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

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TILMICOSIN
(Extension to all food producing species)

SUMMARY REPORT (7)

1. Tilmicosin is a macrolide antibiotic which is currently entered into Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tilmicosin	Tilmicosin	Bovine, ovine, porcine	50 µg/kg 50 µg/kg 1000 µg/kg 1000 µg/kg	Muscle Fat Liver Kidney	
		Ovine	50 µg/kg	Milk	
		Bovine	50 µg/kg	Milk	
		Chicken	75 µg/kg 75 µg/kg 1000 µg/kg 250 µg/kg	Muscle Skin + fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Turkey	75 µg/kg 75 µg/kg 1000 µg/kg 250 µg/kg	Muscle Skin + fat Liver Kidney	
		Rabbits	50 µg/kg 50 µg/kg 1000 µg/kg 1000 µg/kg	Muscle Fat Liver Kidney	

2. Following concern that an insufficient number of medicinal products was available to treat diseases occurring in animals, and especially diseases occurring in minor animal species, the CVMP conducted a review of the risk assessment approach for the establishment of MRLs and adopted a Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMEA/CVMP/187/00-FINAL). The Note for Guidance allows for an extrapolation of MRLs to all food producing species, where identical or slightly different MRLs (i.e. MRL values normally in the same order of magnitude) have been set in cattle (or sheep), pigs and chicken (or poultry).

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3. The MRLs already established for tilmicosin fulfil the above criteria. The existing MRLs for tissues are similar but not identical and so it would not be possible to recommend modification of the entry in Annex I in such a way that the same MRLs values would apply to all food producing species. The distribution of the residues seems to be different in poultry and in mammals. Therefore it was considered appropriate to recommend extension of the existing MRLs for chickens and turkeys to poultry, and extension of the existing MRLs for bovine, ovine, porcine and rabbits to all food producing species except poultry.

4. An analytical method for monitoring residues of tilmicosin in the edible tissues of bovine, ovine, porcine, chickens, turkeys and rabbits and in bovine and ovine milk was available. An assessment of the applicability of this method indicated that extrapolation to the tissues and milk of other species should not be problematic.

Conclusions and recommendation

Having considered that:

- a microbiological ADI of 240 µg/person was previously established for tilmicosin,
- MRLs have previously been established in bovine, ovine and porcine species and in rabbits; the MRLs for these species are identical,
- similar MRLs have also been established for chickens and turkeys,
- an analytical method for the monitoring of residues in tissues and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of tilmicosin in Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tilmicosin	Tilmicosin	All food producing species except poultry	50 µg/kg 50 µg/kg 1000 µg/kg 1000 µg/kg 50 µg/kg	Muscle* Fat** Liver Kidney Milk	
		Poultry	75 µg/kg 75 µg/kg 1000 µg/kg 250 µg/kg	Muscle Skin + fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption

*For fin fish this MRL relates to "muscle and skin in natural proportions".

**For porcine species, this MRL relates to "skin and fat in natural proportions".

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 103% of the ADI. The CVMP previously agreed that this small excess of the microbiological ADI was justified because a fraction of the total residue will consist of microbiologically inactive compounds and compounds which are less microbiologically active than the parent compound.