European Medicines Agency
Veterinary Medicines and Inspections

London, 14 November 2008
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SUMMARY OPINION*
OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE ON THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

OXYTETRACYCLINE

(Extension to honey bees)

On 12 November 2008 the Committee for Medicinal Products for Veterinary Use, further to the request from the European Commission, re-considered its previous opinion regarding the establishment of maximum residue limits for oxytetracycline in honey and agreed to recommend the establishment of a provisional maximum residue limit for oxytetracycline in honey in accordance with Council Regulation (EEC) No 2377/90, as follows:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissue	Other provisions
Oxytetracycline	Sum of parent drug and its 4-epimer	Bees	25 µg/kg	Honey	Provisional MRLs expire on 1.1.2014

The request from the European Commission for the re-consideration of the opinion was based on the fact that the theoretical maximum daily intake of residues calculated with the existing MRLs exceeds the ADI. Although the recommended MRL for honey of 25 µg/kg would represent a theoretical maximum daily intake of residues of 0.25% of the ADI only, the CVMP acknowledged that the current situation, in which the theoretical maximum daily intake of residues exceeds the ADI is not optimal.

The Committee noted that, at an international level, there is an ongoing debate over the question of how consumer exposure should be modelled and about the make up of the food basket used to calculate the daily intake. Therefore, the Committee agreed that the outcome of the ongoing work at Codex Alimentarius (CCRVDF) and JECFA should be awaited before a final conclusion on the establishment of MRLs for oxytetracycline in honey is drawn.

* Summaries of opinion are published without prejudice to the Commission Decision.

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