

Experience and Observations on Implementing Responsible Use of Fluoroquinolones

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Dr. Ludwig Klostermann
IFAH Europe



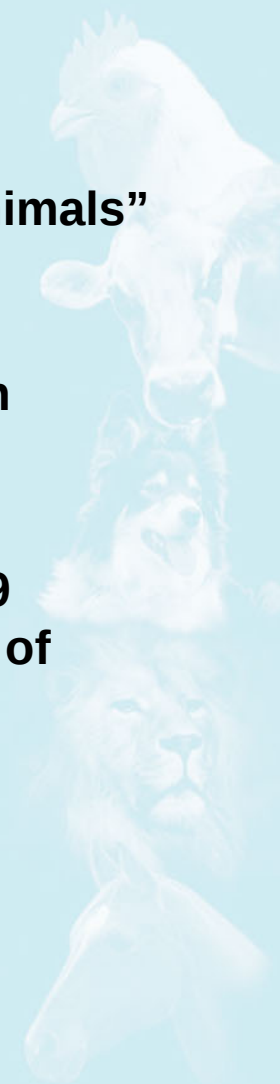
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International Responsible Use Initiatives

- **WHO** Meeting, Berlin, 13-17 October 1997
“The Medical Impact of the Use of Antimicrobials in Food Animals”
- **WHO** Meeting, Geneva, 2-5 June 1998
“Use of Quinolones in Food Animals and Potential Impact on Human Health”
- **OIE** European Scientific Conference, Paris, 24-26 March 1999
“The Use of Antibiotics in Animals. Ensuring the Protection of Public Health”



Responsible Use Measures in the European Union

- Prevention of micro-organisms becoming resistant to antibiotics used in human and veterinary medicine...

...cannot be achieved by national initiatives alone, but requires a common strategy and coordinated action at Community and international level.

(Council Resolution of 8. June 1999, “A strategy against the microbial threat”)

- Implementation by Regulatory Authorities as envisaged 2000 by EMEA in “A risk management strategic plan for controlling antimicrobial resistance through the authorisation of veterinary medicines” and described 2006 by “CVMP strategy on antimicrobials 2006-2010 and status report on activities...”

- e.g. Precautions

- Control measures like monitoring

Implementation in Veterinary Medicine, Livestock & Poultry Production



➤ **Codes of “best practice” to promote responsible use of antimicrobial products have been continuously provided by all relevant parties within the food chain, like**

- **National and European associations of veterinary practitioners**
- **Livestock and poultry producer associations**
- **Animal Health industry associations**

FEDESA, already in April 1996: “Responsible use of antimicrobials to control disease in farm animals”

- **Individual companies (e.g. Bayer 2000)**
- **Joint responsible use guidelines:
Veterinarians-farmers-industry, WVA/FIPA IFAP/COMISA 1999
all European “stakeholders”, EPRUMA 2008**



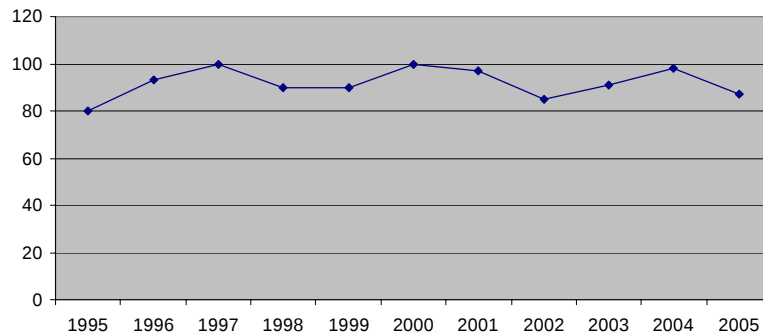
Experiences / Observations

SPC Harmonisation of FQs

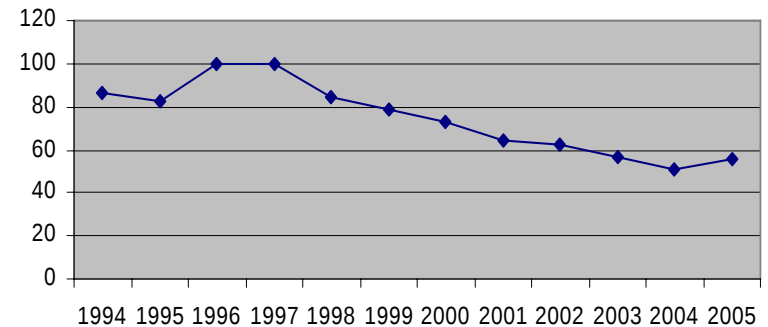
- In Mid Europe responsible use wording almost since first registration
- Commitment of industry (companies) for further implementation and harmonisation of wording at SAGAM stakeholder meeting in 2006
 - agreement on existing packaging material
 - agreement on voluntary action by industry
 - no waiver of variation costs
- In most countries successfully implemented in 2007 and 2008 in line with predicted time for use of existing stocks of packaging material
- Sometimes administrative difficulties in few countries resulting in delays for the change
- Limited information for IFAH Europe on the corresponding status in all EU MS and all marketers

Baytril Volume over Time in Markets with “Responsible Use History”

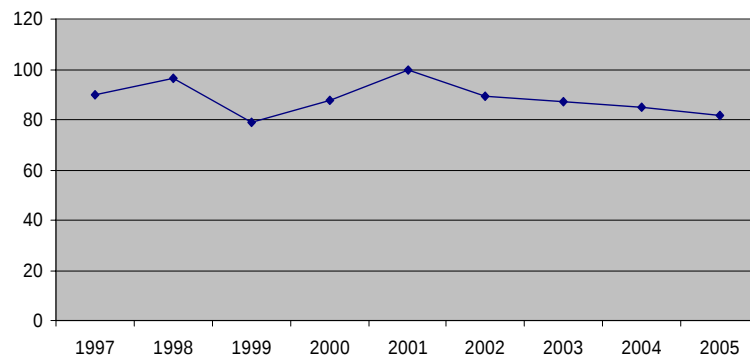
**Baytril Oral Solution Poultry
France (in %)**



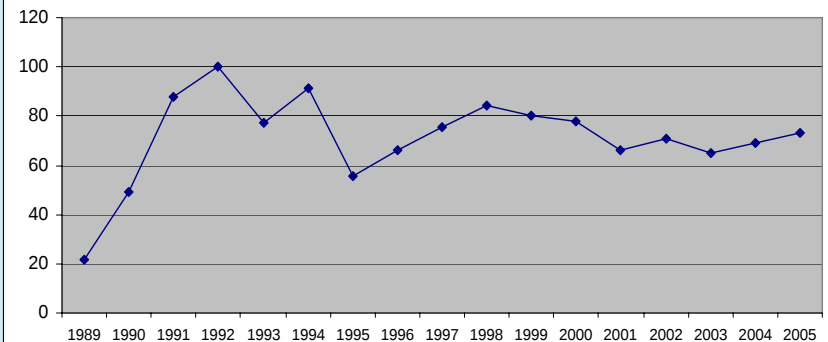
**Baytril 10% Oral Solution Poultry
Belgium (in %)**



**Baytril 10% Oral Solution Poultry
Germany (in %)**

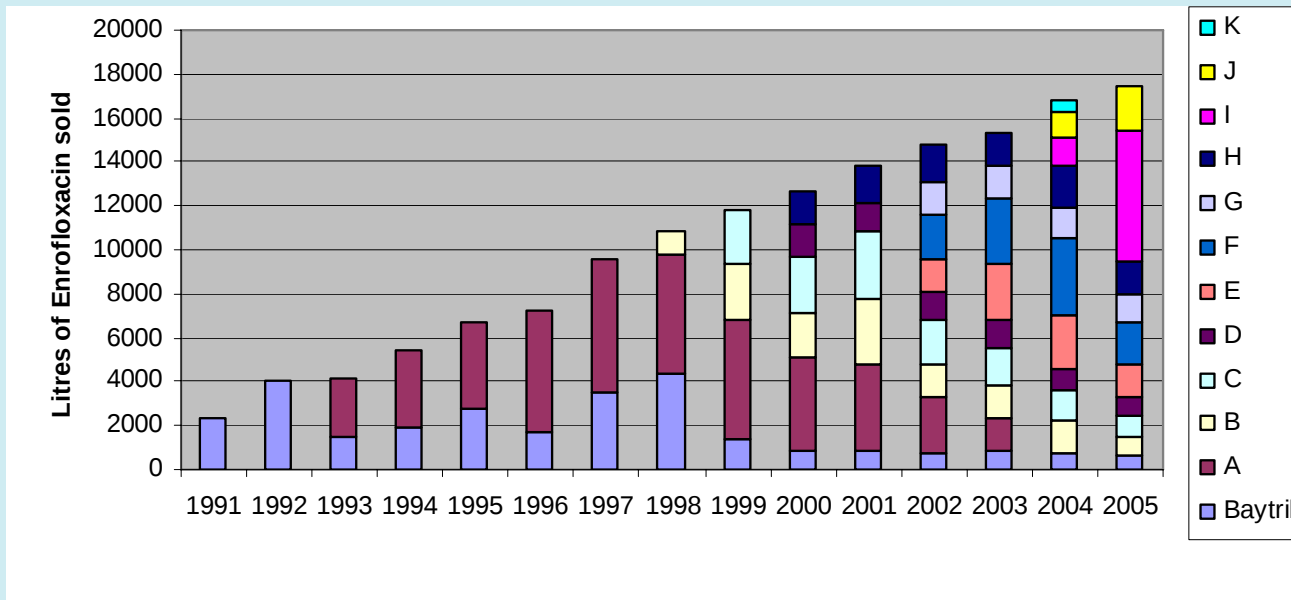


**Baytril 10 % Oral Solution Poultry
Austria (in %)**



Enrofloxacin O.S. Poultry Volume

East EU Member State with increasing number of marketers over time



Conclusions

- Responsible use principles on FQs have a long history in the European Union
- Implementation and effects have been very successful, especially in countries with that history
- Measures are most effective if all license holders are fully committed and competent authorities implement regulatory measures in a pragmatic but consequent manner
- Situation critical that some companies but also national agencies do not seem to / or can not contribute properly re SPC harmonisation
- **Complete and timely implementation urgently required!**

