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 Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

1. General considerations

Article 56(2) of Regulation (EC) No 726/2004 enables the scientific committees of the European Medicines Agency (EMA/the Agency) to establish standing and temporary working parties and scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up scientific opinions for which the committee has responsibility.

In recent years the Agency has received an increasing number of requests for guidance related to therapies that are entirely new to the veterinary domain (novel therapies) and sufficient experience of providing guidance with respect to such novel therapies has now been gained to identify the need for an additional source of guidance to companies.

Where therapies represent a 'first in class' and where there is no experience within the veterinary regulatory community with respect to the therapy concerned, there is a need to provide guidance in a form that is publicly available and that sets a precedent to be followed for future applications based on the same technology.

The CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) is therefore established under Article 56(2) of Regulation (EC) No 726/2004 under the Committee for Medicinal Products for Veterinary Use (CVMP). A preliminary mandate for two years on the concept of ADVENT was endorsed by the EMA Management Board on 12 June 2014. At its December 2016 meeting the EMA Management Board endorsed the group's continued activity for an additional 3 years.

2. Mandate and objectives

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

- Provide and update general guidance on scientific and technical topics on the requirements for authorisation of therapies that are new to the veterinary domain. Therapies may be genuinely novel i.e. not used previously in the context of a medicine, or may merely be new to veterinary

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medicine i.e. well known in terms of research, and possibly in the context of human medicine, but representing the first time that such technology has been presented in the context of a veterinary therapy.
Due to the lack of a dedicated legal framework for many novel therapies in the veterinary domain, the guidance provided by ADVENT will be advisory in nature.
Other sources are to be used by applicants for guidance and guidance on regulatory or legal concerns.
The guidance given will be general in nature and not related to a particular application. Formal scientific guidance is available to applicants when seeking guidance specific to a particular product.

- The guidance to be published is intended to be generally in the form of 'Question and Answer' documents on a particular topic. .
  The objective of the guidance will be to describe an approach to the development of a novel technology product that applicants can follow in order to maximise the likelihood that the studies provided will be acceptable for the purposes of obtaining a marketing authorisation. The guidance will be the best that can be given at the time it is published based on the current state of scientific knowledge. Guidance will be updated in line with subsequent scientific developments. The group can produce draft CVMP guidelines, after sufficient experience has been gained of a particular technology and subject to inclusion on the work programme for the group, as described below.
- Support dossier evaluation and referrals for novel therapies as required by the CVMP.
- International cooperation on novel therapy related issues.
- Advise, through the CVMP, to other working parties, expert groups (for example, the coordination group for mutual recognition and decentralised procedures (CMDv) and/or the European Commission on novel therapy related issues.
- Contribution to novel therapy related workshops and training.

3. Composition and rules of participation

The ADVENT core group is composed of experts selected by the CVMP from the European experts list according to their specific expertise on the basis of nominations from the CVMP. In case of a need to replace a member of the ADVENT core group, the CVMP will agree on the required profile of the expert on the basis of the expertise needed at the time. The core group will be assisted by specialised topic groups, as required, involving experts chosen on the basis of their specialised knowledge on particular technologies and depending on the topics and related specific questions

In order to ensure the working efficacy of the group in meeting the objectives set by the CVMP, ADVENT core group shall comprise of 4-6 members, including the Chairperson, which will be assisted by specialised topic groups, as required. ADVENT core group members will generally be members of the CVMP. Members of other scientific committees, one of their working parties or national experts may also be nominated, subject to their inclusion on the EMA database of European experts, based on an extensive knowledge of the regulation of veterinary medicines.

All members of the ADVENT core group should each have a broad knowledge of the scientific areas related to marketing authorisation applications including regulatory science and the group should be able to cover all the main three scientific areas of the current dossiers with focus on profound knowledge in quality, safety and efficacy with respect to both pharmaceuticals and immunologicals.

The members of the ADVENT core group are identified by the CVMP on the basis of their broad knowledge as described above and specific scientific expertise in pharmaceutical and/or immunological quality, safety and/or efficacy.

Membership of ADVENT core group implies a commitment to participate actively in the work of the group and to attend the meetings of the group regularly.

Members are encouraged to take an active role in the activities of ADVENT.

When generating guidance on a particular novel therapy, the ADVENT core group will assemble a specialist expert group (topic group), usually of between four and six additional experts, with specialist knowledge of the therapy concerned. These experts may be members of committees, working parties, scientific advisory groups (SAGs) or ad hoc expert groups (AHEGs) for veterinary or human medicine, or experts from national authorities, research institutes, academia or independent experts. These groups of additional experts will be convened for a particular topic and then dissolved. At any one time the ADVENT core group may therefore have several specialist expert groups in operation.

It is recognised that the required expertise for new technologies may not exist within the regulatory community and that academic experts with the necessary specialist knowledge may have conflicts of interest. For this reason it is anticipated that ADVENT may need to make extensive use of the 'Expert Witness' concept as described in the European Medicines Agency 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

- ADVENT core group shall meet regularly at the Agency, however, ADVENT core group and topic groups will conduct the majority of their business remotely by correspondence, teleconference or videoconference.
- The dates of meetings are decided on an annual basis in consultation with ADVENT and the CVMP.

The reporting arrangements for the ADVENT core group to the CVMP and of the topic groups to ADVENT will be described in a separate working instruction.

5. Duration of activity (in the case of temporary working parties)

The group will operate for a period of three (3) years. After this time the work of the group will be reviewed by the CVMP and a proposal made for renewal of the mandate, amended as required and depending on the developments in the area of novel therapies and the requirements for CVMP work related to novel therapies.

6. Rules of procedure

6.1. Responsibilities of Chairperson

The Chairperson is responsible for the efficient conduct of the business of the ADVENT core group and shall in particular:

- Be a working member of the ADVENT core group;

- Plan the work of the group together with the Secretariat;
- Conduct and run the ADVENT core group 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 on issues discussed;
- Ensure that scientific grounds are adequately reflected in the ADVENT scientific considerations;
- Ensure the scientific consistency of advice;
- Co-ordinate together with the Secretariat the work of the group with that of the Agency's scientific committees, working parties and other relevant groups of the Agency;
- Report on the activities of the group to the Agency's scientific committees, working parties and other relevant groups of the Agency.

The responsibilities of the Chairperson of the ADVENT core group particularly include:

- To encourage all members to take a position on the scientific issue under debate and refrain from abstentions (unless such abstentions are unavoidable - e.g. due to conflict of interest);
- To ensure that all ADVENT core group members have the opportunity to express their views;
- To ensure that all the views expressed by the ADVENT core group are reflected and justified in the ADVENT scientific considerations to the CVMP;
- To summarise the conclusions of the ADVENT core group on each issue raised by the CVMP, for inclusion in the ADVENT scientific considerations to the CVMP;
- To provide feedback from the ADVENT discussions including divergent views to the CVMP plenary meeting;
- To propose to the CVMP to include or remove experts from the ADVENT core group registry, as appropriate.

6.2. Election of Chairperson

The CVMP shall appoint the Chairperson for the group. A Vice-Chairperson may also be appointed by the CVMP if the group considers it appropriate. The Chairperson of the ADVENT core group shall be elected for the duration of the mandate term.

Nominations for the Chairperson and the Vice-Chairperson, if applicable, should be submitted in writing to the Secretariat no later than the start of the CVMP meeting at which the election is to 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 be by absolute majority of the CVMP members (i.e. favourable votes by at least half of the total number of the CVMP members plus one) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. In the case of a tie in the decisive round, another round is organised with two remaining candidates. If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs

favourable votes by at least half of the total number of the CVMP members plus one, to be elected the Chairperson or the Vice-Chairperson, as the case may be.

In the event of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened.

6.3. Responsibilities of members

Membership implies a commitment to participate actively in the work of the group and to participate regularly in physical or remote meetings.

Members act as coordinators between the topic groups and the ADVENT core group, when needed.

6.4. Organisation of meetings

- The meetings will be held and minuted in English;
- The draft agenda for every meeting shall be circulated, together with the related documents, by the Secretariat, in consultation with the Chairperson, at least 7 calendar days before the meeting;
- The group shall prepare and agree an annual work plan for endorsement by the CVMP.
- When a member of the ADVENT 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

6.5. Topic groups

The majority of the work will take place within topic groups on very specific questions convened by the ADVENT core group, when needed, and consisting generally of at least one ADVENT core group member and in addition the experts necessary that have been chosen for their specialist knowledge of the therapy concerned. The topic groups will report exclusively to the ADVENT core group.

Recognising that product development now takes place on a global scale and that international alignment of regulatory frameworks for new veterinary therapies is in the interests of both industry and regulators, the topic group will take into account guidance generated in other regulatory areas. It is anticipated 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 Agency and FDA.

6.6. 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. 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 Agency, which is accessible to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the European Medicines Agency 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.

Considering that required expertise for new technologies may not exist within the regulatory community and that academic experts with the necessary specialist knowledge may have conflicts of interest, it is anticipated that the ADVENT may need to make extensive use of the 'Expert Witness' concept as described in the European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts (EMA/626261/2014).

6.7. Code of conduct

Members of the ADVENT core group and experts participating in ADVENT core group or any topic group activities shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012).

6.8. Contacts with interested parties

Where relevant, the ADVENT core group, and topic groups when considered appropriate, will establish contacts, on an advisory basis, with parties concerned with the manufacture and control of novel veterinary therapies.

When considered appropriate, oral or written presentations by interested parties can be made or may be invited during the development of advice.

6.9. General provisions

Members of the ADVENT core group 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.