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

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

FLORFENICOL
(Extension to all food producing species)

SUMMARY REPORT (6)

1. Florfenicol is a broad spectrum, synthetic antibacterial agent which is structurally related to D(-)threo chloramphenicol but differs from it by the presence of a p-methyl sulfonyl group instead of the p-nitro group and the presence of a fluorine atom instead of the hydroxyl group in the terminal primary alcohol function. Florfenicol 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
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Bovine	200 µg/kg 3000 µg/kg 300 µg/kg	Muscle Liver Kidney	
		Porcine	300 µg/kg 500 µg/kg 2000 µg/kg 500 µg/kg	Muscle Skin + fat Liver Kidney	
		Chicken	100 µg/kg 200 µg/kg 2500 µg/kg 750 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Fin fish	1000 µg/kg	Muscle and skin in natural proportions	

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 florfenicol fulfil the above criteria. The existing MRLs are not identical and so it was not 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 MRLs to the lowest values, in order to guarantee consumer safety. Therefore it was considered appropriate to recommend the extension of the existing MRLs for bovine species also to ovine and caprine species and the extension of the existing MRLs for chickens to poultry. The existing MRL for fin fish would be retained. It was considered appropriate to extend the lowest MRL values to all food producing species except bovine, ovine, caprine, porcine, poultry and fin fish.

4. An analytical method for monitoring residues of florfenicol in the edible tissues of bovine, porcine, chicken and fin fish 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 toxicological ADI of 600 µg/person and a microbiological ADI of 180 µg/person were previously established for florfenicol,
- MRLs have previously been established in bovine and porcine species and in chickens and fin fish; these MRLs are of the same order of magnitude,
- an analytical method for the monitoring of residues in tissues was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of florfenicol 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
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Bovine, ovine, caprine	200 µg/kg 3000 µg/kg 300 µg/kg	Muscle Liver Kidney	Not for use in animals producing milk for human consumption
		Porcine	300 µg/kg 500 µg/kg 2000 µg/kg 500 µg/kg	Muscle Skin +fat Liver Kidney	
		Poultry	100 µg/kg 200 µg/kg 2500 µg/kg 750 µg/kg	Muscle Skin +fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Fin fish	1000 µg/kg	Muscle and skin in natural proportions	
		All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish	100 µg/kg 200 µg/kg 2000 µg/kg 300 µg/kg	Muscle Fat Liver Kidney	

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 100% of the toxicological ADI whilst at the same time not exceeding 10% of the microbiological ADI..