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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all veterinary medicinal products containing active substances belonging to the class of flukicides for which no maximum residue limit has been established in milk and which are intended for use in ruminants producing milk for human consumption

International non-proprietary names (inn): clorsulon, closantel, nitroxinil, rafoxanide and triclabendazole

Background information

Flukicidal substances are anthelmintics which are active against parasites belonging to the class of trematodes.

On 14 February 2011, the European Commission initiated a referral procedure under Article 35 of Directive 2001/82/EC, as amended, for all veterinary medicinal products containing active substances belonging to the class of flukicides for which no maximum residue limit has been established in milk intended for use in all ruminants producing milk for human consumption. The flukicidal substances for which a maximum residue limit has not been established in milk and that are included as active substances in authorised veterinary medicinal products in the Member States (EU/EEA) are clorsulon, closantel, nitroxinil, rafoxanide and triclabendazole. The CVMP was therefore requested to give its opinion as to whether measures are necessary to ensure that the use, during the non-lactating period, of veterinary medicinal products containing clorsulon, closantel, nitroxinil, rafoxanide and triclabendazole, would not lead to residues in milk that, combined with residues of these flukicidal substances from other foodstuffs, would result in consumer exposure exceeding the acceptable daily intake.

[1] Article 35 of Directive 2001/82/EC, as amended

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The referral started on 9 March 2011. The Committee appointed Mr G. J. Schefferlie as rapporteur and Dr B. Urbain as co-rapporteur. Supplementary information was provided by some of the applicants/marketing authorisation holders by 26 August 2011. Written explanations were provided by a group of marketing authorisation holders on 11 January 2012. Oral explanations were given by a group of marketing authorisation holders on 8 February 2012.

Based on the evaluation of the available data, the CVMP adopted, on 8 March 2012, an opinion recommending variations of the marketing authorisations for the veterinary medicinal products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance and for the veterinary medicinal products administered as pour-on to cattle containing triclabendazole and moxidectin.

On 23 March 2012, MERIAL notified the Agency of their intention to request a re-examination of the CVMP opinion of 8 March 2012.

During its meeting of 11-13 April 2012 the CVMP appointed Dr C. Muñoz as the rapporteur and Dr E. Persson as the co-rapporteur for the re-examination procedure.

The detailed grounds for the re-examination request were submitted by MERIAL on 2 May 2012. The re-examination procedure started on 3 May 2012. The issues considered during the re-examination related to the recommended amendments of section 4.11 Withdrawal period(s) of the summaries of product characteristics for the veterinary medicinal products containing nitroxinil that are administered to cattle. Oral explanations were given by MERIAL on 16 May 2012.

On 14 June 2012 the CVMP adopted a final opinion confirming the recommendation, included in its opinion of 8 March 2012, that variations are necessary in the marketing authorisations for the veterinary medicinal products containing clorsulon, closantel, nitroxinil, rafoxanide or triclabendazole as a single active substance and for the veterinary medicinal products administered as pour-on to cattle containing triclabendazole and moxidectin in order to amend the summaries of product characteristics and package leaflets in line with recommended by the CVMP changes in the product information.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summaries of product characteristics and package leaflets in Annex III.

The final opinion was converted into a Decision by the European Commission on 19 November 2012.