



FVE COMMENTS

ON

CVMP NOTE FOR GUIDANCE ON THE RISK ANALYSIS APPROACH FOR RESIDUES OF VETERINARY MEDICINAL PRODUCTS IN FOOD OF ANIMAL ORIGIN

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FVE welcomes the CVMP proposals to increase medicines availability on two counts. Firstly, FVE welcomes the fact that the CVMP is doing its utmost to address the problem of medicines availability. Secondly, FVE welcomes proposals for a more pragmatic approach to the setting of MRLs.

FVE agrees with the extrapolation route proposed between classes of animals. (point 2.i)

FVE welcomes the proposal that if identical MRLs were derived in cattle, pigs and chicken an extrapolation would be possible to all food-producing animals except fish. FVE also welcomes the proposal that, when the parent compound is acceptable as marker residue in fish muscle and skin, the MRLs could be extrapolated to all-food producing species. (point 2.ii)

FVE supports the extrapolation approach proposed when MRLs vary slightly between major species. (point 2.iii)

FVE recognises that the proposed approach takes fully into account the need to protect consumers from harmful residues and that it does not compromise the safety of the consumer.

FVE is however concerned that this approach might fail to encourage the development of products for minor species and reduce the costs of development of new products, if a number of additional measures are not taken.

Firstly, the requirements for analytical methods in minor species must be limited to demonstrating that the method established for the major species is basically acceptable, as proposed by the CVMP.

Secondly, FVE is concerned that the proposed approach will only apply to future applications and that for the 120 substances already included in Annex I or III, it will be left to the goodwill and interest of individual pharmaceutical companies to request extrapolation. It is therefore feared that this approach would have little impact on the development of products for minor species.

FVE would therefore like to suggest that for compounds, which are already in annex I or III, their MRLs, be automatically extrapolated along the lines of the CVMP proposal and at the initiative of the CVMP.

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From a risk assessment point of view, and taking into account the conclusion of the CVMP ad hoc group that specific MRLs for specific target species may not be necessary to ensure the protection of consumer health, this proposal would have no impact on consumer safety.

Especially so because there are anyhow, or there should be, no product licensed for those species, which are today not covered by an MRL.

However, from a risk management viewpoint, FVE recognises that the CVMP would not necessarily have access to the minimum data necessary to demonstrate that the method established for the major species is basically applicable for the minor species. FVE considers however that these data are not necessary for the purpose of the automatic extrapolation.

Instead, when a pharmaceutical company would apply for the granting of a marketing authorisation¹, the analytical method provided as part of the application submitted to the Member State could be transmitted to the EMEA and the CVMP.

The CVMP would thus have the opportunity to check that the method is acceptable and the EMEA would be in the position of transmitting this analytical method to the relevant Commission Services and further on to the laboratories in charge of residue control.

In conclusion, FVE strongly believes that such an automatic extrapolation would not undermine consumer safety as highlighted in the CVMP proposal but would certainly contribute to encourage the development of products for minor species.

FVE would therefore like to invite the EMEA, the CVMP, Member States, the Commission and the Pharmaceutical industry to discuss this proposal, which goes beyond what is proposed today by the CVMP, but may help to increase the number of products authorised for minor species without compromising consumer safety.

¹ For a product intended for a minor species and containing a substance that would have benefited from the proposed automatic extrapolation.