EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of Novel Therapies Working Party (NTWP)

SME Info-day

Veterinary Info Day for micro, small and medium-sized enterprises (SMEs)

Presented by Susana Casado on 28 October 2021
Vice-Chair of the NTWP

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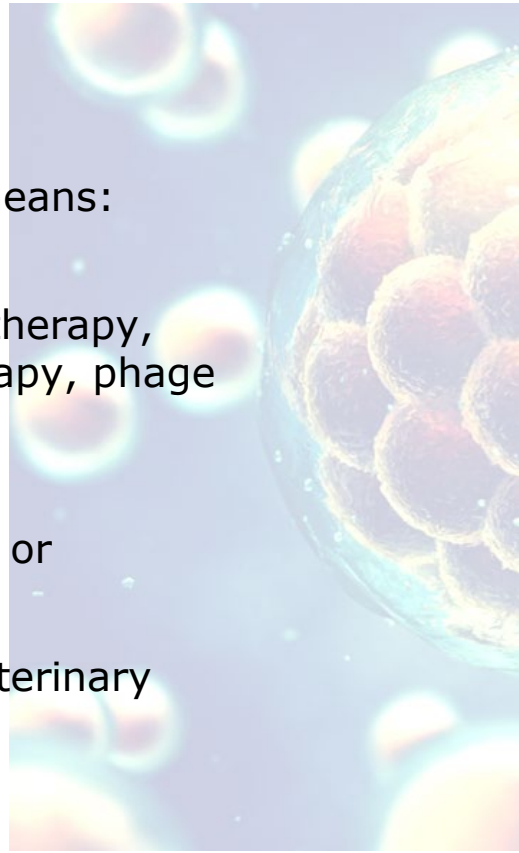
What is a novel therapy?

What is a Novel Therapy (NTT)?



Regulation 6/2019: Novel therapy veterinary medicinal product means:

- A veterinary medicinal product specifically designed for gene therapy, regenerative medicine, tissue engineering, blood product therapy, phage therapy;
- A veterinary medicinal product issued from nanotechnologies; or
- Any other therapy which is considered as a nascent field in veterinary medicine;

The Novel Therapies Working Party (NTWP)

Overview of the Novel Therapies Working Party (NTWP)

- The Committee for Medicinal Products for Veterinary Use (CVMP) establishes a number of working parties at the beginning of each three-year mandate.

- The CVMP consults its working parties on scientific issues relating to their particular field of expertise.

- The Novel Therapies and Technologies Working Party (NTWP) provides recommendations to the Committee for Medicinal Products for Veterinary Use (CVMP) on all matters relating to veterinary novel therapies and technologies.

Objectives of the Novel Therapies Working Party (NTWP)

- The NTWP contributes towards **establishing a future regulatory framework** for the authorisation of novel veterinary therapies and technologies in the EU
- The NTWP contributes **to the implementing**
  - the EMA Regulatory Science Strategy to 2025 [e.g. 4.1 Goal 1, pages 52-54]
  - and the European medicines agencies network strategy [e.g. page 29]
- The NTWP aims **to foster and support innovation**, to enable the timely availability of novel veterinary therapies and technologies in the EU.

Responsibilities of the Novel Therapies Working Party (NTWP)

- To prepare and update European and international **guidelines**
- To give **recommendations and advice to the CVMP**, on topics related to novel veterinary therapies and technologies (NTT)
- To **address queries** from other EMA committees, working parties, the European Union (EU) Member States and other parties
- To contribute to **workshops**
- To contribute to **training on the evaluation of NTTs**

Composition of the Novel Therapies Working Party (NTWP)

- The Novel Therapies and Technologies Working Party (NTWP) started running in May 2021.

- Members
  - European experts nominated and appointed by CVMP
  - Additional observers (EDQM, EFSA, FDA…) may also attend

Jacqueline Poot (Chair)

Susana Casado (Vice-Chair)

Frida Hasslung Wikström

Frédéric Klein

Manuela Leitner

Anja Merle Pfalzgraff

Svenja Rieke

Jean-Claude Rouby

Dariusz Śladowski

Running of the Novel Therapies Working Party (NTWP)

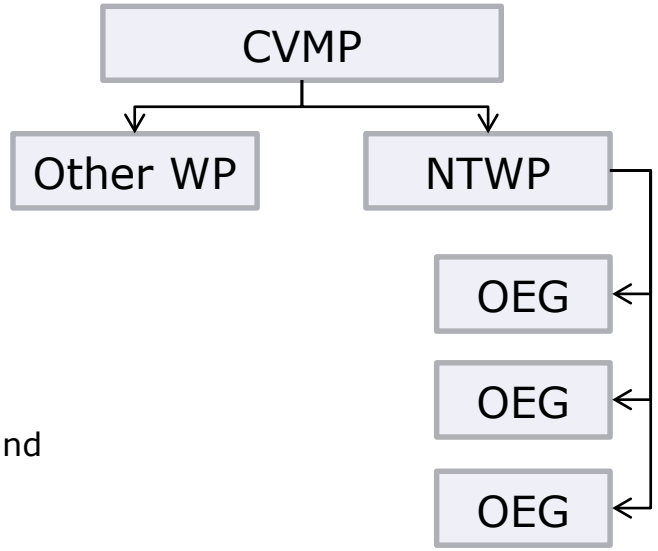
- How we work?

-At least 4 meetings per year

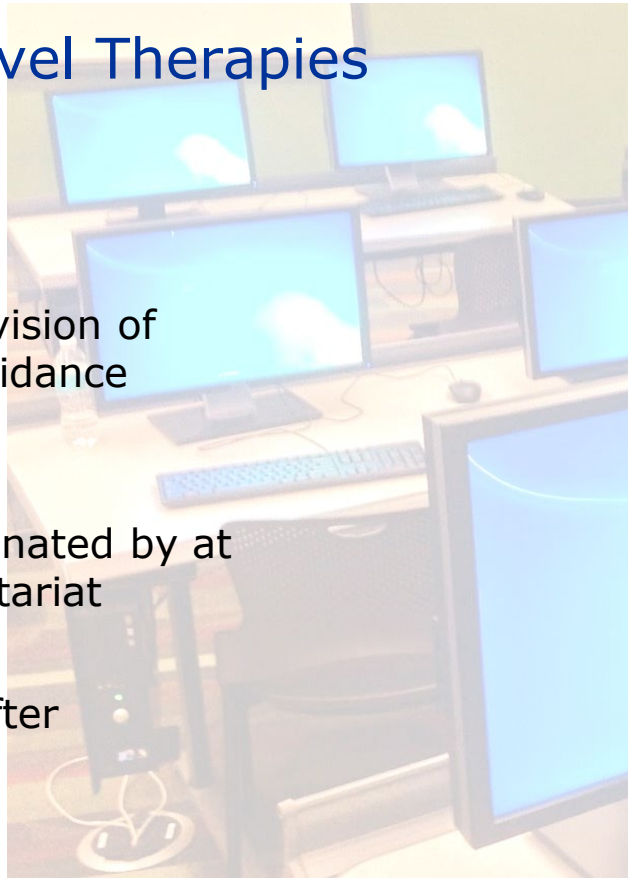
-Meetings in 2021
  - -19th of May 2021
  - -16th of Sept 2021
  - -24th of Nov 2021

-The NTWP will coordinate the work of the operational expert groups (OEG), provide input into on-going work and feedback to CVMP

- OEG are established on an ad hoc basis



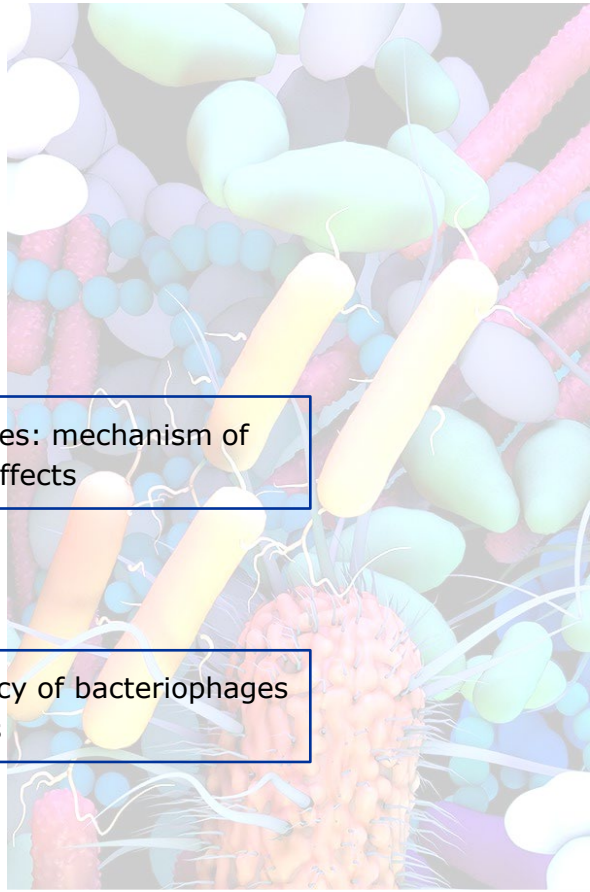
Operational expert groups (OEG) of the Novel Therapies Working Party (NTWP)



- In charge of the operational activities, such as the provision of advice on specific topics and products or drafting of guidance documents
- Composed by relevant experts in specific areas. Coordinated by at least one NTWP member. Supported by the EMA Secretariat
- Assembled to deliver specific tasks and discontinued after completion

NTWP Work Plan 2021/2022

- MRLs for biological substances
- Monoclonal antibodies
- Cell therapies → OEG: Guidance on efficacy of cell therapies: mechanism of action, potency and clinical effects
- Protein and peptides on biological origin
- Bacteriophages → OEG: Guidance on quality, safety and efficacy of bacteriophages as veterinary medicines
- Horizon scanning



OEG on Guidance on efficacy of cell therapies: mechanism of action, potency and clinical effects

Q4 2021	OEG, NTWP and CVMP drafting of the Concept paper (CP)
Q1 2022	CP release for public consultation (3 months)
	OEG, NTWP and CVMP drafting of the Guideline
Q2/3 2022	OEG, NTWP meetings to update and adopt the CP
Q4 2022	Guideline release for public consultation (3 months)
Q2/3 2023	OEG, NTWP meetings to update and adopt the CP
Q4 2023	Guideline adoption by CVMP

OEG on Guidance on quality, safety and efficacy of bacteriophages as veterinary medicines

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Horizon scanning

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

• The objective is to identify emerging needs for targeted regulatory support and guideline.

• Calendar:

- Q4 2021 Launch of the survey
- Q2 2022 Report on the results of the survey

Cooperation

- To ensure cross-domain alignment and international harmonization

More information

• More information on the NTWP's responsibilities, composition, procedures and activities is available in the following documents:

- NTWP - Mandate
- NTWP - Work plan

• Further information on are available under the NT and ADVENT Q&A Documents web page.

Any questions?

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