



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Implementation of the Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin

Having completed the task of setting MRLs for existing substances in accordance with Article 7 of Council Regulation (EEC) No. 2377/90, concern was expressed by the EMEA, European Commission, Member States and Interested Parties, that an insufficient number of medicinal products were available to treat diseases occurring in animals, and especially diseases occurring in minor animal species. To address this problem the CVMP conducted a review of the risk assessment approach for the establishment of MRLs, with a view to establishing a more pragmatic approach in securing the provision of medicines for treating animals, especially those classed as minor species, whilst at the same time guaranteeing consumer safety.

The Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMEA/CVMP/187/00-FINAL) developed subsequently by the CVMP CVMP allows for an extrapolation of MRLs to additional species or even all food-producing animals, provided that certain requirements regarding the availability of analytical methods for these additional species are met. As with any other new Note for Guidance this one applies for any new MRL application from the date of entry into effect, and is also applied for upcoming MRL decisions related to MRL applications in process. Taking account of ongoing concerns regarding the availability of veterinary medicines the CVMP also reviewed how this Note for Guidance could be applied in respect to existing MRLs.

The CVMP has reviewed all substances, which qualify for an extrapolation to all food-producing species, i.e. substances for which identical or slightly different MRLs (i.e. MRL values normally within the same order of magnitude) have been set in cattle (or sheep), pigs and chicken (or poultry), considering in particular the availability of analytical methods providing for residue surveillance in the additional species proposed. The CVMP agreed accordingly to extrapolate the existing MRLs for the substances Danofloxacin, Difloxacin, Enrofloxacin, Erythromycin, Florfenicol, Flumequine, Lincomycin, Paromomycin, Spectinomycin, Tilmicosin, Trimethoprim, and Tylosin. For the substances Doxycycline, Levamisole and Spiramycin such extrapolations could not be recommended, as insufficient analytical methodology is available supporting this.

The CVMP also considered whether the extrapolation of MRLs within classes of animals (e.g. from a major ruminant to all ruminants, from a major monogastric mammal to all monogastric mammals) should be initiated for all theoretically possible cases. In principle the majority of existing MRLs would qualify for such extrapolations, and the review of whether the requirements of the guideline would be met and preparation of the possible of recommendations for such MRL extensions would require a considerable burden of work for the CVMP and its Safety Working Party over a number of years. Furthermore, it was noted that many of the theoretically possible extrapolations would in practice not be relevant, as they often would concern species for which the substances would not be used and for which marketing authorisations are not intended, and work on those would waste

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unnecessarily the available resources of the Committees, and may cause delays in the processing of relevant extensions applications, for which Industry is willing to obtain marketing authorisations in the future. Therefore, the CVMP concluded not to initiate a systematic and automatic review of possible extrapolations of MRLs for such substances at this stage. The EMEA will continue exploring this matter in the near future.

At present, in order to obtain MRLs for such additional species, applications for the extension of existing MRLs will need to be submitted to the EMEA by potential applicants. Provided that appropriate funds would be available and that the “Orphan Drug” criteria for veterinary medicines agreed by the EMEA Management Board would apply for the substances concerned, the EMEA will, in support of the Availability of Medicines initiative, explore the possibility for granting a fee reduction upon request.