPRK.

- The UPhC participated in elaboration of a considerable part of general and specific monographs of the SPRK.
9.1. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

SPU monographs are composed of two parts — a European part (translation of the corresponding monograph of the Eur.Ph.) and a national one.

**National part**

- The national part of the monograph does not contradict with the European one, reflects national specificity of Ukraine, contains additional requirements, informative materials, alternative methods and recommendations.

- The requirements of the national part are not mandatory for those manufacturers that work under GMP recognized in the European Community.

In addition, there are a number of purely national monographs in the SPU which reflect progress of the national science and experience in medicine standardization.
Pursuant to the "Grant of Rights to Copy and Adapt the USP-NF" contract in the Supplement 4 are included 7 harmonized monographs for finished dosage forms and now for the SPU 2-nd Edition have been already elaborated 11 draft monographs. For another 19 monographs – only some specific tests from corresponding monograph of USP-NF are included. It reflects the specificity of the Ukrainian pharmaceutical market.

Draft monographs are available on our website: www.sphu.org
10. Interaction with stakeholders, including regulators

Requirements of the SPU are mandatory for all enterprises and institutions of Ukraine, irrespective of their ownership, manufacturing, storing, controlling and using drugs.

- The SPU is endorsed by the State Service of Ukraine on Medicinal Products (SSUMP), and approved by the Minister of Healthcare.

- Elaboration of registration dossiers (Domestic manufacturers - about 150) – compliance with the SPU.

- Expert evaluation of registration dossiers, recommendation for registration (State Expert Center of the Ministry of Healthcare) – compliance with the SPU.

- Registration (marketing authorization) – Minister of Healthcare.

- State quality control, certification and licensing of medicines, pharmacies and manufacturers (SSUMP) – on the base of the SPU.

Process of the SPU elaboration is based on the effective collaboration and permanent feedbacks with key national scientific organizations, manufacturers and competent regulators.
11. Strategy for the future of the SPU

Principle task – transformation of the Ukraine status from the observer of the European Pharmacopoeia Commission to a membership.

Within this task our actual perspectives

- Development and publication of the 2nd Edition of the SPU.
- Further development of the National System of SPU Reference Standards.
- Strengthening of feedback with users through further development of the National Professional Testing Scheme (PTS).
11.1. Development of the 2\textsuperscript{nd} Edition SPU

- Revision of the monographs in the 2-nd edition (2012-2013) on the base of further harmonization with Eur.Ph. and USP (formulated preparations).

- Development of the national concept of standardization of compounded/unlicensed and homeopathic preparations.
11.2. Further development of the National System of SPU Reference Standards

- Further enlargement of the List of SPU Reference Standards. Now the list of SPU RS is about 450 items, including about 50 impurities and approximately 50 herbal RS.
- Further implementation of procedures of certification of working RS for national manufacturers
- Further harmonization of the SPU RS with RS of the Eur.Ph, USP, WHO and other pharmacopoeias

According to the SPU conception, user may apply - at his choice – RS of the Eur.Ph or those of the SPU. For formulated preparation monographs harmonized with the USP user may apply RS of the USP or those of the SPU.
11.3. Professional Testing Scheme – feedback with SPU users

- Ukrainian Pharmacopoeial Center is an organizer of the National Professional Testing Schemes (PTS) and consider them as an effective feedback with SPU users.

- PTS give opportunities to determine actual metrological characteristics of different pharmacopoeial analytical methods in Ukraine.

- PTS give occasion to make changes and recommendations in the SPU, that are confirmed by large-scale interlaboratory experiments.

- Till now 8 PTS rounds were already held with about 60 participants in every round. Now the 9th round is holding.
Pharmacopoeias global future vision

Vital necessity for more tight collaboration of all pharmacopoeias

- Acceleration of the procedures of international harmonization between world leading pharmacopoeias.
- Elaboration of the mechanisms of interchangeability and accessibility of pharmacopeial texts for regional pharmacopoeias and regulatory authorities.

Support of the world leading pharmacopoeias to implement harmonized standards in the developing countries to facilitate the free movement of high quality medicines.

Development of international bank of harmonized texts for substances and finished dosage forms of most common and vital medicines. (initiative of 1-st Global summit)

Development of pharmacopoeial educational programs and expansion of possibilities for visiting scientist programs.
THANK YOU FOR YOUR KIND ATTENTION!