The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

OXYTETRACYCLINE, TETRACYCLINE, CHLORTETRACYCLINE

SUMMARY REPORT (2)

1. Tetracyclines had previously been scientifically assessed[1] 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[2].

2. Following provisional MRLs for the parent drug for all substances belonging to the tetracycline group were established : 600 µg/kg for kidney, 300 µg/kg for liver, 100 µg/kg for muscle, 200 µg/kg for eggs and 100 µg/kg for milk, applicable to all food-producing species. The combined total residues of all substances within the tetracycline group should not exceed the limits indicated. A time period terminating on 1 January 1994 was applied to the provisional MRLs.

3. Further information on validated analytical methods to determine the various compounds of the tetracycline group was required.

4. Dossiers addressing the questions raised by the previous scientific evaluation of this group of compounds by the CVMP were received from industry and it became evident that scientific studies relating to this matter are currently in progress,

5. According to Article 4 of Council Regulation (EEC) 2377/90, to allow for the completion of the studies in progress, the time period applying for the provisional MRLs is extended until 1 January 1996. The submission of the further information becoming available from the ongoing studies is required before I January 1995.

[1] See oxitetracycline
[2] OJ No L73, 19.3.92, p. 8

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