15 December 2022
EMA/CHMP/CVMP/QWP/822156/2022
Committee for Medicinal Products for Human Use (CHMP)
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the joint CHMP/ CVMP Quality Working Party (QWP) for 2023

Chairperson: Blanka Hirschlerová

The following work plan is a joint human and veterinary plan.

H - indicates a human only topic;

V - indicates a veterinary only topic;

H/V - indicates a joint human/veterinary topic.

1. Meetings scheduled for 2023

Meetings are planned for the following dates*:

PLANNED QWP dates for 2023

6-8 Mar 2023

26-28 June 2023

18-20 Sept 2023 (proposed joint QWP-IWG meeting)

13-15 November 2023

*Given the working party reorganization, the meeting schedule will be subject to change.

Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

All QWP plenary meetings have participants with expertise in the quality of human and veterinary medicinal products, observers from the EDQM (European Directorate for Quality of Medicines and HealthCare), EU accession countries and occasionally from regulatory authorities outside the EU. Each

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meeting is scheduled to take 2.5 days involving about 60 experts per meeting. Break-out sessions on specific subjects, involving a subset of the participants are organised during the meetings.

- H/V interested parties' meetings (1/year);
- Drafting/expert groups involving, if appropriate, external experts and representatives of other working parties and/or inspectors (virtual meetings - as deemed necessary);
- QWP core team (11 virtual meetings/year)* - specific procedures support.

2. Guidelines and Reflection Papers

2.1. New EU Guidelines and Reflection Papers

Action: Lead

2.1.1. Guideline on synthetic peptides (H/V)

Target date Guideline to be finalised Q2 2024

Comments N/A

2.1.2. Guideline on synthetic oligonucleotides (H/V)

Target date Guideline to be finalised Q4 2024

Comments Guidelines on synthetic peptides and oligonucleotides will be developed in parallel to each other, targeting to be final shortly after each other (synthetic peptides in Q2 2024, oligonucleotides in Q4 2024).

2.1.3. Q&A on co-processed excipients (H/V)

Target date Release of the Q&A Q4 2023

Comments In parallel with the drafting of a Q&A, a pilot inspection scheme (IWG-QWP) with focused inspections for products containing CoPE has been established.

Cooperation with IWG.

2.1.4. Guideline on quality and equivalence of topical products (H)

Target date Guideline to be finalised Q4 2023.

Comments Public consultation ended June 2019. Contribution PKWP

2.1.5. Guideline on quality data requirements for applications for non-biological products intended for limited markets (V)

Target date Draft guideline to be adopted by CVMP Q1/Q2 2023

Comments N/A

2.1.6. New GL on risk management requirements for elemental impurities in veterinary medicinal products, including immunological veterinary medicinal products (V)

Target date Release of draft guideline by Q4 2023

Comments Revise the reflection paper on risk management requirements for elemental impurities in veterinary medicinal products - convert into a guideline and include IVMPs within its scope. Involvement of IWP.

Release concept paper for consultation December 2022.

2.1.7. Q&A on comparison of quality attributes as surrogate for in vivo PK data (justification for biowaiver) (H)

Target date Release of Q4 2023

Comments N/A

2.2. EU Guidelines under revision

Action: Lead

2.2.1. Revision of Guideline on the Chemistry of Active Substances (H)

Target date Revised guideline to be released for public consultation: Q4 2023

Comments Concept paper released for public consultation until 31 October 2022.

Review and update of guideline in light of nitrosamine issue as recommended in the sartans LLE.

2.2.2. Revision of Guideline on Radiopharmaceuticals (H)

Target date Concept paper by Q2 2023

Comments N/A

2.2.3. Revision of the guideline on the pharmaceutical quality of inhalation and nasal products (H)

Target date Draft for publication Q2-2023

Comments Revision of the guideline on the pharmaceutical quality of inhalation and nasal products based on the comments received on the concept paper and recent developments.

Contribution to the Q&A on change in propellant – draft Q1 2023

Contribution to the multidisciplinary guidance on equivalence of inhalation products, section 5.2 of Doc. Ref. CPMP/EWP/4151/00 Rev. 1- draft for publication of the draft by Q2-2023.

2.2.4. New Annex to the Guideline on Quality aspects of pharmaceutical veterinary medicines for administration via drinking water (EMEA/CVMP/540/03 Rev.1) to address biocides (V)

Target date Draft Annex release for consultation Q1 2023; final annex Q4 2023.

Comments Concept paper published Q1 2022

2.2.5. Update of existing guidelines and Q&A's to implement revisions required arising from changes arising from Regulation 2019/6 including those relating to the variations requirements and Annex II (V)

Target date Q4 2023

Comments N/A

2.2.6. NfG maximum shelf life for sterile products for human use after first opening or following reconstitution: Q&A (H)

Target date Conclusion of Q&A (+BWP decision tree) and potential revision of guideline at the end of 2023 subject to feedback from the SmPC advisory group.

Comments Feedback from the SmPC advisory group awaited for QWP.

Also relates to European Association of Hospital Pharmacists request on in-use shelf-life of oncology products.

BWP to contribute - QWP lead.

Action: Specialised input

2.2.7. Revision of the Annex to the European Commission Guideline 'Excipients in the Label and Package leaflet for Medicinal Products for Human Use' (H)

Target date Q2 2023

Comments This is led by the Excipient Drafting Group. QWP to contribute to quality aspects.

There is guidance on four excipients under finalization following public consultation: proline, dextrans, polysorbates, lactose.

2.2.8. Revision of the Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev 2: Defining the Scope of an NIRS Procedure (H/V)

Target date Q2 2023

Comments Revisions of NIR addendum (EMA/CHMP/CVMP/QWP/63699/2014)

Review the variation types defined in Table 3 and determine whether certain classifications should be changed. This activity was put on hold in 2018 as part of the Agency's BCP and has not yet re-started. The drafting group will re-start the work and publish an updated addendum as appropriate.

2.3. (V)ICH Guidelines

Action: Specialised input

2.3.1. ICH Quality Discussion Group

Target date N/A

Comments Chair to inform QWP as needed if input is required.

2.3.2. ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Target date 2023

Comments Input to the guideline implementation in EU, jointly with BWP & GMDP IWG. EU implementation is linked to the EU Pharma Strategy initiative to revise the variation framework for medicines, see 4.2.2.

2.3.3. ICH Q13 on Continuous Manufacturing of Drug Substances and Drug Products

Target date 2023

Comments: Input to the development of training materials.

2.3.4. ICH Q2/Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation

Target date Step 2a/Step 2b: March 2022. Step 4 November 2023. Expected formation of an IWG to develop and publish training material.

Comments Input to the development of ICH Guideline Q14 and revision of Q2(R1), led by QWP, with contributions from BWP and where relevant, IWG.

2.3.5. ICH Guideline M4Q(R2) on Common technical document for the registration of pharmaceuticals for human use – quality

Target date Step 1/2: Q3 2023

Comments Input to the revision of ICH Guideline M4Q, jointly with BWP and GMDP IWG.

2.3.6. ICH Q3D Elemental Impurities - new appendix 5 with PDEs for the cutaneous/transdermal route of administration and correction of some PDEs

Target date Upon request from SWP

Comments: No urgency at this point.

2.3.7. ICH Q3E: Guideline for Extractables and Leachables (E&L) - Final Concept Paper

Target date Step 1 sign-off, endorsement Step 2a/b November 2023. Public consultation May 2024. Step 3 sign-off and Step 4 adoption of final GL November 2025.

Comments Input to the development of ICH Guideline Q3E, led by QWP, with quality aspects pertaining to Biologicals/Biotechnological products.

2.3.8. ICH Q9 Quality Risk Management

Target date Step 3 on regional regulatory consultation in December 2021 – April 2022, the target completion date for the revision has been delayed by 6 months to March 2023.

Comments Input to the revision of ICH Q9(R1) and training material, led by IWG, with contributions from BWP and QWP.

2.3.9. ICH Q1/Q5C revision

Target date Q4/2022 - Final Concept Paper, Business Plan

Q4/2024 – Complete Step 1

Q4/2025 – Complete Step 4 and initiate training materials

Comments Input on the revision of ICH Guideline Q1/Q5C jointly with BWP (*with contribution of IWG where relevant*)

2.3.10. VICH GL18 – Impurities: Residual solvents in new veterinary medicinal products, active substances and excipients

Target date 2023

Comments Step 9 - develop revised guideline, bringing it in line with revisions made in ICH Q3C (R5) to ICH Q3C (R8). Public consultation during 2022.

2.3.11. New VICH GL on in vitro dissolution

Target date Beyond 2023

Comments Concept Paper agreed by VICH Steering Committee in September 2019. As a second step a new GL will be developed to cover biowaivers.

2.3.12. New VICH GL on GMP for active substances for VMPs

Target date Beyond 2023

Comments VICH guideline to parallel ICH Q7. Concept Paper agreed by VICH Steering Committee in November 2020. QWP will liaise with IWG as required.

2.3.13. Review VICH GL8 on stability of medicated premixes

Target date Beyond 2023

Comments Concept Paper agreed by VICH Steering Committee in November 2020.

As a second step a new GL (with a new concept paper) will be developed to cover other quality aspects of premixes.

2.3.14. New VICH GL on Pharmaceutical development

Target date Beyond 2023

Comments VICH guideline to parallel ICH Q8. Concept Paper already agreed by VICH Steering Committee in November 2021.

3. Medicinal Products-specific activities and other activities

3.1. Pre-Authorisation activities

3.1.1. Contribution to the scientific advice and protocol assistance provided by the SAWP (H) upon escalation

3.1.2. Contribution to Innovation Task Force

3.2. Evaluation and Supervision activities

3.2.1. Contribution/recommendation to CHMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP Rapporteurs, MS, EMA in the case of human medicinal products or upon request from CVMP for veterinary medicinal products.

3.2.2. Input on non-centrally authorised product evaluation/referral procedures upon request of CMDh/CMDv

3.2.3. Contribution to referral discussions upon request from CHMP/CVMP

3.2.4. Nitrosamines: activities resulting from Sartans Lessons Learnt exercise (https://www.ema.europa.eu/en/documents/report/lessons-learnt-presence-n-nitrosamine-impurities-sartan-medicines_en.pdf) and Article 5(3) referral (Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu)), managed through QWP nitrosamines operational expert group

- Maintenance of and updates to Q&A on root causes for formation (Nitrosamines EMEA-H-A5(3)-1490 - Q&A Art. 5(3) Implementation_12 October 21_for CHMP silent adoption (europa.eu)) to be updated as science progresses
- Development of new policy on nitrosamines as scientific understanding evolves.
- Input on specific product-related assessments as needed.
- Liaison with relevant stakeholders including international regulators (NITWG) and industry.
- Provision of training to network quality assessors

3.2.5. Recommendation to CHMP, as appropriate, on scientific opinion in cooperation with WHO for evaluation of medicinal products intended exclusively for markets outside the community

3.2.6. Support, as requested, to Inspections activities, quality defects, sampling and testing and liaison with OMCL network and EDQM on activities of mutual interest

3.2.7. Liaison with and specialised input to CHMP, CVMP, BWP, BPWP, and GMDP-IWG, QIG and other groups, working parties and committees, where required, on activities of mutual interest

3.2.8. Quality support to public health activities related to chemical medicinal products

3.3. Other activities

3.3.1. Support the replacement/removal of TiO2 in medicinal products (H/V)

Target date ongoing

3.3.2. How to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV) – QWP Q/As (H/V)

Target date 2023

3.3.3. Q&A on use of Ph. Eur. medicinal products monographs.

Target date 2023

3.3.4. Recommendation on the assessment of the quality of medicinal products containing existing/known active substances (H/V)

Target date Q2 2023

4. Input in European activities

4.1. Training for the network and knowledge building

4.1.1. QWP Assessors Training

4.1.1.1. QWP Quality Assessors Follow-up Training on the Pre-Authorisation Risk Assessment Model

4.1.1.2. Training on the Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products. Joint SWP-V and QWP vet training

4.1.1.3. Training on bioequivalence for veterinary medicinal products. Joint EWP

and QWP vet training

4.2. Other input in European activities

4.2.1. H/V collaboration with EDQM on:

- Project for impurities: review of qualification and limits of impurities of existing medicinal products authorised on the market in the EU/EEA with regards to new or revisions of specific monographs
- Scientific input for the elaboration and revision of European Pharmacopoeia monographs, general chapters and notices
- Risk assessment and test recommendations for sampling and testing activities of decentralised products (as of 1st March 2020)
- Contribution to Group 7, 17
- HMA Post-Marketing Risk-Assessment Tool Working Group
- Pharmacopoeial discussion group (PDG), through matters referred to the QWP by EDQM
- Involvement in and contribution to CEP procedures; Member of CEP Steering Committee - DCEP chemical TAB, Ad-Hoc Committee
- Involvement in and contribution to quality related seminars organised by EDQM
- Participation in various EDQM meetings as required

4.2.2. Contribute to development and implementation of Pharma Strategy

- Contribute quality input to flagship initiatives on regulatory efficiency
- To revise the pharmaceutical legislation to provide for simplification, the streamlining of approval procedures and flexibility for the timely adaptation of technical requirements to scientific and technological developments, in order to address the challenges relating to the interplay of medicines and devices, and to strengthen pro-competitive elements.
- To revise the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to digitalisation.

4.2.3. Contribute to the EMA regulatory science strategy

- Contribute to quality aspects for chemical medicinal products from the EMA regulatory science strategy

4.3 Support the work of other WPs, Committees, WGs etc, ad hoc

4.3.1. IWG-QWP

4.3.1.1. QP declaration group (on hold - subject to BCP)

Comments: Collaboration between IWG and QWP on issues and guidance related to audits and QP declarations. The aim of the group is to evaluate, and update published guidance such as Q&As and to evaluate any need for new guidance.

4.3.1.2. Joint meeting and other activities with GMDP IWG

See 2.1.3. Q&A on co-processed excipients (H/V)

4.3.1.3. Annex 4&5 of GMP guidance

5. Input in International activities (beyond (V)ICH guidelines)

5.1. Activities with other regulators

5.1.1. H/V collaboration with drug regulatory authorities outside the EU/EEA in addition to (V)ICH activities

- Collaboration with international regulatory authorities outside of Europe including WHO, FDA, Health Canada and PMDA and contribution on matters of common interest.
- PAI implementation in the context of the US MRA (if work is restarted).
- Joint EU/FDA Q&As on early access (PRIME/Breakthrough): control strategy, stability, process validation and product launch from clinical site.
- This is a joint EU/FDA follow-up to the workshop on support to quality development in early access approaches (PRIME/BD) and the guidance is developed jointly with BWP and IWG.

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

- Contribution to EMA Regulatory & scientific conference on RNA based medicines
- QWP/MSWP/PKWP expert group to progress with IQ consortium project and workshop on PBBM-biopharmaceutical applications topical

6.2. Other activities with stakeholders and external parties

- Interested Parties meeting with Industry stakeholders timing to be confirmed for 2023.

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004663.pdf