



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### ERYTHROMYCIN

(Extension to all food producing species)

### SUMMARY REPORT (3)

1. Erythromycin 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
Erythromycin	Erythromycin A	Bovine	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 40 µg/kg	Muscle Fat Liver Kidney Milk	
		Ovine	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Porcine	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Muscle Skin + fat Liver Kidney	
		Chicken	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 150 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 erythromycin fulfil the above criteria. The existing MRLs for tissues are identical and so it was considered appropriate 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.

4. An analytical method for monitoring residues of erythromycin in the edible tissues of bovine, ovine, porcine and chickens and in bovine milk and hens' eggs 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 300 µg/person was previously established for erythromycin,
- MRLs have previously been established in bovine, ovine and porcine species and in chickens; the tissue MRLs for these species are identical,
- an analytical method for the monitoring of residues in tissues, milk and eggs was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of erythromycin 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
Erythromycin	Erythromycin A	All food producing species	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 40 µg/kg 150 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 90% of the ADI.