EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Mandate, objectives and rules of procedure for the CVMP Veterinary **N**ovel **T**herapies & Technologies **W**orking **P**arty (**NTWP**)

1. General considerations

According to the Committee for Medicinal Products for Veterinary Use (CVMP) rules of procedure, the CVMP may consult its working parties on any scientific issue related to their specific fields of expertise. The CVMP may also delegate certain tasks associated with the scientific evaluation of applications or drafting of guidelines to the relevant working parties. The tasks identified by the CVMP should be included in the work programme of each working party to be adopted by the CVMP.

The CVMP NTWP is therefore established to provide recommendations to the CVMP on all matters relating directly or indirectly to veterinary novel therapies and technologies as well as to perform the tasks described under section 2. Novel includes 'novel therapy veterinary medicinal products' as specified under article 4 (43) of Regulation (EU) 2019/6, but also other products and technologies which are 'nascent' in the veterinary domain, as classified by the group.

2. Mandate and objectives

The NTWP is established to provide guidance to the CVMP on all issues relating to veterinary novel therapies and technologies, including but not limited to the tasks defined below:

- Establish and continuously update an overview of current and emerging topics and technologies (horizon scanning), in order to remain up to date with latest developments on novel therapies and technologies in the veterinary domain;
- Advise the CVMP on matters related to preparation, review and update of guidelines and other sources of information and guidance for applicants for veterinary novel therapies and technologies;
- On request, provide recommendations on strengthening expertise for Scientific Advice and ITF meetings on novel veterinary medicinal products and technologies by enhancing scientific capabilities and procedural improvements, in order to ensure an innovation friendly environment;
- Provide recommendations to encourage the development and authorisation of novel veterinary therapeutic approaches as an alternative to antimicrobial treatment;

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- Provide recommendations on training and establishing required expertise, enabling the EMRN (European medicines regulatory network) to implement efficient regulatory procedures;
- At the request of the CVMP, provision of scientific advice on general and product specific matters related to novel therapies or technologies, including support to other working parties (e.g. SAWP, SWP, QWP, IWP), expert groups (e.g. CMDv) and/or the European Commission;
- Initiate and establish a continuous discussion with relevant stakeholders and interested parties in order to strengthened early interaction, transparency and communication (see "rules of procedure");
- Contribute and foster international cooperation on novel therapy related issues (e.g. via VICH);
- Contribute to the implementation and further development of the EMA and HMA Regulatory Science Strategies by providing recommendations for the veterinary medicines' domains, aiming to improve timely access to innovative treatments;
- Advise on data requirements for the evaluation of quality, safety and/or efficacy for novel veterinary therapies as and when needed, including recommendations for generation of post-authorisation evidence if applicable;
- Provide ad hoc support to product classifications and dossier evaluation for new applications (and post-authorisation procedures, if relevant) for novel therapies as required by the CVMP or the European Medicines Agency (EMA) upon specific request from CVMP;
- The mandate and objectives of the NTWP shall be agreed by the CVMP. They shall be reviewed every 3 years by the CVMP.

3. Composition and rules of participation

The NTWP will consist of the working party itself (referred to as NTWP in the following text) and operational expert groups established on an *ad hoc* basis.

The NTWP has a strategic role and is composed of a limited number of experts, ideally between 6 and 8, selected by the CVMP based on nominations from the CVMP or the EMA. Members of CVMP, scientific committees, working parties and national experts may be nominated, subject to their inclusion on the EMA database of European experts.

The members of the NTWP are selected based on their regulatory experience and scientific knowledge in the field of innovative veterinary medicines. A proactive role in the area of novel therapies and technologies, e.g. assessment of applications for novel therapies or provision of scientific advice, will be highly desirable for NTWP members. When selecting members of the NTWP, efforts should be made to diversify selection across different areas of expertise. The NTWP will coordinate the work of operational expert groups, provide relevant input into on-going work and feed back to CVMP accordingly.

The majority of operational activities, such as the provision of advice on specific topics and products or drafting of guidance documents, will be carried out by operational expert groups. The number, scope and mode of operation of the operational expert groups and the activities planned for implementation will be specified in the annual workplan for endorsement by CVMP.

The operational expert groups will be composed of relevant experts in specific areas of expertise, as defined below. These groups will be assembled to deliver specific tasks and will be discontinued after

completion, unless a specific need is identified to maintain the group active for a longer period of time. The decision to extend the activity of operational expert groups beyond the completion of specific tasks will be considered by the NTWP and presented to CVMP for endorsement. The selection procedure to appoint experts to operational expert groups will be carried out by CVMP, through a selection committee, including the Chairperson of the NTWP, following a call for nominations. The selection of experts for specific groups shall be agreed by the CVMP on the basis of their expertise in the areas within the scope of the activity defined by the NTWP, as outlined in the relevant Work Plan.

In order to ensure that the tasks assigned to operational expert groups can be accomplished, the following areas of expertise are considered relevant, upon definition of priorities established by the working party and outlined in the relevant Work Plan:

- Gene therapies;
- Cell therapies (such as regenerative medicine);
- Tissue engineering;
- Therapeutic vaccines;
- Novel blood product therapies;
- Monoclonal antibodies;
- Phage therapies;
- Other novel alternatives to antimicrobial treatments (e.g. microbiome-based approaches or antimicrobial peptides);
- Nanotechnology;
- Novel manufacturing technologies and innovative approaches, including risk-based approaches and application of Good Manufacturing Practice, with respect to novel veterinary therapies;
- Innovative platform technologies for novel veterinary therapies;
- Nascent technologies and approaches in the veterinary domain (e.g. demonstration of similarity for novel / biological veterinary medicinal products);
- Genetics and 'omics' technologies, including e.g. gene editing;
- Individualised medicines (treatment of individual animals or farm-level based approaches).

Membership of NTWP and operational expert groups implies a commitment to participate actively in the work of the group and to attend the meetings of the group regularly.

A member of the NWTP may nominate a replacement to participate in those exceptional cases where she or he is unable to attend specific meetings. In any case, members of the NTWP can only be replaced exceptionally and based on pertinent justification.

If members of the NTWP want to include additional experts in specific meetings, this should be notified to the Secretariat in advance, and their participation will be subject to the agreement of the Chairperson.

In case a member of the NTWP or operational expert groups will not have the capability to continue contributing as required, an expert with relevant expertise and capability will be appointed in order to replace and ensure timely implementation of the NTWP's responsibilities. When appointment of a new

member is required, the CVMP will agree on the required profile of the expert based on the expertise needed.

It is recognised that the required expertise for certain new technologies may not exist within the regulatory community and that experts with the necessary specialist knowledge may have conflicts of interest. For this reason, it is anticipated that the operational expert groups may need to make use of the 'Expert Witness' concept as described in the EMA policy on the handling of declarations of interests of scientific committees' members and experts, adopted by the Management Board (EMA/626261/2014).

4. Meeting frequency and method of operation

The NTWP shall meet at least 4 times per year in accordance with the adopted Work Plan. The dates of the meetings shall be included in the Work Plan. Regular meetings will be scheduled virtually or on site at EMA, however, the NTWP and operational expert groups will conduct the majority of their business remotely by correspondence, teleconference or videoconference. Operational expert groups meetings will be scheduled according to the NTWP annual work programme.

Recognising that product and technological development takes place on a global scale and that international alignment of regulatory frameworks for innovative veterinary therapies is in the interests of citizens, industry and governments, the NTWP and its operational expert groups will keep up to date with and take into consideration, if relevant, guidance generated in other regulatory areas. It is expected that regular exchanges will take place with other regulatory authorities outside the EU (in particular the US FDA in the context of the confidentiality arrangement that exists between the EMA and FDA).

5. Rules of procedure

5.1. Responsibilities of Chairpersons

The Chairpersons are responsible for the efficient conduct of the business of the NTWP and shall in particular:

- Be a working member of the NTWP;
- Plan the Work Plan of the group together with the Secretariat;
- Prepare and run the NTWP meetings;
- Monitor together with the Secretariat that the rules of procedure are respected;
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed;
- Aim to achieve consensus and ensure that scientific grounds are adequately reflected;
- Ensure that NTWP members have the opportunity to express their views, take a position on the scientific issue under debate, are involved in the drafting of recommendations and that the views expressed by the members are reflected in the NTWP scientific considerations to the CVMP;
- Ensure the consistency of the scientific advice provided;

- Co-ordinate together with the Secretariat the work of NTWP with EMA's scientific committees, working parties and other relevant groups or stakeholders;
- Report on the activities of the group to the Agency's scientific committees, working parties and other relevant groups of the Agency. The Chairperson will be invited to attend plenary meetings to report on the activities on the NTWP and ensure liaison with the work of the CVMP;
- Provide feedback from the NTWP discussions including divergent views and summarise the conclusions of the NTWP for the CVMP;
- Propose to the CVMP to include or remove experts from the NTWP registry, as appropriate.

5.2. Election of Chairpersons

The CVMP shall appoint the Chairperson and Vice-Chairperson for the group. The Chairpersons of the NTWP shall be elected for the duration of the mandate term.

Nominations for the Chairperson and the Vice-Chairperson should be submitted in writing to the Secretariat no later than the start of the CVMP meeting at which the election will take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the Chairperson and the Vice-Chairperson shall follow the same procedure as that for the election of the Chairperson of CVMP as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CVMP.

In the event of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened as soon as possible. In the event of resignation of the Vice-Chairperson a new election will be scheduled at the next possible date.

5.3. Organisation of meetings

Meeting documentation will be distributed to an agreed list of recipients drawn up by the Secretariat with the agreement of the Chairpersons. Agenda and minutes of the meetings of the working party will be circulated to the CVMP.

Observers may participate with the agreement of the Chairpersons and the EMA. Specific confidentiality rules will apply to observers.

The draft agenda for every meeting shall be circulated, together with the related documents, by the Secretariat, in consultation with the Chairpersons, at least 7 calendar days before the meeting.

The NTWP shall prepare and agree an annual Work Plan for endorsement by the CVMP.

When a member of the NTWP is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance in writing. Given the limited membership of the NTWP, the number of meetings a member does not participate should be limited to 3 per calendar year, excluding conflicts of interests or personal reasons, such as personal health issues. When considered appropriate by the NTWP, oral presentations by stakeholders can be made during working party meetings on matters directly related to the activities of the working party, following agreement of the CVMP.

5.4. Operational expert groups

The operational expert groups will generally consist of at least one NTWP member (coordinator/s) in addition to the experts chosen for their specialist knowledge in the topic area of interest. The expert groups will have a focus on the preparation of one or more specified documents, such as guidelines, as requested and defined by the NTWP. All operational expert groups will report exclusively to the NTWP.

Depending on the topic, the operational expert groups will be chaired either by one or two coordinators. These coordinators should be members of and will be nominated by the NTWP.

The coordinators have a specific role ensuring that the outcome produced by operational expert groups is of the adequate quality, fit-for-purpose when viewed in the veterinary regulatory context and takes account of relevant advice, decisions and positions taken by the CVMP. The coordinators are responsible for timely (i) planning and conduct of meetings, workshops or contributions to conferences; (ii) drafting and finalising of documents, such as reflection papers, recommendations or guidelines; (iii) ensure that all potential conflicts of interests are identified and handled appropriately; as well as (iv) report on the operational expert groups' activities to the NTWP. The coordinators of operational expert groups will be supported by the EMA Secretariat.

5.5. Guarantees of independence

The members of the group and experts referred to above shall not have any direct interests in the pharmaceutical industry that could affect their impartiality (except possibly 'expert witnesses'). They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the EMA, which is accessible to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMA policy on the handling of declarations of interests of scientific committees' members and experts, adopted by the Management Board (EMA/626261/2014) are applicable to members of the group and experts participating in the activities of the group.

5.6. Code of conduct

Members of the NTWP and experts participating in NTWP or any operational expert groups' activities shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012).

5.7. EMA Secretariat

1. Under the authority of the Executive Director, the Secretariat shall provide technical, scientific and administrative support to the working party. This includes the following:

    - Provide technical and scientific support to rapporteurs (guidelines), and other members of the working party;
    - Provide legal, regulatory and scientific support to the working party;
    - Prepare and co-ordinate the work of the working party in consultation with their Chairpersons;
    - Ensure, if appropriate, that the periods laid down by Community legislation for the adoption of the opinions are complied with;

- Organise meetings of the working party ensuring timely circulation of meeting documents and ensure that the deadlines fixed during each NTWP meeting are respected;
- Facilitate the necessary contacts between the working party and the CVMP;
- Ensure adequate co-ordination of the work carried out within the working party, the scientific Committee(s) and other concerned working parties and/or scientific advisory groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents / recommendations of the working party in co-operation with the Chairperson or Vice-Chairperson, as appropriate;
- Prepare the agenda and minutes of the meetings of working party in consultation with the Chairpersons;
- Communicate when necessary any CVMP recommendations relevant to the working party to interested parties;
- Contribute to the identification of experts.

2. The Executive Director of the Agency, members of the Secretariat, and representatives of the European Commission, may attend all meetings of the working party.

5.8. Contacts with interested parties

Where relevant, the NTWP, and operational expert groups when considered appropriate, will establish contacts, on an advisory basis, with parties concerned with the research and development, manufacture, control and use of novel veterinary therapies.

When considered appropriate, oral or written presentations by interested parties can be made or may be invited for virtual or on-site meetings and discussions.

Draft concept papers and guidelines and general regulatory developments will be subject to public consultation of all interested parties.

In any case, the working party shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

Before any consultation session, interested party representatives and working party members will communicate to the Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the working party Chairpersons and circulation by the Secretariat.

5.9. General provisions

Members of the NTWP and all experts shall be bound, even after the cessation of their duties, not to disclose any information which, by its nature, must be covered by individual professional secrecy.

When participating in international or other fora on behalf of the CVMP, members shall ensure the views expressed are those of the CVMP.

When participating in international or other fora not specifically on behalf of the CVMP, members shall make clear that the views expressed are their own views and not those of the CVMP.