7 October 2025
EMA/CVMP/314118/2025
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the ADRA temporary Working Party (tWP) 2025-2026

Chairperson	Status
Chair: *to be appointed* Co-Chair: *n/a*	Adopted by CVMP in October 2025

The activities outlined in the work plan for 2025-2026 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency following the applicable procedure.

1. Meetings scheduled for 2025-2026

Plenary meetings: based on the concrete needs, approximately 3-4 official meetings per scientific advice* (virtual; Chair plus ADRA tWP members, designated CVMP rapporteur and co-rapporteur for the specific scientific advice procedure under Article 141(1), point (i), of Regulation (EU) 2019/6, if needed).

2025

October 2025 – virtual meeting to outline the tasks for the CVMP rapporteurs and ADRA tWP experts, and to organise workload distribution across the various teams based on their areas of expertise.

2026

Dates to be confirmed

**Refers to the meetings in which the participation of experts from all relevant areas of expertise is essential, i.e., to share individual assessments and facilitate discussion within the designated sub-groups. Additionally, members of the respective sub-groups may choose to hold informal meetings among themselves to further exchange insights and align on specific topics within their domain.*

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Scientific advice procedures under Article 141(1), point (i), of Regulation (EU) 2019/6

In the context of the Dosage Review and Adjustment of established veterinary Antibiotics (ADRA) project, the ADRA tWP is tasked with providing ad-hoc support to the CVMP (co-)rapporteurs on matters related to the preparation of the respective scientific advice under Article 141(1), point (i), of Regulation (EU) 2019/6. Pursuant to this provision, the CVMP is empowered to provide scientific advice on the use of antimicrobials in animals in order to minimise the occurrence of resistance in the Union. The aim of each scientific advice delivered in the context of the ADRA project would be to review and refine the dosage regimen (i.e., dose, frequency and treatment duration)[1] in the product information (PI) of selected antimicrobial substances. This ensures continued efficacy and safety of antibiotics and minimising the occurrence of antimicrobial resistance in the Union.

The CVMP will use non-experimental approaches to refine the relevant PIs (i.e. not necessitating the generation of new data), including pharmacokinetics/pharmacodynamics (PK/PD) integration for dose review and adjustment, PK modelling for withdrawal period adjustment, and scientific review approaches to address the safety of both target animals and the environment, and the treatment duration, if possible. It will not be possible to request new data from marketing authorisation holders. Therefore, the CVMP will need to improve the PI using the data already available and modelling techniques as indicated above.

A clear scope will be identified before starting each procedure, including which veterinary medicinal products (VMPs) will fall under the scope of each scientific advice (i.e., a group of VMPs containing a specific active substance, administered via the same route and indicated for a target species and a particular disease).

In general, the review should aim to preserve efficacy and availability while avoiding loss of VMPs or indications.

2.1. Number of scientific advice procedures provided

It is intended to start the ADRA project with the forecast of one procedure per year, i.e. the CVMP to deliver one scientific advice per combination of "antimicrobial substance-target species-route of administration-pharmaceutical form-disease'', which would facilitate the assessment and ultimately the national-level implementation of the outcome. Where feasible, the pharmacokinetic modelling used for that combination could be applied for additional diseases, which would be part of the same scientific advice outcome, thereby optimising the use of resources. This approach will be followed on a case-by-case basis.

2.2. First procedure under Article 141(1), point (i), of Regulation (EU) 2019/6

2.2.1 *''Amoxicillin (single active substance) – pig - oral use (in drinking water or in feed) – respiratory indications''*

Action:

- Provide expert advice and input on specific aspects of the assessment and respond to CVMP questions in relation to the dosage review and adjustment of antibiotics containing amoxicillin as a single active substance, authorised in pigs for use in drinking water or in feed, specifically for respiratory indications. This would also include the implications that a change in the dosage regimen of a VMP might have for target animal safety ("TAS") and, in

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

the case of food-producing species, for the withdrawal period, as well as for the environmental risk assessment ("ERA").

- Provide ad-hoc support to the CVMP (co-)rapporteurs on matters related to the preparation of the respective scientific advice under Article 141(1), point (i), of Regulation (EU) 2019/6.

Draft scientific advice report to be discussed/adopted by the CVMP.

Priority 1. Start date: November 2025, Completion date: Q4 2026.

Comments: 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 containing amoxicillin as a single active substance, authorised in pigs for use in drinking water or in feed, specifically for respiratory indications. To achieve this, the Committee has tasked the ADRA tWP, under the responsibility of the appointed rapporteur and co-rapporteur, with leading on the delivery of scientific assessment in the following areas: PK/PD modelling on antibiotics, efficacy of antibiotics, TAS, withdrawal periods/withdrawal period modelling, and ERA.

3. Regulatory activities

3.1. Revision of legislative documents

None foreseen.

3.2. Coordination with other CVMP working parties

3.2.1 Coordination with specific CVMP working parties

3.2.1.1. Coordination with AWP, SWP, EWP-V, ERAWP

Action: On request.

Comments: n/a

3.3. Activities with external parties

3.3.1 Meeting with interested parties

None foreseen.

4. Organisational matters

4.1. List of adopted organisational documents

- Mandate, objectives and rules of procedure for the ADRA temporary Working Party (tWP) (EMA/CVMP/182608/2025)

4.2. List of organisational documents to be developed/revised in the forthcoming 2 years

None foreseen.