Council for International Organizations of Medical Sciences

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

1 June 2026, virtual meeting

Minutes

Summary

The CIOMS Working Group (WG) XVII on the Long-term Safety of Medicinal Products met virtually to review progress made by the two drafting subgroups ahead of the forthcoming in-person meeting in Geneva. Both subgroups reported substantial progress in developing draft chapters, with several sections already available for cross-review and additional chapters expected to be shared by 10 June. The meeting focused on drafting status, coordination between subgroups, preparation for the next face-to-face meeting, and discussion of a proposal regarding a potential additional topic area. Members agreed that any decisions regarding scope expansion should be considered by the full WG during the in-person meeting.

Minutes of discussion

Opening and welcome

- Lembit Rägo, CIOMS Secretary General, welcomed the participants to the meeting.
- He invited the two drafting subgroups to provide updates on progress made since the previous meeting, including the status of chapter development and plans for cross-review ahead of the Geneva meeting.
- Kateriina was rapporteur.

Subgroup 1 progress update

- The Subgroup 1 lead thanked members for their continued contributions. Internal review activities were supported through regular subgroup meetings.
- Several chapters had been substantially drafted and were available for review, while the remaining chapters were undergoing refinement, including the incorporation of references and additional comments.
- The target date for sharing materials with Subgroup 2 remained 10 June.
- Members recognised that substantial editorial work would be required to ensure consistency, remove duplication and harmonise the style across chapters.
- It was acknowledged that the introductory chapter would require revision once all substantive chapters had been completed, although the existing draft text would provide a useful foundation.
- A recent cross-company initiative involving CAR-T manufacturers was highlighted. The initiative examined experience with mandated long-term follow-up programmes, including challenges associated with patient retention, the value of extended follow-up and the timing of emerging safety signals. The findings were noted to contribute to ongoing discussions regarding the duration and methodology of long-term follow-up requirements for advanced therapies.

Subgroup 2 progress update

- The Subgroup 2 lead provided an overview of drafting activities.
- All assigned chapters, with the exception of one chapter intentionally deferred for later development, had been initiated.
- Progress varied across chapters, with some sections containing substantial draft content and others remaining at the outline stage.
- Contributors had adopted different drafting approaches, ranging from detailed near-final text to high-level structural outlines.
- Additional work was ongoing, and some material had not yet been incorporated into the shared draft.
- The subgroup confirmed that all available draft materials would be shared with Subgroup 1 by 10 June to allow approximately two weeks for cross-review before the Geneva meeting.
- Members acknowledged that further editing, consolidation and removal of duplication would be required once all sections became available.

Proposed Addition to the Report Framework

- A proposal relating to organovigilance and its potential relevance to the evaluation of long-term safety was discussed. Members recognised the innovative nature of the proposal and its possible contribution to discussions on long-term monitoring, data collection and safety surveillance.
- Questions were raised regarding alignment with the agreed scope of the WG, particularly whether aspects of the proposal extended beyond medicinal product safety into broader healthcare interventions.
- It was agreed that the proposal should be circulated to all WG members before the Geneva meeting to enable review by the full group. Any decision regarding inclusion of organovigilance-related concepts or examples in the report will be discussed in plenary.

Regulatory perspectives

- Regulatory members welcomed the progress made by both drafting groups and confirmed their continued review of draft chapters.
- Ongoing work on the chapter addressing the regulatory landscape was highlighted, including consideration of how best to present international requirements while acknowledging regional differences in approaches to long-term safety assessment and post-authorisation monitoring.
- Members noted that the regulatory landscape for long-term safety continues to evolve, particularly for advanced therapies and other innovative products. It was emphasised that the report should provide a durable framework that remains relevant as scientific knowledge and regulatory expectations continue to develop.
- Recent discussions concerning long-term follow-up requirements for advanced therapies were referenced, including emerging evidence on the practical challenges associated with extended follow-up programmes and ongoing evaluation of the duration and methodologies currently required.
- Regulatory reviewers indicated that they would continue to assess examples and case studies included in the draft chapters, particularly those relating to advanced therapies, vaccines and other product classes, to ensure scientific accuracy and broad applicability.
- It was noted that the chapter addressing the regulatory environment would likely require further refinement as other sections of the report mature, allowing alignment between the conceptual framework, methodological recommendations and current regulatory expectations.
- Members emphasised the importance of ensuring that the examples and recommendations presented in the report are applicable across multiple jurisdictions and healthcare settings, while recognising that implementation approaches may differ between regions.
- Regulatory participants committed to providing further comments and revisions ahead of the Geneva meeting, particularly in relation to long-term follow-up requirements, product-specific considerations and emerging areas of interest.

Next steps / next meeting

- Lembit emphasised the importance of sharing as much draft content as possible by 10 June to allow sufficient time for review before the in-person meeting. The CIOMS Secretariat will support the consolidation of draft material.
- Members were encouraged to review draft sections and provide comments in advance of the meeting.

- It was agreed that references would be added to each chapter. At this stage, the focus should remain on drafting the content. The CIOMS Secretariat will circulate the CIOMS editorial guidelines.
- Next in-person meeting will take place in Geneva, on 29-30 June, where the WG will review the draft report in detail.
- The structure of the Geneva meeting will remain flexible and may include both plenary and subgroup discussions, depending on the maturity of the draft chapters and the issues identified during review.
- Additional discussion will be needed on chapters relating to limitations and challenges, future directions, and annexes, as these sections have not yet been fully developed.

Closing remarks

- Lembit thanked the WG participants for their continued contributions. The forthcoming in-person meeting would provide an important opportunity to integrate the work of both subgroups and establish a clearer roadmap towards completion of the report.

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), Claire Brulle-Wohlhueter (Sanofi), Marie-Pierre Caby-Tosi (Moderna), Ian Douglas (London School of Hygiene & Tropical Medicine), Khedidja Hedna (International Society of Pharmacoepidemiology – ISPE / University of Gothenburg), Leigh Henderson (Medicines and Healthcare products Regulatory Agency), Jean-Marie Heim (Takeda), Martin Huber (Federal Institute for Drugs and Medical Devices, Germany), Claudia Ianos (Pfizer), Nadiya Jirova (Health Canada), Susan Kaplan (Merck), Sheetal Khedkar (Johnson & Johnson), Yukiko Komori (Pharmaceuticals and Medical Devices Agency, Japan), Hussein Laljee (Gilead), Leila Larbi (AbbVie), Andrea Machlitt (Bayer), Christina Mahl (Eli Lilly Deutschland GmbH), Nokuthula Mayela (South African Health Products Regulatory Authority), Dirk Mentzer (Paul-Ehrlich-Institut), 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), Esther Straghan (Pfizer), and Qun-Ying Yue (Uppsala Monitoring Centre).

Apologies

Andrea Best (Gilead), Judith Sanabria Cabrera (Hospital Universitario Virgen de la Victoria, Málaga), Mahlodi Moropa (South African Health Products Regulatory Authority), and Wang Yi (Center for Drug Reevaluation, China).