



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ENROFLOXACIN

(Extension to all food producing species)

SUMMARY REPORT (5)

1. Enrofloxacin is a synthetic fluoroquinolone antimicrobial agent 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
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Bovine	100 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
		Ovine	100 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Porcine	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Skin + fat Liver Kidney	
		Poultry	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Skin + fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Rabbits	100 µg/kg 100 µg/kg 200 µg/kg 300 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 (EMA/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).

3. The MRLs already established for enrofloxacin fulfil the above criteria. The existing MRLs are 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. It was not considered necessary to reduce the existing MRL values to the lowest values, in order to guarantee consumer safety. Therefore it was considered appropriate to recommend extension of the existing MRLs for bovine species also to ovine and caprine and to retain the existing MRLs for porcine, rabbits and poultry. It was also considered appropriate to extend the lowest existing MRL values to all food producing species except bovine, ovine, porcine, caprine, rabbits and poultry.
4. An analytical method for monitoring residues of enrofloxacin in the edible tissues of bovine, ovine, porcine, poultry and rabbits and in bovine milk was available. An assessment of the applicability of this method indicated that extrapolation to the edible tissues and milk of other species should not be problematic.

Conclusions and recommendation

Having considered that:

- a microbiological ADI of 372 µg/person was previously established for enrofloxacin,
- MRLs have previously been established for the edible tissues of bovine, ovine, porcine, poultry and rabbits; these MRLs are of the same order of magnitude,
- an analytical method for the monitoring of residues in edible tissues and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of enrofloxacin 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
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Bovine, ovine, caprine	100 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine, rabbits	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Fat** Liver Kidney	
		Poultry	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		All food producing species except bovine, ovine, porcine, caprine, rabbits and poultry	100 µg/kg 100 µg/kg 200 µg/kg 200 µg/kg	Muscle* Fat Liver Kidney	

*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 74% of the ADI.