8 September 2022
EMA/484831/2023
Veterinary Medicines Division

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

## Procedure no: EMEA/V/MRL/003477/EXTN/0004

## Name of the substance: Praziquantel (INN)

### Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009, Vethellas AEBE submitted to the European Medicines Agency on 27 July 2021 an application for the extension of maximum residue limits for praziquantel to fin fish.

On 12 May 2022, the Committee for Veterinary Medicinal Products adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 9 August 2022.

### Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the extension of maximum residue limits for praziquantel to fin fish. 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 recommends extrapolation of the "No MRL required" entry established in ovine species to other ruminants except cattle, in accordance with the following table:

| Pharmaco-logically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions | Therapeutic classification |
|---|---|---|---|---|---|---|
| Praziquantel | NOT APPLICABLE | All ruminants except bovine, *Equidae* | No MRL required | NOT APPLICABLE | NO ENTRY | NO ENTRY |
| | Praziquantel (sum of isomers) | Fin fish | 20 µg/kg | Muscle and skin in natural proportions | NO ENTRY | NO ENTRY |

The Norwegian CVMP member agrees 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 analytical method for monitoring of residues is appended to 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)