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Committee for Veterinary Medicinal Products (CVMP)

Mandate, objectives and rules of procedure for the CVMP temporary Working Party (tWP) on the ADRA project

1. General considerations

According to Article 139 of Regulation (EU) 2019/6 and to the Committee for Veterinary Medicinal Products ("CVMP") rules of procedure, temporary working parties may be established when work of a temporary or ad-hoc nature is required such as preparation of proposals on a specific scientific topic, or preparation of responses to specific questions raised by the Committee.

The CVMP has identified the need to support particular scientific or technical matters that require specialised knowledge for the 'Dosage Review and Adjustment of established Antibiotics (ADRA)' project. To achieve this, it is necessary to consult a group of experts with relevant expertise: pharmacokinetic/pharmacodynamic (PK/PD) modelling on antibiotics, efficacy of antibiotics, target animal safety ("TAS"), withdrawal periods/withdrawal period modelling, and environmental risk assessment ("ERA").

The CVMP has therefore established a temporary Working Party ("tWP") to deal with specific aspects of the assessment and respond to CVMP questions related to the ADRA project.

The group will be reporting to the Committee via its Chairperson, who will keep the appointed rapporteur and co-rapporteur informed for the respective scientific advice(s) conducted under Article 141(1)(i) of Regulation (EU) 2019/6.

The tasks identified by the CVMP should be included in the work plan of each working party to be adopted by the Committee.

2. Mandate and objectives

The temporary Working Party on the ADRA project (hereafter "ADRA tWP") is established to provide relevant expertise and input to the CVMP on matters related to the ADRA project including, but not limited to, the following tasks:

- Provide ad-hoc support to the (co-)rapporteurs on matters related to the preparation of the respective scientific advices under Article 141(1)(i) of Regulation (EU) 2019/6. The aim of the scientific advices would be to review and refine the dosage regimen (i.e., dose, frequency and

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treatment duration)[1] in the product information of selected antimicrobial substances, ensuring the continued efficacy and safety of antibiotics and minimising the occurrence of antimicrobial resistance in the Union.

- Provide expert advice on specific questions addressed to the ADRA tWP by the CVMP in relation to the dosage review and adjustment of the selected combination of 'antimicrobial active substance+pharmaceutical form+route of administration+target species+disease'. This would also include the implications that a change in the dosage regimen of a veterinary medicinal product ("VMP") might have for TAS and also, in the case of food-producing species, for the withdrawal period, as well as for the ERA. The use of advance analytics tools for the delivering of the expert advice should be explored.

The mandate and objectives of the ADRA tWP shall be agreed by the CVMP and reviewed at the end of the period for which the ADRA tWP has been created or after three years, whichever comes first.

3. Composition and rules of participation

The ADRA tWP is a multidisciplinary working party, composed of a limited number of experts. It includes 2-3 members per relevant area of expertise as described under part 1 "General considerations" above, appointed by the CVMP based on nominations from the CVMP or the EMA.

In order to ensure that the mandate and objectives of the ADRA tWP can be accomplished, the following areas of expertise are considered necessary:

- Pharmacokinetic/pharmacodynamic (PK/PD) modelling on antibiotics;
- Efficacy of antibiotics;
- Target animal safety ("TAS");
- Withdrawal periods/withdrawal period modelling;
- Environmental risk assessment ("ERA").

Members of CVMP and its working parties, or other national experts may be nominated, subject to their inclusion on the EMA database of European experts. All members of the ADRA tWP must be registered in the European Experts database and have a valid (up-to-date) declaration of interests (DoI), which will be assessed according to the principles and rules set out in the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (Policy 0044).

The members of the ADRA tWP are selected based on their scientific knowledge in the above-mentioned areas of expertise, and preferably with knowledge of the regulatory framework for veterinary medicinal products in the European Union.

When selecting members of the ADRA tWP, efforts should be made to establish a stable and experienced group of experts that will be available for the whole ADRA project (currently estimated to cover 3-5 years).

The list of members of the ADRA tWP is publicly accessible on the Agency's website.

[1] The intention is to review/adjust both the dose and the treatment duration, if possible.

The ADRA tWP will be led by a Chairperson; a committee member, an alternate or a member of the tWP may be elected to fulfil this role.

Membership of a working party implies a commitment to participate actively in the activities outlined in the workplan of that working party and to regularly attend the entire meetings of the working party, providing written input between meetings when needed.

ADRA tWP members are expected to support the activities outlined in the ADRA tWP workplan and should take on coordination or lead role within the activities of WPs and expert groups within that tWP. Additionally, they are to provide scientific leadership across the European Medicines Regulatory Network (EMRN) on relevant topics, including trainings.

Failure to comply with these expectations may lead to the termination of membership of a tWP member.

In specific circumstances, members may be temporarily replaced; i.e., a member may nominate a replacement to participate in those exceptional cases where he or she is unable to attend a meeting.

4. Meeting frequency

The meeting frequency of the ADRA tWP is based on the needs related to the requests received from the CVMP and the ADRA tWP timetable. All meetings will be conducted remotely, unless otherwise agreed by the CVMP or EMA Secretariat. The rapporteur and co-rapporteur for the procedure under Article 141(1)(i) of Regulation (EU) 2019/6 can also participate in the meetings but are not considered as members of the ADRA tWP, unless they are appointed as members in their own right.

5. Duration of activity

The ADRA tWP is constituted for the period of time needed to complete the tasks assigned by the CVMP (currently estimated to cover 3-5 years). After completion, the CVMP will re-evaluate the need for the group.

The group can be put on hold, reinstated and/or its composition modified at any time depending on the ongoing needs.

6. Rules of procedure

6.1. Responsibilities of Chairperson

The Chairperson shall be a working member of the ADRA tWP who will report back to the Committee and CVMP (co-)rapporteurs and is responsible for the efficient conduct of the business of the ADRA tWP and shall in particular:

1. Prepare and run the ADRA tWP meetings.
2. Co-ordinate together with the EMA Secretariat to align the work of the ADRA tWP with other relevant groups and working parties of the EMA.
3. Monitor, together with the EMA Secretariat, that the rules of procedure are respected.
4. Contribute, with the EMA Secretariat, to setting up the agendas for the ADRA tWP meetings and chair the meetings.

5. Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the ADRA tWP.
6. Aim to achieve consensus and ensure that scientific grounds are adequately reflected.
7. Ensure, together with the Secretariat, the regulatory and scientific consistency of the scientific advice provided.
8. Report on the activities of the ADRA tWP and provide feedback to the CVMP (co-)rapporteurs or other working parties as appropriate.

6.2. Election of Chairperson

The Chairperson of a working party shall be elected by the members of the Committee for a term of three years, which may be renewed once. The election of the 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 CVMP Rules of Procedure.

Upon completion of their mandate, the Chairperson may continue as an ADRA tWP member if he/she was elected from the tWP. If he/she was elected from the Committee, he/she can retain the status as ADRA tWP member if the size of the group allows.

A CVMP member, an alternate or a member of the ADRA tWP may be elected by the CVMP to fulfil this responsibility.

A call for interest is launched for the election of the Chairperson. Both ADRA tWP members and Committee members or alternates can express interest to be a Chairperson.

The start date of the mandate of a new Chairperson is the day following the end of the mandate of the current Chairperson. If there is a nomination for a position currently not filled, the start date of the mandate is the last day of the CVMP meeting during which the candidate is elected.

In the event that there is no ADRA tWP Chairperson available to chair a meeting, the CVMP chairperson shall appoint a temporary Chairperson for a single meeting or until a Chairperson is elected by the CVMP via the normal election procedure. The temporary Chairperson shall be appointed from amongst the ADRA tWP members.

In the event of resignation of the Chairperson, a new election will be scheduled as soon as possible.

6.3. Organisation of meetings and reporting arrangements

Meeting documentation will be distributed to an agreed list of recipients drawn up by the EMA Secretariat with the agreement of the Chairperson. Although formal agenda and minutes are not strictly required, meetings require objectives set in advance and a concrete work output, such as a status report on the progress which shall be monitored by the EMA secretariat.

Additional experts may be invited to participate in specific discussions or to listen to the meetings.

The ADRA tWP shall prepare an annual work plan for adoption by the CVMP which shall include tasks identified by the CVMP in the mandate and any other topics for CVMP's consideration. The work plan shall be regularly reviewed and updated as necessary with the agreement of the CVMP.

6.4. Guarantees of independence

The members of the ADRA tWP shall not have any financial or other interests in the pharmaceutical industry, which 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 relevant interests are entered in the European Experts database, which is accessible to the public.

EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) applies to all ADRA tWP members, as well as to any additional experts attending tWP meetings.

ADRA tWP members and any other experts attending ADRA tWP meetings shall declare at the beginning of each meeting any interests which may be prejudicial to their independence with respect to the points of the agenda. This will be documented in the meeting minutes.

6.5. Code of conduct

Members of the ADRA tWP and all other attendees to their meetings and activities shall abide by the principles set out in the European Medicines Agency Code of Conduct[2].

7. EMA Secretariat

Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the ADRA tWP. This includes the following:

- Provide legal, regulatory, technical and scientific support to the Chairperson and other members of the ADRA tWP.
- Organise meetings and ensure, together with the respective Chairperson, the timely availability of meeting documents.
- Ensure adequate co-ordination of the work carried out within ADRA tWP, the CVMP (co-)rapporteurs and other concerned working parties.
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the ADRA tWP in cooperation with the Chairperson, as appropriate.
- Support the preparation of relevant meeting records where needed (record of attendance, declaration of interests at the beginning of the meeting, objectives discussed, and decisions taken shall be maintained for each meeting, even if formal minutes are not produced), in consultation with the Chairperson.
- Contribute to the identification of experts.
- Liaison with stakeholders, including concerned MAHs, on behalf of the ADRA tWP/CVMP, as appropriate.

The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission, may attend all meetings of the ADRA tWP.

[2] https://www.ema.europa.eu/en/about-us/how-we-work/handling-competing-interests

8. General provisions

The members of the ADRA tWP shall be bound to individual professional secrecy and not to disclose any information, even after the cessation of their duties.

When participating in international or other fora on behalf of the EMA/CVMP, members shall get prior agreement by the EMA/CVMP and ensure that the views expressed are those of the EMA/CVMP.

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