EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2014
EMA/CVMP/139369/2014 Endorsed
Veterinary Medicines

Mandate, objectives and rules of procedure for the CVMP Ad Hoc Group on Novel Veterinary Therapies

1. General considerations

In recent years the Agency has received an increasing number of requests for advice related to therapies that are entirely new to the veterinary domain. To date, these have been channelled to the CVMP Scientific Advice Working Party (SAWP) in the form of requests for scientific advice. Recognising the need for less formal advice at an earlier stage of product development, in 2013 the Agency extended the scope of the Innovations Task Force (ITF) to enable companies to request briefings in relation to veterinary therapies.

Sufficient experience of providing advice with respect to novel veterinary 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 (e.g. monoclonal antibodies, stem cells). The guidance needs to be sufficiently detailed that it is useful to those developing new therapies yet sufficiently flexible that it does not constrain innovation or access to market.

In the human domain the requirements for advanced therapies are governed by specific legislation (Regulation (EC) No 1394/2007) and a dedicated committee has been established to provide opinions on advanced therapy medicinal products. The committee is supported by a range of expert groups dedicated to particular therapies. There is not sufficient demand or resource to establish an equivalent structure in the veterinary domain and therefore a leaner solution is required.

A flexible *ad hoc* Group on Novel Veterinary Therapies (ADVENT) is therefore established comprising a 'core' group of experienced regulators with a wide knowledge on the regulation of veterinary medicinal products that will be supplemented, as required, with experts chosen on the basis of their specialised knowledge on particular technologies. Specialised experts may be from the human or veterinary domain and may come from regulatory agencies, research institutes,

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

academia or be independent. Groups of experts will be convened to produce advice on particular therapies and will then disband until the 'core' group again requires their expertise.

This *ad hoc* group is established under Article 56 (2) of Regulation (EC) No 726/2004 which enables the scientific committees of the EMA to establish standing and temporary working parties.

2. Mandate and objectives

The *ad hoc* Group on Novel Veterinary Therapies is an *ad hoc* expert group of the CVMP.

The group will provide advice to applicants 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 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 advice provided by the *ad hoc* group will be advisory in nature and cannot be considered binding. It is not anticipated that the group will produce draft CVMP guidelines, at least during the first years of operation and until sufficient experience has been gained of a particular technology. Advice will generally take the form of 'Question and Answer' documents on a particular topic. Advice will be limited to scientific and technical topics as other sources exist for guidance and advice on regulatory or legal concerns.

The objective of the advice will be to describe an approach to the development of a novel technology 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 advice will be the best that can be given at the time it is published based on the current state of scientific knowledge. Advice will be updated in line with subsequent scientific developments.

The advice given will be general in nature and not related to a particular application. Applicants should apply for formal scientific advice when seeking advice specific to their particular product.

3. Composition and rules of participation

The group shall comprise a 'core' group of 4-6 members, which will be supplemented, as necessary, by additional experts nominated for their specialist expertise in a particular technology or therapy. Core group members will generally be members of CVMP or one of its Working Parties but national experts may also be nominated, subject to their inclusion on the EMA database of Experts, based on an extensive knowledge of the regulation of veterinary medicines.

When generating advice on a particular novel therapy, the core group will assemble a specialist expert 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, SAGs or Ad Hoc Expert Groups 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 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 the group may need to make extensive use of the 'Expert Witness' concept as described in the EMA policy on conflicts of interest (EMA/513078/2010).

4. Meeting frequency and method of operation

The core group will physically meet at least 2 times per year. The dates of the meetings shall be included in the work plan. The group will conduct the majority of their business remotely by correspondence, teleconference or videoconference.

It is anticipated that for each new area of therapy on which the group provides advice at least one physical meeting will take place between the core group and the respective group of specialised experts in order to initiate the work of the experts. Further physical meetings will be organised as necessary to complete the work, particularly if input is required from expert witnesses.

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 group will take into account guidance generated in other regulatory areas. It is anticipated that regular exchanges will take place with the US FDA in the context of the confidentiality arrangement that exists between the EMA and FDA.

5. Duration of activity

The group will operate for an initial period of two years. After this time the work of the group will be reviewed by CVMP and a proposal made for renewal of the mandate, amended as required.

6. Rules of procedure

6.1. Responsibilities of chairperson

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

- Plan the work of the group;
- Monitor 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 the regulatory and scientific consistency of advice;

- Co-ordinate the work of the group with that of the Agency's Scientific Committees, Working Parties and other relevant groups of EEA, Heads of Medicines Agency or European Commission;
- Report on the activities of the group to the Agency's scientific committees, working parties and other relevant groups of EMA, Heads of Medicines Agency or European Commission as appropriate.

6.2. Responsibilities of EMA secretariat

The EMA Secretariat shall provide technical, scientific, legal, regulatory and administrative support to group. This includes the following:

- Prepare for and co-ordinate the work of the group;
- Organise meetings and ensure timely circulation of meeting documents;
- Facilitate the necessary contacts between group and other bodies;
- Ensure adequate co-ordination of the work carried out by the group and other concerned groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the advice published by the group;
- Prepare, with the Chair, the agenda, table of actions and summary records of meetings ;
- Communicate, in a pro-active manner, any output of the group to interested parties;
- Transmit any recommendations of group to the relevant body for adoption and/or publication as appropriate.

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:

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 EMA Secretariat, in consultation with the chairperson, at least 7 calendar days before the meeting;
- The group is an advisory group of the CVMP which aims to produce guidance by consensus. Voting shall not take place and any issues on which agreement cannot be reached shall be presented by the Chair to CVMP for resolution.
- The group shall prepare and agree an annual work plan for endorsement by the CVMP

6.5. Drafting groups

The majority of the work will take place within drafting groups convened by the 'core' group and consisting generally of at least one core group member and between 4 and 6 experts chosen for their specialist knowledge of the therapy concerned. The drafting groups will report exclusively to the core group.

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.

Members and experts attending meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (Policy 0044) are applicable to members of the group and experts participating in the activities of the group.

6.7. Code of conduct

Members of the group and experts participating in EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

6.8. Contacts with interested parties

- Where relevant, the group 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 group as well as observers 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.