

8 November 2024 EMA/CVMP/495258/2024 Veterinary Medicines Division

MRL summary opinion<sup>1</sup>

## Ketoprofen

All ruminants, porcine and Equidae

On 7 November 2024 the Committee for Veterinary Medicinal Products adopted an opinion<sup>2</sup> recommending the modification of the entry for ketoprofen in table 1 of the Annex to Regulation (EU) No 37/2010 of 22 December 2009. Maximum residue limits for ketoprofen in bovine and porcine are recommended. Furthermore, with reference to Article 5 of Regulation (EC) No. 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed that the proposed maximum residue limits could be extrapolated to all ruminants and *Equidae*. Therefore, the amendment of the entry for ketoprofen in table 1 of the Annex to Regulation (EU) No 37/2010 of 22 December 2009, is recommended as follows:

| Pharmaco-<br>logically<br>active<br>substance | Marker<br>residue | Animal<br>species               | MRLs   | Target tissues   | Other<br>provisions  | Therapeutic classification |
|---|-------------------|---------------------------------|--|--|--|----------------------------|
| Ketoprofen                                    | Ketoprofen        | All ruminants, porcine, Equidae | 50 μg/kg<br>20 μg/kg<br>20 μg/kg<br>50 μg/kg<br>20 μg/kg | Muscle Fat Liver Kidney Milk                           | For porcine species the fat MRL relates to 'skin and fat in natural proportions'         | NO ENTRY                   |
|   | Ketoprofen        | Poultry                         | 10 μg/kg<br>30 μg/kg<br>10 μg/kg<br>10 μg/kg             | Muscle Skin and fat in natural proportion Liver Kidney | Not for use in<br>animals from<br>which eggs<br>are produced<br>for human<br>consumption | NO ENTRY                   |

<sup>&</sup>lt;sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision.

<sup>&</sup>lt;sup>2</sup> Applicants may request re-examination of any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to request such re-examination within 15 days of receipt of the opinion.

