16 December 2022
EMA/CVMP/NTWP/701391/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the CVMP Novel Therapies & Technologies Working Party (NTWP) 2023

Chairperson	Status
Chair: Jacqueline Poot Co-Chair: Susanna Casado	Adopted by CVMP in December 2022

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: 4 per year* (per meeting: 2 Chairs plus 7 members)

2023

February 2023

April 2023

June 2023

September 2023

November 2023

*An *ad hoc* plenary meeting may be organised, if needed.

Other meetings:

OEG meetings	To be organised as appropriate
Workshop / Focus group	Stakeholders event on bacteriophages

Training	None

2. Priority areas

2.1. MRLs for biological substances

2.1.1. Guideline on determination of the need for an MRL evaluation for biological substances (EMA/CVMP/SWP/591282/2021)

Action: Guideline has been released for public consultation – prepared by SWP-V.

Priority 1. Start date: on-going, Completion date: *to be updated when new timelines are known.*

Comments: Multidisciplinary topic led by SWP-V, two NTWP experts have been appointed to coordinate the contributions of the NTWP with the coordinator of the guideline.

2.2. Monoclonal antibodies

2.2.1 VICH Draft guideline on target animal safety evaluation for veterinary monoclonal antibody products

Action: Contribute as required to the development of the VICH guideline.

Priority 1. Start date: June 2021, Completion date: December 2023 (to be determined)

Comments: Based to the already available guidance, the NTWP will provide contributions to the VICH Guideline. The activity will be coordinated by the EU advisor and the EU expert for this VICH draft guideline.

2.3. Cell therapies

2.3.1 Guideline on the development and data requirements of potency tests for cell-based veterinary therapy products and the relation to clinical efficacy (EMA/CVMP/NTWP/179287/2022)

Action: Guideline to be adopted by CVMP and released for public consultation (Q4 2022).

Priority 1. Start date: September 2021, Completion date: Q2 2023.

2.4. Bacteriophages

2.4.1 Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy

Action: Guideline to be adopted by CVMP and released for public consultation (Q4 2022 - Q1 2023).

Priority 1. Start date: September 2021, Completion date: Q4 2023

2.5. Nanomedicines

2.5.1 Guideline on the safety data requirements for the assessment of VMPs containing non-degradable nanomaterials

Action: Concept paper to be developed and released for public consultation (Q2 2023).

Draft guidance to be drafted by OEG/NTWP, shared with relevant working parties for consultation if required, and discussed/adopted at CVMP for release for public consultation (Q3 2024)

Priority 1. Start date: October 2022, Completion date: Q4 2024.

Comments: The CVMP has recognised the need for specific data requirements to evaluate the quality, environmental and consumer safety and target animal safety of veterinary medicines containing nanomaterials and has asked the NTWP to lead on the delivery of this task.

One or more operational expert group will be established.

2.6. Proteins and peptides of biological origin

2.6.1 Guidance on proteins and peptides of biological origin

Action: The NTWP is committed to provide advice and guidance based on request of CVMP and working parties.

Priority 2. Start date: September 2021, Completion date: December 2023.

Comments: The NTWP will provide contributions on request.

The QWP will draft a 'Guideline on the development and manufacture of synthetic peptides' and a 'Guideline on the development and manufacture of synthetic oligonucleotides. The NTWP will provide comments as relevant.

2.7. Future topics

2.7.1 Horizon scanning

2.7.1.1. Survey on scientific advice and discussions meetings on innovative products, carried out by National Competent Authorities

Action: Report on the results of the survey (Q4 2022).

Completion date: Q3 2023.

2.7.2 Other novel therapies

2.7.2.1. Initial consideration on the need for guidance on the quality, safety and efficacy of gene therapy veterinary medicinal products

Action: Initial consideration from the group on the need to develop general guidance with a focus on the establishment of a suitable regulatory framework for gene therapy products.

Completion date: Initial consideration Q2 2023.

2.7.3 Other activities

2.7.3.1. Initial consideration on the need for further guidance on post-authorisation measures to monitor the safety and/or efficacy of specific novel therapy products.

Action: The group will consider if further guidance is needed on post-authorisation measures for specific novel therapy products.

Completion date: Q4 2023

3. Operational Expert Groups (OEGs)

3.1. NTWP OEG on nanomaterials

Scope: Guideline on the safety data requirements for the assessment of VMPs containing non-degradable nanomaterials

3.1.1. Coordinator(s)

One or two NTWP members will be nominated as coordinators for this OEG/s.

3.1.2. Tasks

- Concept paper to be developed and released for public consultation (Q2 2023)
- Guideline to be developed and released for public consultation (Q3 2024)

- Response to questions requested by CVMP and working parties.

3.1.3. Required expertise

- Quality and safety of medicinal products containing nanoparticles (to be further defined)

One or more OEGs will be set up, according to the agreed scope of the guideline.

3.2. NTWP OEG on Cell therapies

Scope: Guideline on the development and data requirements of potency tests for cell-based veterinary therapy products and the relation to clinical efficacy.

3.2.2. Tasks

- Finalisation of GDL.
- Response to comments and questions from by CVMP and working parties.

3.3. NTWP OEG on Bacteriophages

Scope: Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy.

3.3.2. Tasks

- Finalisation of GDL.
- Response to comments and questions from CVMP and working parties.

4. Guidance documents

4.1. Guidance documents to be finalised after the consultation period

- Guideline on the development and data requirements of potency tests for cell-based veterinary therapy products and the relation to clinical efficacy.
- Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy.

4.2. Concept papers to be prepared

- Guideline on the safety data requirements for the assessment of VMPs containing non-degradable nanomaterials

4.3. Guidance documents to be released for consultation

- Guideline on determination of the need for an MRL evaluation for biological substances *(dates to be confirmed)*
- Concept paper for the Guideline on the safety data requirements for the assessment of VMPs containing non-degradable nanomaterials.

4.4. Reflection papers

None foreseen.

4.5. Q & A documents

None foreseen.

4.6. VICH Guidelines and activities

- VICH Draft guideline on target animal safety evaluation for veterinary monoclonal antibody products [see section 0].

5. Regulatory activities

5.1. Revision of legislative documents

None foreseen.

5.2. Coordination with other CVMP working parties

5.2.1 General coordination with other CVMP working parties

Action: On request.

Priority 1. Completion date: December 2023.

Comments: The NTWP is committed to provide advice and guidance on all matters related to veterinary novel therapies and technologies.

5.2.2 Coordination with specific CVMP working parties

5.2.2.1. Coordination with QWP

- The QWP plans to draft a guideline or reflection paper on synthetic peptides [see section 0].

5.2.2.2. Coordination with SWP-V

- Guideline on determination of the need for an MRL evaluation for biological substances [see section 0].

5.2.2.3. Coordination with SWP, IWP, QWP, EWP

- Guideline on the safety data requirements for the assessment of VMPs containing non-degradable nanomaterials

5.3. Collaboration with EDQM

5.3.1 Collaboration with the EDQM expert group on phage therapies

Action: Continue collaboration in areas of common interest.

In particular, regular exchange should be continued before and after completion of the GDL on bacteriophages.

5.4. Assessor training

Action: Training on the Guideline on the development and data requirements of potency tests for cell-based veterinary therapy products and the relation to clinical efficacy is foreseen,

Completion date: Q4 2023.

5.5. Activities with external parties

5.5.1 Meeting with interested parties

5.5.1.1. Meetings with industry stakeholders

Action: Organise a 'Focus group meeting' on bacteriophages during the consultation period for the Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy.

Priority 1. Completion date: Q3 2023.

5.5.2 Regulatory authorities outside the EU

5.5.2.1. Meetings with FDA

Action: Continue collaboration in areas of common interest.

In particular, regular exchange should be continued before and after completion of the GDL on bacteriophages.

6. 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	1

6.1. Coordination of contributions of the NTWP for scientific advice

Action: A mechanism for the timely involvement of the NTWP and the NTWP OEGs in scientific advice has been established for providing advice on all matters relating to veterinary novel therapies and technologies.

Comments: Multidisciplinary topic, bilateral coordination and collaboration between NTWP and SAWP should be continued through the year as agreed.

7. Organisational matters

7.1. List of adopted organisational documents

- Mandate, objectives and rules of procedure for the CVMP Novel Therapies & Technologies Working Party (NTWP) (EMA/CVMP/VNTWP/706123/2020-Rev.1)
- Workplan for the CVMP Novel Therapies & Technologies Working Party (NTWP) (EMA/CVMP/NTWP/701391/20221).

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

- Mandate, objectives and rules of procedure for the CVMP Novel Therapies & Technologies Working Party (NTWP) (EMA/CVMP/VNTWP/706123/2020-Rev.1)
- Workplan for the CVMP Novel Therapies & Technologies Working Party (NTWP) (EMA/CVMP/NTWP/701391/2022).