Council for International Organizations of Medical Sciences

Second meeting of the CIOMS Working Group (WG) XVII on Long-term safety of medicinal products

23 February 2026, virtual meeting

Minutes

Summary

The CIOMS Working Group (WG) XVII on the Long-term Safety of Medicinal Products held its second meeting virtually on 23 February 2026. The purpose of the meeting was to review the progress made since the previous meeting and to hear updates from the subgroups responsible for drafting different sections of the report. The main focus was on updates from Subgroups 1 and 2, discussion of drafting progress, identification of potential overlaps between sections, and planning of the next drafting steps ahead of the next WG meeting.

Minutes of discussion

Day 1

Opening and welcome

- Lembit Rägo, CIOMS Secretary General, welcomed the participants to the meeting.
- Lembit noted that several CIOMS Working Group reports had been published during the year 2025:
    - WG report on Severe Cutaneous Adverse Reactions – SCAR;
    - WG XII report on Benefit-risk balance for medicinal products
    - WG XIV on Artificial Intelligence in Pharmacovigilance was published in December 2025.
- There are several ongoing CIOMS WGs (more information at https://cioms.ch/).
- The agenda was adopted.
- Kateriina was rapporteur.

Subgroup 1 progress update

- Subgroup 1 had been actively working on its assigned chapters. The subgroup has adopted an approach whereby relevant content is collected and drafted first**,** without focusing at this stage on final wording or structure. It was noted that refinement and consolidation will be undertaken at a later stage once all relevant material has been assembled.
- It was highlighted that, during drafting, the subgroup had identified a potential overlap between Chapter 8 and material being developed by Subgroup 2**.** This overlap relates to conceptual areas that may be addressed in more than one section of the report. Participants agreed that identifying overlaps at an early stage is beneficial.
- It was agreed that early sharing of draft material between subgroups would support alignment and reduce the need for later restructuring.

Subgroup 2 progress update

- Subgroup 2 has organised its work through internal meetings and collaborative drafting.
- A shared repository of working documents has been established, where individual chapters are drafted separately. This approach was considered more manageable than working within a single large document.
- The subgroup had already held internal meetings and planned to continue meeting regularly. These meetings are used to coordinate responsibilities, review draft content and discuss conceptual issues.
- Jean-Marie reported that he had been in contact with Sheetal to ensure coordination between Subgroup 1 and Subgroup 2.

- Both subgroups agreed on the importance of aligning timelines, sharing draft sections and avoiding duplication across chapters.
- Subgroup 2 aims to make substantial progress in drafting ahead of the Geneva in-person meeting, where the WG will review the draft report in more detail.

Discussion on draft content

- Referring to a detailed draft addressing carcinogenicity and teratogenicity, it was noted that the document currently contains extensive material. It was suggested that all relevant content should be retained at this stage, with refinement and possible reduction to follow at a later stage. Participants expressed general agreement with this approach.
- The WG agreed that once Subgroup 1 circulates its draft, Subgroup 2 could similarly share its draft sections with the full WG. This would allow earlier identification of overlaps, improved coordination between subgroups and more efficient review by WG members.
- Subgroups are using a shared online document system**,** which facilitates collaboration within the subgroup, but not all participants have access to the same platforms due to institutional IT restrictions. Maintaining separate working documents for each chapter was therefore considered a practical interim solution.
- It was agreed that subgroup leads should continue to communicate regularly and review related sections as drafting progresses.
- Ian Douglas agreed to review the Questions and Answers (Q&A) document, with particular attention to Clinical Trials Regulation (CTR) and Reference Safety Information (RSI) aspects, and to provide comments.
- Lembit will explore the possibility of inviting a participant with expertise in ethics to contribute to the WG's work.

Next steps / next meeting

- Subgroups will continue drafting their assigned chapters, and draft sections will be shared with the full WG, while subgroup leads will coordinate to ensure alignment between sections.
- The CIOMS Secretariat will support consolidation of draft material.
- Members were encouraged to review draft sections and provide comments in advance of the next meeting.
- The next virtual meeting will be held on 1 June and the next in-person meeting will take place in Geneva, 29-30 June, where the WG will review the draft report in detail.

Closing remarks

- Lembit thanked the WG participants for their active engagement and contributions and emphasized the importance of continued collaboration and timely feedback as the drafting process moves forward.

Subgoup 1 lead and members (listed in no particular order):
Sheetal (lead), Nadiya, Hussein, Yukiko, Khedidja, Nokuthula, Mahlodi, Mariette, Qun-Yin, Claudia, Esther, Pilar, Andrea, Wang.

Subgroup 2 lead and members (listed in no particular order):
Jean-Marie (lead), Leila, Andrea, Martin, Agnieszka, Christina, Leigh, Susan, Claire, Marie, Monica, Ian, Dirk, Ravi, Dimple

Annex 1: List of participants

Attending

Samvel Azatyan (CIOMS), Mariette Boerstoel-Streefland (Bristol Myers Squibb), Marie-Pierre Caby-Tosi (Moderna), Ian Douglas (London School of Hygiene & Tropical Medicine), Leigh Henderson (Medicines and Healthcare products Regulatory Agency), Jean-Marie Heim (Takeda), Claudia Ianos (Pfizer), Nadiya Jirova (Health Canada), Susan Kaplan (Merck), Sheetal Khedkar (Johnson & Johnson), Hussein Laljee (Gilead), Leila Larbi (AbbVie), Andrea Machlitt (Bayer), Christina Mahl (Eli Lilly Deutschland GmbH), Nokuthula Mayela (South African Health Products Regulatory Authority), Dimple Mirchandani (Unither), Monica Munoz (United States Food and Drug Administration), Ravi Patel (Unither), Pilar Rayon (Spanish Agency of Medicines and Medical Devices), Kateriina Rannula (CIOMS), Lembit Rägo (CIOMS), Agnieszka Szmigiel (European Medicines Agency), and Qun-Ying Yue (Uppsala Monitoring Centre).

Apologies

Andrea Best (Gilead), Claire Brulle-Wohlhueter (Sanofi), Judith Sanabria Cabrera (Hospital Universitario Virgen de la Victoria, Málaga), Khedidja Hedna (International Society of Pharmacoepidemiology – ISPE / University of Gothenburg), Martin Huber (Federal Institute for Drugs and Medical Devices, Germany), Yukiko Komori (Pharmaceuticals and Medical Devices Agency, Japan), Dirk Mentzer (Paul-Ehrlich-Institut), Mahlodi Moropa (South African Health Products Regulatory Authority), Esther Straghan (Pfizer), and Wang Yi (Center for Drug Reevaluation, China).