



WORLD HEALTH ORGANIZATION

**WHO Technical Working Group Meeting to Discuss the Revision of
WHO Recommendations for IPV, WHO TRS 910, Annex 2**

14- 15 May 2013, WHO/HQ

Provisional Agenda

(Version 23 Jan 2013)

Day 1, Tuesday, 14 May 2013

08:30	<i>Registration (Badge Office, Main Building)</i>	Participants
09:00	Opening remarks	D Wood
09:10	Self-introduction	Participants
	Assessment of declaration of interests	WHO

Session 1 Background and Objectives

09:20	Update on WHO Biological Standardization	I Knezevic
09:40	Background, Objectives and Expected Outcomes of the meeting <i>(Housekeeping information)</i>	TQ Zhou

10:00 - 10:30 *Coffee Break*

**Session 2 Review of up-to-date experience in development, production, quality
control and evaluation (non-clinical and clinical) of IPV/sIPV, and discuss perspectives on
international technical specifications for the vaccines**

Global research and development of IPV, challenges and future strategies
R Sutter/ H Okayasu (40 min)

Update on WHO global action plan for laboratory containment of polioviruses (GAP III)
C Wolff (15 min)

Discussion (15 min)



Experience in the development, quality control, non-clinical and clinical evaluation of sIPV and perspectives on international technical specifications

W. A.M. Bakker (30 min)

Discussion

12:30 - 13:30 **LUNCH**

13:30 **Session 2. Cont'd**
(15min for each presentation below)

Experience in the development, production, QC, non-clinical and clinical evaluation of sIPV and perspective on international technical specifications

- Chinese manufacturer
- Japanese manufacturer
- Representative of WHO sIPV technology transfer project partners

Regulatory considerations in the evaluation and licensure of sIPV

- Chinese NRA
- Japanese NRA

Discussion (10 min)

Critical issues identified from experience in the production of wIPV and new development of wIPV that need to be addressed in the revision of WHO TRS 910 (A2)

- Involved manufacturers

Discussion (10 min)

15:40 - 16:00 **Coffee Break**

Regulatory issues and pathways for Intra Dermal (ID) IPV and new Intra Muscular (IM) products (adjuvanted IM IPV) Pieter Neels (15 min)



Regulatory challenges for fractional and adjuvanted IPV

K Mahmood/PATH (15 min)

Discussion (15 min)

Virus strains used for current IPV production

- Information from a WHO survey

K Chumakov (10 min)

Critical issues identified in the quality control and regulatory considerations of IPV/sIPV and need for international standardization

J Martin (20 min)

Discussion

17:30

Conclusion of discussions

Chair/Rapporteur

Closure of meeting

Day 2, Wednesday, 15 May 2013

Session 3. Review of proposed revision outline of TRS 910, Annex 2 (IPV)

The aim is to review and discuss the proposed “pre-draft 1”, taking into consideration issues discussed on Day 1, propose further major issues need to be addressed in the revision, and reach consensus.

9:00

Presentation: Proposed outline of the revision of WHO TRS 910, Annex 2 (IPV)

- *Outcomes of past consultation (March 2012 meeting)*

- *Summary of feedback to WHO survey on IPV*

M Lennon

Drafting group to lead the review by highlighting major issues being addressed in the draft revision and any issues for consultation at this meeting

- General considerations (led by M Lennon)
- Part A. Production and QC (led by J Martin)

10:30 - 11:00

Coffee Break



- Part A. Production and QC (Cont'd)

12:30 - 13:30 **LUNCH**

- Part B. Nonclinical evaluation (led by T Wu)
- Part C. Clinical evaluation (led by T Wu)

15:30 - 16:00 **Coffee Break**

- Part D, and appendix (led by M Lennon)

Any other issues for discussion

Conclusions of the review and discussions

Chair /Rapporteur

The way forward in the TRS revision
-Actions and timeline

TQ Zhou

Session 4. Closed session: recommendations to WHO (to be attended by NRAs/NCLs)

Advice to WHO regarding proposed revised recommendations for IPV

17:30 **Closure of meeting**