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Veterinary Medicines Division

Background to the addendum to the scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products

European Commission's request for reviewing the additional scientific information provided for the substance midazolam regarding 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

Following the publication of the Agency's advice[1] under Article 115(5) of Regulation (EU) 2019/6, the European Commission received two communications from the Association of Veterinary Anaesthetists (AVA) and the European College of Veterinary Anaesthesia and Analgesia (ECVAA) questioning the recommendation to remove midazolam from the list. A first letter (Ares(2024)6980209) was received by the European Commission on 27 September 2024; a second letter (Ares(2024)8365149), with additional references to those mentioned in the Agency's advice, was received on 22 November 2024.

Considering the letters and the discussion that took place at the Veterinary Standing Committee meeting of 27 November 2024, the European Commission requested from the Agency a review of the additional evidence for midazolam provided in the letters, supported by a complementary literature search to ensure that the latest available evidence was captured. The request was received on 28 November 2024, and proposed deadline was by the end of February 2025.

Considering this, the expert group providing the recommendations to the CVMP was reconvened to conduct the review of the additional data provided. The same principles outlined in sections 1 (terms of reference and scope) and 2 (methodology) of the advice were followed. Please refer to these sections in the Agency's advice for further details. For midazolam, considering alternatives available, the discussion focused on whether the substance brings added clinical benefit compared to other treatment options and where the condition to treat would, if untreated, put at risk animal or public health, or cause unacceptable suffering of the animal.

With due note of the short deadline proposed by the European Commission, and with the aim to complete in time the two-tiered assessment agreed for all substances deemed essential or bringing added clinical benefit, the expert group decided to exceptionally conduct the determination of the

[1] With reference to the scientific advice provided to the European Commission on 19 July 2024, accessible via this link.

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added clinical benefit of the substance and the evaluation of the consumer safety aspects of the proposed substance in parallel.

The outcome of this two-tiered approach is presented as an addendum to the scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products (EMA/CVMP/159047/2023).