12 December 2025
EMA/CVMP/NTWP/228977/2025
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the CVMP Novel Therapies & Technologies Working Party (NTWP) 2026

Chairperson	**Status**
Chair: Jacqueline Poot Co-Chair: Anja Pfalzgraff	Adopted by CVMP in December 2025

The activities outlined in the work plan for 2026 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 2026

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

2026

February 2026

April 2026

June 2026

September 2026

November 2026

*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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Training	To be organised as appropriate

2. Priority areas

2.1. Nanoparticles

2.1.1 Guideline on the safety of nanoparticles

Action: Draft guideline to be discussed/adopted at CVMP for release for public consultation (Q4 2025).

Final guideline publication (Q3 2026).

Priority 1. Start date: March 2023, Completion date: Q3 2026.

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

2.2. RNA interference and RNA antisense therapies

2.2.1 Guideline(s) on RNA interference and RNA antisense therapies

Action: Develop general guidance on the specific requirements on Quality and Safety for RNA interference and RNA antisense veterinary therapies.

Priority 1. Start date Q4 2025, Completion date: Q3 2028.

2.3. Post-authorisation measures

2.3.1 Guidance and template on the risk management plan for veterinary novel therapies according to the requirement in section V.1.1.6 of Annex II of Regulation (EU) 2019/6

Action: The group in collaboration with the PhV-WP will draft a guidance on risk management plan for novel therapy products.

Priority 1. Start date: Q3 2025, Completion date: Q3 2026.

2.4. Guideline on the quality aspects of secretomes as veterinary medicinal products

2.4.1 Guidance on the quality aspects of secretomes as veterinary medicinal products.

Action: Develop guidance on the quality aspects of secretomes as veterinary medicinal products.

Priority 2. Start date Q3 2026, Completion date: Q3 2028.

2.5. Future topics

2.5.1 Novel therapies classification. Procedure and criteria for classification (EMA/216413/2025)

Action: Further consideration by the NTWP.

2.5.2 Other activities

None foreseen.

3. Operational Expert Groups (OEGs)

3.1. NTWP OEG on nanomaterials

Scope: Guideline on the safety of nanoparticles.

3.1.1. Coordinator(s)

Three NTWP members were nominated as coordinators for this OEG.

3.1.2. Tasks

- Guideline to be adopted and released for public consultation (Q4 2025)
- Final guideline publication (Q3 2026).

3.2. NTWP OEG on RNA interference and RNA antisense veterinary therapies

Scope: Guideline on the quality and safety of RNA interference and RNA antisense veterinary therapies.

3.2.1. Coordinator(s)

Four NTWP members were nominated as coordinators for this OEG.

3.2.2. Tasks

- Concept paper to be developed (Q4 2025)
- Concept paper to be released for public consultation (Q4 2026)
- Guideline to be developed (Q4 2026).

4. Guidance documents

4.1. Guidance documents to be finalised after the consultation period

None foreseen.

4.2. Concept papers to be prepared

Guideline on the quality and safety of RNA interference and RNA antisense veterinary therapies.

Guideline on the quality aspects of secretomes as veterinary medicinal products.

4.3. Guidance documents to be released for consultation

Guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisation.

4.4. Reflection papers

None foreseen.

4.5. Q & A documents

None foreseen.

4.6. VICH Guidelines and activities

None foreseen.

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 2026.

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

Guideline on the quality and safety of RNA interference and RNA antisense veterinary therapies.

5.2.2.2. Coordination with PhV-WP

Guidance on risk management plan (RMP) for novel therapies.

5.2.2.3. Coordination with SWP

The SWP planned to develop the "Guideline on consumer safety of active substances of IVMPs acting against endogenous targets" The development of this guideline is planned in collaboration with IWP and NTWP.

This group also plans to revise the Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances". The revision is planned in collaboration with NTWP.

5.3. Coordination with other CHMP working parties

5.3.1. General coordination with other CHMP working parties

Action: Coordination with QIG.

Priority 1. Completion date: December 2026.

Comments: The NTWP and QIG are committed to provide updates on their respective activities to each other.

5.3.2 Coordination with specific CHMP working parties

None foreseen.

5.4. Collaboration with EDQM and EFSA

5.4.1 Collaboration with the EDQM expert group on phage therapies

Action: On request.

Priority 1. Completion date: December 2026.

5.4.2 Collaboration with the EFSA expert group on nanoparticles

Action: On request.

Priority 1. Completion date: December 2026.

5.5 Assessor training

Action: Training on the Guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations

Priority 1. Completion date: Q4 2026.

5.6. Activities with external parties

5.6.1 Meeting with interested parties

None foreseen.

5.6.2 Regulatory authorities outside the EU

5.6.2.1. Meetings with FDA

Action: Continue collaboration in areas of common interest.

In particular, regular exchange on ongoing (GL on nanoparticles) and future (i.e. GL on RNAi, GL on secretomes) topics of common interest

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 working parties under the quality, non-clinical, methodology, clinical and veterinary domains (EMA/299541/2025).

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

None foreseen.