18 April 2024
EMA/CVMP/151185/2024
Committee for Veterinary Medicinal Products (CVMP)

Call for scientific data for use in CVMP assessment work of ketoprofen: review of the CVMP opinion for the establishment of maximum residue limits

Submission period: 30 April 2024 – 31 August 2024

Pursuant to Article 11 of Regulation (EC) No 470/2010 the European Commission requested the CVMP to review its previous opinion for the establishment of maximum residue limits (MRLs) for ketoprofen in view of concerns relating to residue concentrations in tissues from the target populations (i.e. bovine, porcine and *Equidae*) that may exceed the ADI.

The CVMP invites all interested parties such as pharmaceutical industry, learned societies, governmental institutions as well as EU and EEA-EFTA Member States **to submit scientific data** for use in the review of the residue assessment of ketoprofen. The CVMP is seeking to obtain any relevant data, not already reported when a "No MRL required" status was agreed by the CVMP for ketoprofen in the aforementioned species (please refer to EMEA/MRL/020/95 and EMEA/MRL/076/96-FINAL), **that may be available on the pharmacokinetics, residue depletion, analytical methods and monitoring results of ketoprofen in bovine, porcine and *Equidae*** and that could impact the final conclusions.

The CVMP currently considers that MRLs for ketoprofen could be established in tissues and milk of bovine, porcine and *Equidae* as follows:

Tissue	MRL
Muscle	20 µg/kg
Fat	20 µg/kg
Liver	20 µg/kg
Kidney	150 µg/kg
Milk	20 µg/kg

With these values, the maximum theoretical consumer intake represents 52.3% of the ADI for cattle and 54.5% of the ADI for swine. In both cases, a portion of the ADI is available for a possible future extension to eggs.

Scientific contributions should be sent to: mrl@ema.europa.eu. A list of all scientific contributions and their references should be enclosed. The name and contact details of the interested party providing the scientific contributions is required.

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

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The CVMP will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should also take duly into account the rights of interested parties, as the documentation provided will be used for the review of the assessment for the establishment of MRLs for ketoprofen. Such revision is underpinned by an assessment report, which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

As regards copyright, it is important to clarify that the use by the CVMP of the bibliographic material is entirely for a non-commercial purpose. As its non-commercial use by the Committee is guaranteed, any interested party will not incur any liability as to the use intended by the CVMP by forwarding the bibliographic literature to the Committee. The CVMP is in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

Documents should be submitted in English where possible since this is the working language of the CVMP, but documents in other official languages of the European Union will be accepted. In order to facilitate the assessment, the CVMP appreciates the submission of an abstract in English when original references are provided.

Conditions for data submissions

Scientific contributions should be relevant to the purpose of the assessment. The acceptance of scientific contributions will be based on compliance with the following general criteria:

1. Scientific contributions should be classified by the interested party as (i) peer-reviewed data; or (ii) non peer-reviewed data. The Agency encourages submission of peer-reviewed data/publications (not just the reference) as the most relevant and reliable documents. Non peer-reviewed data can be taken into consideration provided that they are of an adequate quality.
2. A document providing a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search should be enclosed.