

## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### LINCOMYCIN

(Extension to all food producing species)

### SUMMARY REPORT (3)

1. Lincomycin is an antibiotic which belongs to the lincosamide group. It 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
Lincomycin	Lincomycin	Bovine	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk	
		Ovine	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg	Muscle Skin + fat Liver Kidney	
		Chicken	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg 50 µg/kg	Muscle Skin +fat Liver Kidney Eggs	

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 lincomycin fulfil the above criteria. The existing MRLs are identical and so it was considered appropriate 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 lincomycin in the edible tissues of bovine, ovine and porcine species, and in chickens, and in bovine and ovine milk and in hens' eggs was available. An assessment of the applicability of this method indicated that extrapolation to the tissues, milk and eggs of other species should not be problematic.

### Conclusions and recommendation

Having considered that:

- a microbiological ADI of 600 µg/person was previously established for lincomycin,
- MRLs have previously been established in bovine, ovine and porcine species and in chickens; these MRLs are identical,
- an analytical method for the monitoring of residues of lincomycin in tissues, milk and eggs was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of lincomycin 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
Lincomycin	Lincomycin	All food producing species	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg 150 µg/kg 50 µg/kg	Muscle* Fat ** Liver Kidney Milk Eggs	

\* For fin fish this MRL relates to “muscle and skin in natural proportions”

\*\* For porcine and poultry 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 64% of the ADI.