26 January 2024
EMA/CVMP/NTWP/425065/2023
Committee for Veterinary Medicinal Products (CVMP)

# Work plan for the CVMP Novel Therapies & Technologies Working Party (NTWP) 2024

| **Chairperson** | **Status** |
|---|---|
| Chair: Jacqueline Poot<br><br>Co-Chair: Susana Casado | Adopted by CVMP in January 2024 |

*The activities outlined in the work plan for 2024 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 2024

**Plenary meetings:** 4-5 per year* (per meeting: 2 Chairs plus 7 members)

**2024**

February 2024

April 2024

June 2024

September 2024

November 2024

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

**Other meetings:**

| | |
|---|---|
| OEG meetings | To be organised as appropriate |
| Workshop / Focus group | To be organised as appropriate |

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

# 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 to be finalised further to public consultation – prepared by SWP-V.

**Priority 1.** Start date: on-going, Completion date: Q1 2024

**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: 2024 (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. Nanomedicines*

### 2.3.1 Guideline on the safety data requirements of nanomedicines

**Action:** Concept paper to be reviewed after public consultation (Q1 2024).

Draft guideline 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 (Q4 2024)

**Priority 1.** Start date: March 2023, Completion date: Q1 2025.

**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.

## *2.4. Future topics*

### 2.4.1 Horizon scanning

#### *2.4.1.1. Survey on innovative products in development, specifically focusing on alternatives to antimicrobials, e.g. gene therapy, targeted to industry (and National Competent Authorities)*

**Action:** Report on the results of the survey (Q1 2025).

Completion date: Q4 2025.

**Priority 2.** Start date: Q1 2024, Completion date: Q4 2025.

### 2.4.2 Other novel therapies

#### *2.4.2.1. Consideration on the need for guidance on the quality, safety and efficacy of gene therapy veterinary medicinal products*

**Action:** 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 (depending on the horizon scanning mentioned under 2.4.1).

Completion date: Consideration Q1 2025.

**Priority 3.** Start date: Q1 2024, Completion date: Q1 2025.

### 2.4.3 Other activities

#### *2.4.3.1. 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 2024

**Priority 2.** Start date: Q1 2024, Completion date: Q4 2024.

# 3. Operational Expert Groups (OEGs)

## *3.1. NTWP OEG on nanomaterials*

**Scope:** Guideline on the safety data requirements for nanomedicines

### 3.1.1. Coordinator(s)

Three NTWP members were nominated as coordinators for this OEG/s.

### 3.1.2. Tasks

- Concept paper to be reviewed after public consultation (Q1 2024)
- Guideline to be developed and released for public consultation (Q4 2024)
- Response to questions requested by CVMP and working parties.

# 4. Guidance documents

## *4.1. Guidance documents to be finalised after the consultation period*

None foreseen.

## *4.2. Concept papers to be prepared*

None foreseen.

## *4.3. Guidance documents to be released for consultation*

Guideline on the safety data requirements for nanomedicines

## *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 2.2.1].

# 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 2024.

**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 SWP, IWP, QWP, EWP*

- Guideline on the safety data requirements for nanomedicines

## *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 quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy is foreseen,

Completion date: Q4 2024.

## *5.5. Activities with external parties*

### 5.5.1 Meeting with interested parties

None foreseen.

### 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 Guideline on nanomedicines.

# 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/425065/2023

### *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/425065/2023).