FIFTY-THIRD MEETING OF THE EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS
Salle B, WHO Geneva, 22 to 26 October 2018

Draft Agenda

Monday, 22 October 2018 (am)

Private session (invited participants, international organizations and state actors)

OPENING

Election of chairpersons and rapporteurs

1. General policy

   – Process for development of World Health Organization (WHO) norms and standards.
   – Participation in Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meetings.

Open session (invited participants, international organizations, state actors and non-state actors) (and Geneva missions if they express an interest in participating).
Introduction and welcome

2. General updates and matters for information

- Cross-cutting pharmaceuticals quality assurance issues (including local manufacturing, Member State mechanisms (MSM), Expert Committee on Biological Standardization (ECBS), Expert Committee – The Selection and Use of Essential Medicines List (EC-EML), antimicrobial resistance (AMR), and the International Conference of Drug Regulatory Authorities (ICDRA)).
- International collaboration.

3. Quality assurance – collaboration initiatives

- International meetings of world pharmacopoeias.
- Inspection guidelines and good practices, including revision of good manufacturing practices (GMP) for sterile products by the European Union (EU), the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and WHO.

4. Nomenclature, terminology and databases

- International Nonproprietary Names for pharmaceutical substances.
- Quality assurance terminology.
- Guidelines and guidance texts adopted by the Expert Committee.

5. Prequalification of priority essential medicines and active pharmaceutical ingredients

- Update on the prequalification of medicines.
- Update on the prequalification of active pharmaceutical ingredients (API).
6. **Quality control – prequalification and WHO monitoring projects**

   - Update on the prequalification of quality control laboratories.
   - Update on WHO quality monitoring projects.

7. **Quality control – national laboratories**

   - External Quality Assurance Assessment Scheme.
   - Update and recommendations from laboratory specialists’ meeting.

**Monday, 22 October 2018 (pm)**

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8. **Quality control – specifications and tests**

   - *The International Pharmacopoeia.*
   - General policy.

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9. **Quality control – specifications and tests (continued)**

   - General chapters.
   - General monographs for dosage forms and associated method texts.
   - Specifications and draft monographs for medicines, including pediatrics and radiopharmaceuticals.

   - General policy.

11. **General policy – chemistry**

   - Revision of guidance on representation of graphic formulae.

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**Wednesday, 24 October 2018**

12. **Quality assurance –GMP and inspection**

   - Guidelines on GMP for heating, ventilation and air-conditioning systems (HVAC)
     - illustrative part.
   - Guidance on GMP for validation:
     - General main text
     - Validation of HVAC systems
     - Validation of water systems for pharmaceutical use
     - Cleaning validation
     - Analytical method validation
     - Validation of computerized systems
     - Qualification of systems, equipment and utilities
     - Non-sterile process validation
– Update on review of existing WHO inspection guidance, including *Inspection of drug distribution channels* and *Quality system requirements for national GMP inspectorates*.

– Update and recommendations from inspectors’ meeting, including on GMP and environmental issues.

13. **Quality assurance – distribution and supply chain**

– Guidelines on import procedures for pharmaceutical products.

– Update on review of existing WHO guidance, procedures and operational documents for pharmaceutical procurement

**Thursday, 25 October 2018 (am)**

14. **Regulatory guidance and model schemes**

– WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

– Good practice guidance document on implementing the collaborative procedures.

– Guidance document to support and facilitate the implementation of quality management systems for national regulatory authorities.

– Good regulatory practices.

– Proposal to waive *in vivo* bioequivalence requirements for medicines included in the WHO List of Essential Medicines.

– Recommendations from the meeting on regulatory guidance for multisource products.
15. Miscellaneous

**Thursday, 25 October 2018 (pm)**

*Private session for chairs and rapporteurs*

Report writing

**Friday, 26 October 2018**

*Closed session for Expert Committee members*

Adoption of report