54th MEETING OF THE EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Salle D, WHO headquarters, Geneva, Switzerland
14 to 18 October 2019

Draft Agenda

Monday, 14 October 2019 (a.m.)

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

**OPENING**

Election of chairpersons and rapporteurs

1. **General policy**

   - Participation in Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meetings.

   - Process for development of the World Health Organization (WHO) norms and standards.

**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:
     
     o Local manufacturing;
     o Member State mechanism (MSM);
     o Expert Committee on Biological Standardization (ECBS);
     o Expert Committee – The Selection and Use of Essential Medicines List (EC-EML);
     o Antimicrobial resistance (AMR);
     o Regulatory Authorities Strengthening; and
     o International Conference of Drug Regulatory Authorities (ICDRA).

   – International collaboration
     
     o The Global Fund to Fight AIDS, Tuberculosis and Malaria (to be confirmed);
     o International Atomic Energy Agency (IAEA) (to be confirmed);
     o Pharmacopoeia Discussion Group (PDG); and
     o United Nations Children’s Fund (UNICEF) (to be confirmed).

3. Quality assurance – collaboration initiatives

   – International meetings of world pharmacopoeias.

4. Nomenclature, terminology and databases

   – International Nonproprietary Names for pharmaceutical substances.
Draft agenda: Friday, 14 June 2019

4. 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 (EQAAS).

Monday, 14 October 2019 (p.m.)

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

8. Quality control – specifications and tests

- The International Pharmacopoeia.
- Procedure for the development of monographs and other texts for inclusion in The International Pharmacopoeia.
− Workplan.
− General policy.

**Tuesday, 15 October 2019**

8. **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.

− Update and recommendations from the consultation on screening technologies, laboratory tools and pharmacopoeial specifications.


− Update on International Chemical Reference Substances, including:

  o Report of the custodian centre.

− General policy.
10. General policy – chemistry

- Revision of guidance on representation of graphic formulae.

Wednesday, 16 October 2019

11. Quality assurance – GMP and inspection

- Inspection guidelines and good practices with partner organizations, including revision of good manufacturing practices (GMP) for sterile product and GMP for radiopharmaceuticals.

- Update on the Cleaning Validation.

- Update on Water for Injection.

- Guidance on Good Data and Record Management Practices.

- Update on the development of Good Chromatography Practices.

- Quality system requirements for national GMP inspectorates.

- Environmental aspects for the prevention of AMR in relation to manufacturing and inspection

- Update and recommendations from the meeting on good practices for health products and inspection.
12. **Quality assurance – distribution and supply chain**

   - Update of the Good Distribution Practices (GDP) guideline (including aspects of inspection of drug distribution channel and Good Storage Practices (GSP)).

   - Guidance on shelf life for supply and procurement of medicines.

   - Update and new WHO guidance, procedures and operational documents for pharmaceutical procurement, including collaborative projects with the United Nations Population Fund (UNFPA) on prequalification of condoms

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**Thursday, 17 October 2019 (a.m.)**

13. **Regulatory guidance and model schemes**

   - Proposal to waive in vivo bioequivalence requirements for medicines included in the WHO List of Essential Medicines (EML).

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

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

   - Good regulatory practices.

   - Update on new regulatory concepts and tools.

   - Recommendations from the meeting on regulatory guidance for multisource products.
13.  Miscellaneous

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