EXPERT GROUP MEETING, 24 APRIL 2026

RECOMMENDATIONS

The Expert Group noted that the terms of the marketing authorisation provide for the indications, target species and conditions of use of the veterinary medicinal product (including dosage and withdrawal periods for food producing species) for which safety and efficacy have been demonstrated. It was also noted that marketing authorisations typically do not cover all the scenarios that may be encountered in clinical practice.

The Expert Group also noted that Article 106(1) of Regulation (EU) 2019/6 is to be read and implemented in conjunction with Articles 112 to 114 ("cascade use").

The Expert Group discussed scenarios encountered in clinical practice and made the following recommendations:

1) The cascade use aims at addressing specific animal health/welfare needs where a suitable veterinary medicinal product is not available ("unmet clinical need"). However, the cascade use is not aimed at addressing widespread lack of efficacy or safety concerns arising from the use of a veterinary medicinal product in accordance with the terms of the marketing authorisation (*i.e.* systematic deviation from the terms of the marketing authorisation unrelated to specific health conditions of individual animals).

2) The cascade use includes cases where there is no veterinary medicinal product authorised to treat the relevant condition or target species, or when that veterinary medicinal product is not available. It also covers cases where a specific clinical setting is not addressed under the terms of the marketing authorisation.

3) Further, the terms of the marketing authorisation reflect the conditions of use that have been generally demonstrated to be efficacious and safe. However, individual responses may vary. If, after initiating treatment, the treated animal does not adequately respond or if it experiences adverse events that need to be addressed, the cascade use is justified as, in such circumstances, the terms of the marketing authorisation are not suitable to address the specific clinical needs of the animal *(i.e.* the specific clinical needs are not covered by the terms of the marketing authorisation). The lack of efficacy or adverse events should be reported.

4) Resort to the cascade use may also be necessary to comply with legal/regulatory requirements.

5) There may be other clinical circumstances where the cascade use may be justified, if no suitable veterinary medicinal product is authorised/available and the veterinarian considers that such use is in the best interest of the animal.

Examples of uses under Articles 112 to 114 of the Regulation[1]

Scenarios of unmet clinical need	Cascade use allowed?
Specific animal subset not covered by the terms of the marketing authorisation (*e.g.* pregnant animal, new born, very old animal).	Yes.
Underlying health conditions of the animal are not covered by the terms of the marketing authorisation *(e.g.* renal or liver impairment, gastrointestinal ulcer, hypersensitivity).	Yes.
Concomitant use with other veterinary medicinal products that is not specifically addressed in the marketing authorisation.	Yes.
Animal does not adequately respond to treatment (lack of efficacy).	Yes. The event should be reported.
Treated animal suffers from adverse events which require clinical response.	Yes. The event should be reported.
The specific clinical setting is contraindicated.	Only if an alternative veterinary medicinal product covering the clinical needs of the animal is not available.
Use for a more severe condition than the one specifically foreseen in the marketing authorisation *(e.g.* marketing authorisation only covers early stages of disease and treated animal has an advanced stage).	Only if an alternative veterinary medicinal product covering the more severe condition is not available.
Route of administration not covered by the marketing authorisation is necessary to address the specific clinical need of the animal.	Only if an alternative veterinary medicinal product with the required route of administration is not available.
A specific vaccination schedule not covered by the marketing authorisation is required to comply with legal/regulatory requirements.	Only if an alternative veterinary medicinal product with the required vaccination schedule is not available.

As regards antiparasitics, the group acknowledged that there is a problem of resistance for some parasites in some target species. The situation varies across the Union and it was noted that this is an issue that cannot be solved through a single action.

[1] The examples contained in this Annex are provided for illustration purposes and are not meant to be exhaustive.