

Industry Proposals for Implementation of Prudent Use Wording

**Focus Group Meeting of CVMP Experts and Interested
Parties**

**Reflection paper on the use of fluoroquinolones in
food producing animals**

EMA Thursday 12 October 2006



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1. Agreement of "the industry" to voluntarily put prudent use wording on the product literature of the products concerned or adapt the existing wording
2. For quinolone / fluoroquinolone containing products
3. The companies who have taken the responsibility and committed to that are Bayer, Fort Dodge, Pfizer, and Vetoquinol, i.e. the pioneer companies
4. The "Prudent use" wording will be that proposed and submitted with IFAH-Europe's comment paper to the CVMP

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5. Intention to do that in the SPCs with each new edition and on the leaflet
6. The latter requires an implementation period of 1 - 2 years, i.e. to avoid destroying existing packaging material
7. These changes should be possible by simple notification and submission of changed SPC and leaflet to the agencies by the companies, i.e. a non-bureaucratic approach

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8. A waiver of all fees regarding the above mentioned necessary variations (as this is a voluntary action of industry) should be granted

9. IFAH-Europe notifies all national associations on this action asking that all marketers of concerned products in that country should follow this action. In case companies do not implement it would be up to the national agencies to take actions

10. Finally, we ask CVMP and the member states to agree from their side to a single wording, to avoid repeated protracted discussions again at Member State level.