



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

PAROMOMYCIN

(Extension to all food producing species)

SUMMARY REPORT (3)

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

Pharmacological active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Paromomycin	Paromomycin	Bovine	500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Porcine, rabbits	500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle Liver Kidney	
		Chicken	500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle Liver Kidney	Not for use in animals from which eggs are produced for human consumption

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 paromomycin fulfil the above criteria. The existing MRLs for tissues are identical and so it would be possible to recommend extension of the MRLs in such a way that the same MRLs values would apply to all food producing species.
4. An analytical method for monitoring residues of paromomycin in bovine, porcine, chicken and rabbit tissues was available. An assessment of the applicability of this method indicated that extrapolation to the tissues of other species should not be problematic.

Conclusions and recommendation

Having considered that:

- a microbiological ADI of 1500 µg/person was previously established for paromomycin,
- MRLs have previously been established in bovine and porcine species and in chickens and rabbits; the MRLs for these species are identical,
- an analytical method for the monitoring of residues of paromomycin in tissues was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of paromomycin 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
Paromomycin	Paromomycin	All food producing species	500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle* Liver Kidney	Not for use in animals from which milk is produced for human consumption. 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”

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 26% of the ADI.