



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### DIMETRIDAZOLE (2)

#### SUMMARY REPORT

- 1 Dimetridazole had previously been scientifically assessed according to the requirements of Council Regulation (EEC) 2377/90. The measures taken according to this assessment had been published in Commission Regulation (EEC) 675/92<sup>1</sup>.
- 2 Dimetridazole is a nitroimidazole compound used for the treatment of histomoniasis in turkeys, trichomoniasis in pigeons, genital trichomoniasis in cattle and the prevention and treatment of dysentery.
- 3 Dimetridazole was shown to be mutagenic in *in vitro* mutagenicity studies using bacteria, possibly due to the activities of bacterial nitroreductases. Other genotoxicity studies showed negative results and equivocal results were seen in carcinogenicity studies.
- 4 A provisional MRL of 10 µg/kg for all residues with intact nitroimidazole structure was established for the tissues muscle, liver, kidney and fat applicable to all food-producing species. A time period terminating on 1 January 1994 was applied to the provisional MRL pending further information on the possible carcinogenicity, the nature of bound residues and the identity of a market metabolite.
- 5 Dossiers addressing the questions raised by the previous scientific evaluation of this compound by the CVMP were received from industry.
- 6 To allow for the assessment of the new information submitted, the time period applying for the provisional MRL is extended until 1 January 1995.

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<sup>1</sup> OJ No L73, 19.3.92, p.8