

Antimicrobial Policy Options - Updated February 2nd, 2012

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Summary

- Common Goal
- Policy Context
- “Proposals” from various Stakeholders
- CVO Conclusions
- Recommendations
- 4 Strategy Strands
- TPMP
- EPRUMA Activities
- Conclusions



Common goal for the use of antibiotics

- IFAH-Europe proposes the following common goal with all stakeholders

“The common goal is to protect public health, animal health and welfare and to ensure that antimicrobials are effective now and in the future for relevant indications in all species”

Policy Context - 1

- TATFAR (EU/US Transatlantic dialogue)
- ESVAC (volume collection)
- CVMP views on Staff Working Paper
- Revision of Medicated Feed & Veterinary legislation
- Introduction of Animal Health Law
- Berenschot Report – supports right of vet to prescribe & dispense

Policy Context - 2

- Dutch & French developments – reduce by 50% & 25% respectively!
- Legislative changes in Germany?
- CVMP strategy for antimicrobials 2011-2015
- HMA Strategy
- EFSA reports on cephalosporins & zoonoses
- Commission Communication

“Proposals” from various parties - 1

- Ban of new or existing classes of antimicrobials
- Ban advertising
- Impose taxes
- Mandatory volume collection
- Develop minor species antimicrobials
- Apply the Precautionary Principle
- Refuse authorisation if product is highly likely to be misused
- Control Off Label use via SPC
- Clinical studies according to prudent use principles
- Advertising ‘strap line’ re Responsible Use

“Proposals” from various parties - 2

- Limit usage by country or species
- Do not allow vet to dispense
- Restrict meat and/or animals with resistant germs
- Use diagnostics – IFAH-Europe
- Restrict off label use – IFAH-Europe
- Provide extended data protection – IFAH-Europe
- Transparency at the prescription & use phase – IFAH-Europe
- Target Pathogen Monitoring Programme – IFAH-Europe
- Gene transfer in relation to resistance – IFAH-Europe
- ‘Responsible Use’ – EPRUMA initiative – Stakeholders

CVO Conclusions – Reality Check

- Use existing legislation to counter inappropriate & excessive use
- Minimise preventative use
- Bio-security, good husbandry & good management to prevent disease
- Monitor use at farm level
- Cascade by exception
- Responsible Use – communication, education & training
- Continue work to identify risk factors

Recommendations - 1

- We should use all existing & new classes strategically – guided by diagnostics - to minimise resistance development to all classes
- Use diagnostics to inform future antimicrobial choices
- Strict interpretation of the ‘cascade’ is necessary - critical to have the cascade

Recommendations - 2

- No Off-Label outside the cascade
- Policies and SPC changes need to be scientifically driven and not by the Precautionary Principle by default
- We propose extended data protection for new molecules to ensure innovation continues
- Ensure Responsible Use

Recommendations – 3

- Continuous inappropriate use on an individual farm may promote resistance
- CVO's support on farm monitoring
- IFAH-Europe supports the CVO concept
- Transparency at the prescription & use phase
 - Collect electronic data from the veterinarian
 - Ensure usage is in line with responsible use patterns

Recommendations - Summary

- With a combination of diagnostics, strict interpretation of the 'cascade', no off label use outside the cascade, transparency at the use phase, appropriate use of new molecules & classes coupled with extended data protection, we believe we have addressed all concerns
- Therefore, ban of classes, advertising, taxes, price concerns, generic entry, volume decreases, right of vet to prescribe & dispense do not need to be pursued

4 Strategy Strands

1. Recommendations concerning “Proposals”
2. Promote Target Pathogen Monitoring Programme (TPMP)
3. Pursue studies on possible gene transfer – literature review & risk assessment
 - a) Campylobacter
 - b) E. coli
 - c) Salmonella
 - d) Enterococci
4. Pursue ‘Responsible Use’ – EPRUMA as vehicle

TPMP Objectives

- Generate data to establish the facts concerning susceptibility of target pathogens
- Ensure standardised methodology
- Provide scientific data in the debate concerning the hypothesis that veterinary use leads to resistance that transfers to humans
- Action n° 10 from the Commission Communication proposes such an initiative under the Animal Health Law!

TPMP Protocol

- Draft 'Protocol' developed by IFAH-Europe to facilitate a harmonised approach
- Suggest alignment with CEESA/VetPath protocol (industry initiative dating back to 2000) as this protocol has served its purpose well & a similar protocol would facilitate future comparisons of data
- Harmonised sample collection, susceptibility testing and data analysis
- Publish results on an annual basis

EPRUMA Activities

- Website www.epruma.eu
- Translations - Czech, Dutch, English, French, German, Hungarian, Italian, Polish, Portuguese, Romanian, Spanish & Turkish –Finnish, Greek & Russian to follow – 15 languages
- CVO's – promote Responsible Use
- Communication with stakeholders – EMA, ECDC, OIE, EFSA, FAO, Codex, WHO – website in place, etc.
- Booklet, Website, Leaflet, Poster, Videos, Vet 2011
- Vets, Farmers, Feed Trade, EISA, FESASS, Pharmacists, Industry – all involved in EPRUMA
- Seeking support from the Commission to promote the communication of Responsible Use

Conclusions - 1

- “Recommendations” are intended to identify the critical steps we need to take to protect the future efficacy of antimicrobials
 - Use all strategically
 - Use diagnostics to inform future choices
 - No Off-Label use outside the cascade
 - Data protection to encourage innovation
 - Transparency at the prescription & use phase

Conclusions - 2

- 4 Strands
 - Recommendations
 - TPMP
 - Transfer studies
 - Responsible Use (EPRUMA)
- TPMP will fill gap in data concerning efficacy in target pathogens
- Policies and SPC changes need to be scientifically driven and not by the Precautionary Principle by default

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Thank You!

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