# Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

## Procedure no: EMEA/V/MRL/005009/FULL/0002

## Name of the substance: Bupivacaine (INN)

### Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Medical Ethics UK Ltd submitted to the European Medicines Agency on 23 April 2019 an application for the establishment of maximum residue limits for bupivacaine in bovine.

On 12 September 2019 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 20 March 2020.

### Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for bupivacaine in accordance with the following table:

| Pharmaco-logically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions | Therapeutic classification |
|---|---|---|---|---|---|---|
| Bupivacaine | NOT APPLICABLE | Bovine | No MRL required | NOT APPLICABLE | For use in calves up to 2 months of age only. For cutaneous and | Local anaesthetic |

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The Norwegian and Icelandic CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

**Annex I**

**European public MRL assessment report (EPMAR)**