

Minor Use / Minor Species Policy Industry Feedback

EMA/IFAH-Europe Infoday 12-13 March 2015

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Introduction / Differentiation

- The veterinary pharmaceutical market is rather small
ca. 2.5% of Human Health (HH)
- Highly fragmented in animal species and local market sizes
- Few major indication areas also for major species
- Very competitive direct business especially for food
producing animals = the market dictates the product value
- Number of companies which can afford development of new
products is much smaller compared to HH



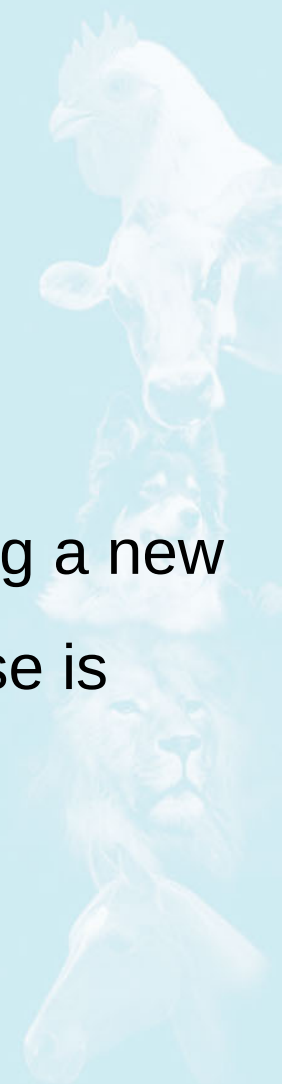
Situation

- Complex issue difficult to resolve also in the future
- Problems for the veterinarian in daily practice...
and for Animal Welfare are understood by all parties
- Efforts to improve ongoing since long time
- Recent good initiatives but also less good proposals



- Opening / flattening the Cascade
- Understandable from a welfare point of view
- Wrong signal and dis-incentive for industry
- Discrepancy between regulatory hurdles in obtaining a new registration versus the possibilities of an off label use is getting bigger and bigger!

=> Cannot be the only answer!



☺ Proposals / efforts

- Efforts from EMA / CVMP appreciated
- Com proposals regarding data protection very positive and welcomed!
- Limited to new products

=> Not the solution for everything but a good direction!



Conclusion

- How many new developments.?. => Limited!
- Existing portfolio is key
- Incentives needed for investments (data packages) on existing products!
=> e.g. 5 years data protection
- IFAH Europe is going to propose to legislators



Thank you for your attention

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