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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/D4/ALH/DM/ci (2023)1091501

Sent by e-mail only

Subject: **Implementing measures under Article Art 115(5) of Regulation (EU) 2019/6 as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months**

Dear Ms Cooke,

According to Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products ('VMP Regulation'), the Commission is to adopt, by means of an implementing act, a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months ("the list" hereafter).

Article 153(4) requires the Commission to adopt the implementing act at the latest by 29 January 2025. In light of the strict timeline set for the adoption of the required implementing act, I would like to request the Agency to provide scientific advice to inform the adoption of the measure on the substances that may be considered for inclusion in the list, by taking into account the following:

- The overall objective of the VMP Regulation to increase the availability of VMPs.
- Experience gained with the application of the current list of substances essential for the treatment of Equidae as listed in Regulation (EU) 1950/2006 as amended by Regulation (EU) 122/2013. For this purpose, the Agency should review the existing entries in the current list and carry out a survey among national competent authorities and relevant stakeholders, on the possible need to add other substances as a result of newly available evidence and the need for updating the information on use, advantages and alternatives of the entries in the current list.

Ms Emer Cooke
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- A substance should only be considered as essential if i) no satisfactory alternative treatment for an indication is authorised for food-producing animals of the equine species or ii) it brings added clinical benefit compared to other treatment options and where the condition would, if untreated, put at risk animal or public health, or cause unacceptable suffering for the animal.
- A substance should only be considered as bringing added clinical benefit where no medicinal product authorised for food producing animals of the equine species would yield equally satisfactory results based on robust evidence in terms of successfully treating the animal, avoiding unnecessary suffering for the animal, or ensuring the safety of those treating the animal.
- Substances listed in table 1 of the Annex to Commission Regulation (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, including those not having an MRL status in equine species, should not be considered for inclusion in the list. Substances included in table 2 of that Annex should be considered unless there are concerns related to consumer protection.
- Substances listed in the Annex to Commission Implementing Regulation (EU) 2022/1255 designating antimicrobials or groups of antimicrobials reserved for human treatment of certain infections in humans, should not be considered.
- Coherence should be ensured with the ongoing work of the EMA on its scientific advice to the Commission, and the resulting implementing act, setting a list of antimicrobials, which shall not be used in accordance with Articles 112, 113 and 114 or which may be used in accordance with these articles subject to certain conditions.
- The overall objective of maintaining a high level of consumer protection should be kept in mind. Therefore, substances can only be included in the list of essential substances when they do not compromise consumer safety.
- The advice should consist of a proposed list of substances along with the aimed indication, explanation of use, identification of alternatives and a justification for the inclusion of each of the substances.

Examples of the relevant excerpts from the VMP Regulation are included in Annex I for your convenience.

We would appreciate receiving your scientific advice by 31 March 2024. We would also ask that the Agency updates our services on the main progress of its work quarterly.

We would like to thank you for your collaboration.

Yours sincerely,

[e-signed]
Sandra GALLINA

Enclosure: Annex I

c.c.: Mr I. Claassen (EMA)
Ms E. Zamora Escribano, Mr A. Las Heras, Mr D. Minne (SANTE)

Annex I

EXCERPTS FROM THE VMP REGULATION CONTAINING REFERENCES TO THE LIST OF SUBSTANCES WHICH ARE ESSENTIAL FOR THE TREATMENT OF EQUINE SPECIES, OR WHICH BRING ADDED CLINICAL BENEFIT COMPARED TO OTHER TREATMENT OPTIONS AVAILABLE FOR EQUINE SPECIES AND FOR WHICH THE WITHDRAWAL PERIOD FOR EQUINE SPECIES SHALL BE SIX MONTHS

Article 115(5)

Withdrawal period for medicinal products used outside the terms of the marketing authorisation in food-producing animal species

…

5. By way of derogation from Article 113(1) and (4), the Commission shall, by means of implementing acts, establish a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 153

Transitional provisions regarding delegated and implementing acts

…

4. Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Article 109(1) and the implementing acts referred to in Articles 17(2) and (3), 93(2), 109(2) and 115(5) at the latest by 29 January 2025. Such delegated and implementing acts shall apply at the earliest on 28 January 2022.

Article 158

Review of measures regarding animals of the equine species

No later than 29 January 2025, the Commission shall present a report to the European Parliament and to the Council on its assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries, to be accompanied by any appropriate action by the Commission taking into account, in particular, public health, animal welfare, the risks of fraud and the level playing field with third countries.