27 January 2023
CVMP/IWP/820589/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2023

Chairperson	Status
Chair: E. Werner	Adopted by CVMP in January 2023

The activities outlined in the work plan for 2023 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency.

1. Meetings scheduled for 2023

Plenary meetings:	2* (per meeting: Chair plus 12 members) 24-25 April 2023 (1.5 days) – face-to-face October 2023 (1.5 days) – virtual meeting *An *ad hoc* plenary meeting (1.5 days) may be organised, if needed.
Other meetings:	
Drafting / Expert groups	6-8 (approximately 6 participants)
Workshop / Focus group	None
Training	– Training on requirements for VAMFs – Training on requirements for vPTMFs – Training on plasmid DNA vaccines guideline

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Drafting / Expert group meetings are mainly regarded as complementary to plenary meetings.

2. Product related issues

The following table provides the expected number per year of contributions (number of involvements in dossier) for scientific advice and product assessment, including pre- and post-authorisation issues.

Expected contribution in Scientific Advice	Expected contribution in Product Assessment
2	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1 Guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats (EMA/CVMP/IWP/170689/2016)

Action: Finalise guideline after the consultation period.

Priority 2. Start date: Ongoing, Completion date: Q4 2023

Comments: Replaces the previous guidance on "Specific requirements for the production and control of allergen products (7BIm11a, September 1994). Public consultation period ended on 31 August 2019 (activity put on hold since then).

3.2. Guidance documents to be released for consultation

3.2.1 Development of guidance for limited market products not deemed eligible for Article 23 of Regulation (EU) 2019/6 (on quality for biological veterinary medicinal products)

Action: Finalise draft guideline on quality data requirements for applications for biological products (including IVMPs) taking into account the comments received during the consultation of the concept paper (EMA/CVMP/435071/2021) (ending 15 December 2021) and comments from EC, and publish for public consultation.

Priority 1. Start date: Ongoing, Completion date: Q4 2023 (release of draft guideline for public consultation in Q1 2023, expected publication of final guideline in Q4 2023.

Comments: None.

3.2.2 Development of guidance for limited market products not deemed eligible for Article 23 of Regulation (EU) 2019/6 (on safety and efficacy for IVMPs)

Action: Finalise draft guideline on quality data requirements for applications for biological products (including IVMPs) taking into account the comments received during the consultation of the concept paper (EMA/CVMP/435071/2021) (ending 15 December 2021) and comments from EC, and publish for public consultation.

Priority 1. Start date: Ongoing, Completion date: Q4 2023 (release of draft guideline for public consultation in Q1 2023, expected publication of final guideline in Q4 2023.

Comments: None.

3.2.3 Note for Guidance 'DNA vaccines non-amplifiable in eukaryotic cells for veterinary use' (EMA/CVMP/IWP/07/98)

Action: Prepare revised guideline based on comments received during the public consultation of the concept paper.

Priority 2. Start date: Ongoing, Completion date: release of draft revised guideline for public consultation (Q1 2023), publication of revised guideline (Q4 2023)

Comments: Concept paper was released for public consultation on 26 April 2018 until 31 July 2018. Activity put on hold when IWP activity was halted.

3.2.4 New guideline on risk management requirements for elemental impurities in veterinary medicinal products

Action: Conversion of the Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) into a guideline covering also IVMPs. IWP to contribute to the drafting of the guideline.

Priority 2. Start date: March 2022, Completion date: release of concept paper for consultation December 2022. Release of the draft guideline by Q4 2023.

Comments: Activity led by QWP.

3.3. New topics/concept papers to be prepared/other

3.3.1 Guideline on live recombinant vector vaccines for veterinary use (EMEA/CVMP/004/04-FINAL)

Action: Concept paper to be developed for the revision of the guideline.

Priority 2. Start date: January 2023, Completion date: Release of concept paper for consultation Q2 2023.

Comments:

3.3.2 Reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015 Rev. 1)

Action: Explore possible inclusion of nucleic acid test methods in the list of methods found suitable for demonstrating freedom from extraneous agents.

Priority 2. Start date: January 2023, Completion date: Q1 2024

Comments:

4. VICH guidelines and activities

4.1. Proposal for advancing the work on extraneous viruses in veterinary vaccines - Development of a guideline listing methods found suitable in different regions

Action Contribution to EU position (development of guidelines).
Priority 1. Start date: ongoing, Completion date: tbd

Comments CVMP accepted the revised concept paper at the September 2019 meeting. The concept paper was subsequently adopted by VICH Steering Committee in November 2019. First draft from the topic leader (USDA) is still awaited.

5. EU regulatory activities

5.1. Queries raised by CMDv

Action: Provide response to queries raised by CMDv via CVMP, as required.

Comments: None.

5.2. Collaboration with EFSA

Action: Provide contribution to EFSA opinions in accordance with Article 59 of Regulation (EC) No 726/2004 as amended, as required.

Comments: None.

5.3. Collaboration with EDQM

Action: Continue the collaboration with EDQM on guidance regarding the implementation of veterinary vaccine monographs.

Comments: In particular in key areas such as the management of extraneous agents (EA) in IVMPs and requirements for non-conventional veterinary vaccines.

5.4. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2023 are indicated in section 1 of this document.

Comments: IWP to reflect on needs for training for 2023 and consider the immunologicals curriculum.

5.5. Other

Action: Provide contributions to guidelines and questions raised by other working parties and *ad hoc* expert groups, as required.

Comments: None.

6. Activities with external parties

6.1. Meeting with interested parties

One meeting (Q4 2023).

6.2. Regulatory authorities outside the EU

As required.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (EMEA/CVMP/IWP/208689/2004-Rev.5).

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

None foreseen.

*7.3. List of proposed scientific guidelines for the next work plan**

*The actual items to be included in the IWP work plan for 2023 will be considered and agreed by the CVMP.