The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Inspections

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NOTE REGARDING THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR FLUGESTONE ACETATE

An application for the establishment of Maximum Residue Limits for flugestone acetate was submitted to the European Commission in 1994 followed by an updated dossier submitted to the EMEA in January 1998 under Article 7 of Council Regulation (EEC) No 2377/90, as a so-called "old substance".

The Committee for Veterinary Medicinal Products (CVMP) concluded the assessment of the data in March 1998 and recommended the establishment of a provisional MRL for ovine milk. Regarding other target tissues, the CVMP considered that there was no need to establish maximum residue limits for flugestone acetate, mainly taking into account the fact that in tissues residues are rapidly depleted after treatment. Therefore, the CVMP recommended the inclusion of flugestone acetate in Annex II of Council Regulation 2377/90 for ovine and caprine species in all tissues except milk, and restricted to intravaginal use for zootechnical purposes.

In May 1999 The European Commission requested the CVMP to re-consider the assessment of sexual hormones in view of the opinion of the Commission's Scientific Committee on Veterinary Measures Relating to Public Health. The CVMP concluded the re-evaluation of the concerned hormones in December 1999 and for flugestone acetate confirmed the previous recommendation for the establishment of provisional MRLs for milk and inclusion in Annex II of Council Regulation (EEC) No 2377/90 in ovine and caprine tissues.

The response to the list of questions regarding ovine and caprine milk was submitted in December 2000 and the CVMP adopted in March 2001 a new opinion recommending the establishment of final MRLs for flugestone for ovine milk and provisional MRLs for caprine milk. The Council adopted the recommended MRLs for milk in December 2001. Such maximum residue limits for milk were established by Council Regulation (EC) No 2584/01[1] [2]

The European Commission decided, in view of the opinion of the SCVPH, that there was a need to establish control limits for tissues other than milk for flugestone acetate. In April 2002 the Commission requested the CVMP to consider if based on the existing data, quantitative maximum residue limits could be proposed for flugestone acetate in edible tissues other than milk on a temporary basis. Taking into account the residue data available and the ADI established for flugestone, the CVMP suggested limits of 0.5 µg/kg for muscle, fat, liver and kidney. Subsequently, the Commission adopted Commission Regulation (EEC) No 665/2003 establishing provisional MRLs for flugestone acetate in tissues other than milk as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flugestone acetate	Flugestone acetate	Ovine, caprine	0.5 µg/kg 0.5 µg/kg 0.5 µg/kg 0.5 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2008. For therapeutic and zootechnical purposes only

Article 12 of Council Regulation (EEC) No 2377/90 requires that after amendment to the annexes of the Regulation, the summary of the assessment of the substances concerned that have been examined by the CVMP be published. The summary report (1) on flugestone acetate published on the EMEA Website is the summary of the initial assessment carried out by the CVMP, which concluded on a

[1] OJ L 345, 29.12.2001, p. 7
[2] OJ L 96, 14.4.2003

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

recommendation for the establishment of provisional MRLs for flugestone acetate in ovine and caprine milk and the inclusion in Annex II of Council Regulation 2377/90 for other tissues except milk. For the reasons given above, the MRLs adopted by the European Commission are not consistent with the recommendation of the CVMP.

Flugestone acetate summary report (1)

Flugestone acetate summary report (2)