

Veterinary Medicines Legislation Update

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Veterinary Medicines Package

- Review of **Directive 2001/81**- approval, distribution, prescribing & use of **vet. Medicines**
- Review of **Directive 90/167** – manufacture, distribution, prescribing and use of **medicated feed**



Directive 2001/82

- Comprehensive review in 2003/2004
- Ongoing Problems identified:
 - Variation in availability in MS
 - Operation of Single market
 - Administration Burdens

Availability of Veterinary Medicines

- Smaller countries—↓ no. of authorised medicines
- Few authorised medicines for minor species
- Few authorised medicines for some therapeutic categories
- Innovation – low no. of new MA, insufficient data protection

Single Market

- Majority of MA holders only have MA in single national market

Administration Burdens

- Costs of Regulatory Requirements:

EUR 538 million / year → 13% of turnover

-91 million-cost of applying for MA

-184 million-packaging & labelling,

- 262 million – existing MAs

Objectives for Revision

- Improve functioning of single market
- ↑ level of protection of human & animal health
- ↑ availability of veterinary medicines
- ↓ administration burden
- Improved response to AMR

Direction of Commission Review

- Commission proposals -2013
- Policy options for discussion:
 - Authorisation procedure - *Coalition of IFAH-Europe, FVE, EGGVP, COPA-COGECA – 1-1-1*
Other stakeholders – 2 authorisation routes and European-wide binding
 - Data Protection – *Industry 8 years for new products, +3 for each additional species, max 20*
Other stakeholders 13 years for major species, 15 for minor species

Direction of Commission Review

- Packaging & Labelling – simplify requirements
- Pharmacovigilance and monitoring – simplify requirements, risk based approach
- Off-label use
- Harmonisation of already authorised products
- Antimicrobial resistance

Directive 90/167

- Last reformed 1990 - outdated
- Mainly pig and poultry sectors
- Expect more specific & restrictive control provisions



Who's hogging our antibiotics?

Up to 70% of U.S. antibiotics go to farm animals that aren't sick.

SaveAntibiotics.org

THE PEW CAMPAIGN ON HUMAN HEALTH AND INDUSTRIAL FARMING

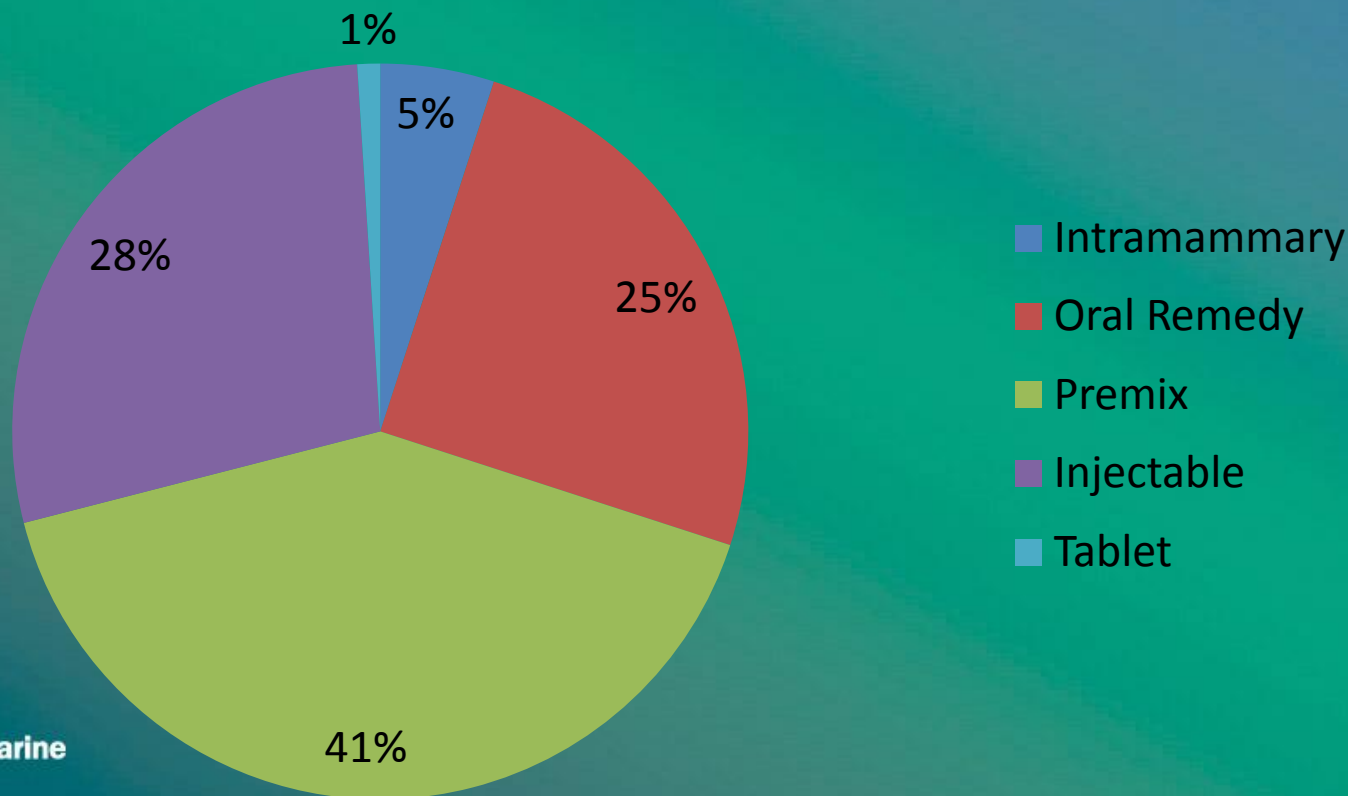
THE PEW CHARITABLE TRUSTS

Production & Use of medicated feed in EU

- Size of market varies between Member States
- No. of authorised premixes varies
- Importance of medicated feed compared to oral administration is reduced
- Cost of mixing medicated feed is higher if production levels low & technology requires investment

IMB Data

Breakdown of Veterinary antimicrobial substances used in 2010 in Ireland.

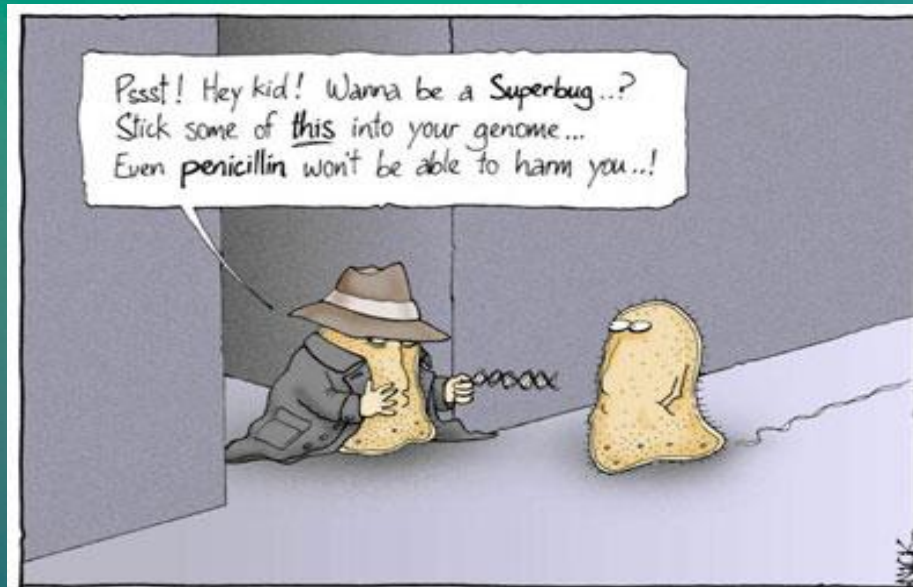


→ public health priority

→ 25,000 deaths in EU annually WHO

AMR → EUR 1.5 BILLION (lost productivity,
healthcare)

→ 4 million patients/year acquiring a
healthcare associated infection

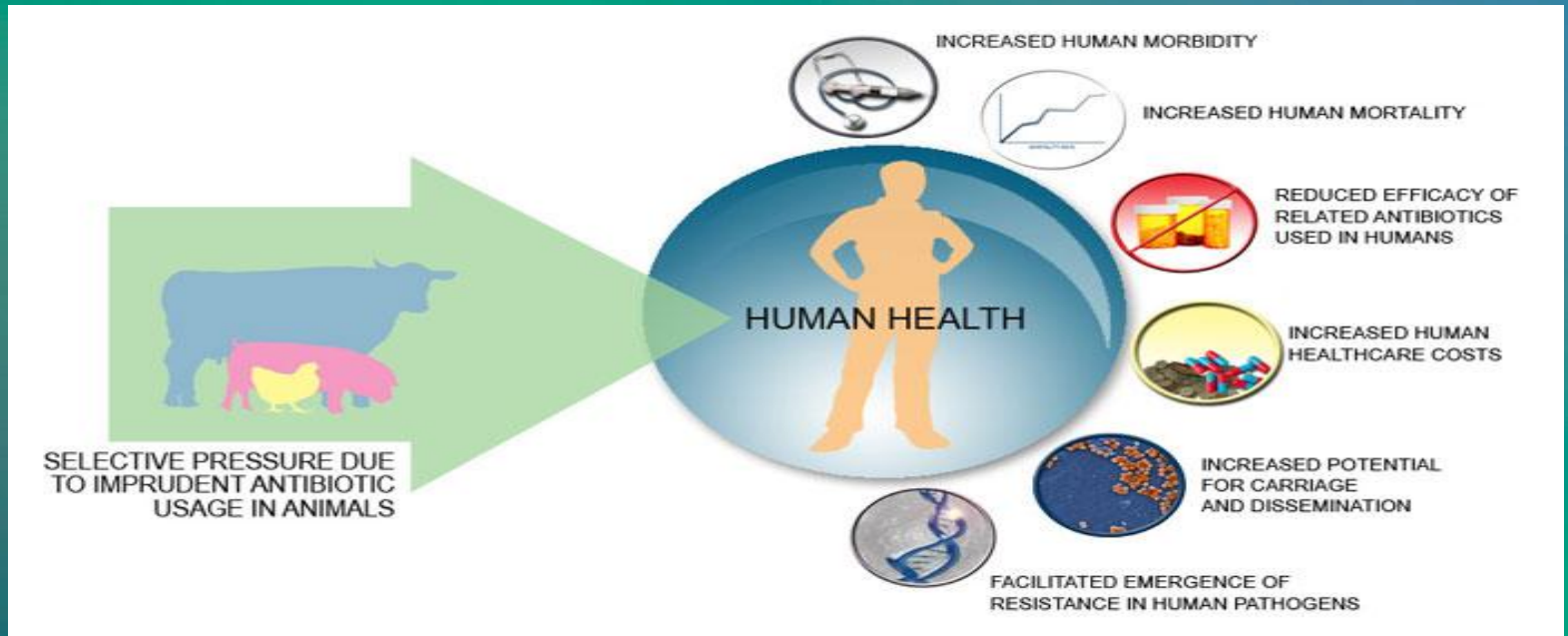


It was on a short-cut through the hospital kitchens that Albert was first approached by a member of the Antibiotic Resistance.

Antimicrobial Resistance



Human Animal



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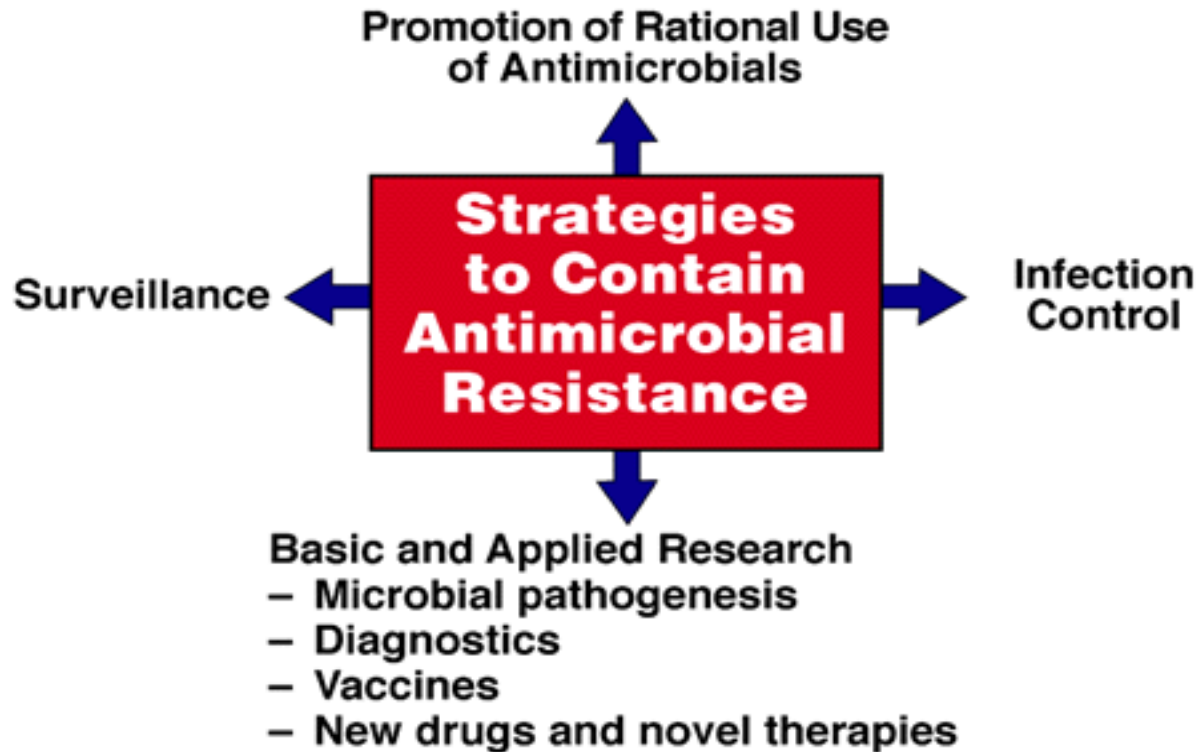
European Parliament Resolutions

- Prudent use of antimicrobials- maintain efficacy in humans & animals
- Importance of Monitoring & surveillance of AMR system- EFSA/ECDC
ESVAC/ EARS-Net & ESAC-NET
- Continued research & development of new antimicrobials , alternatives – vaccines
- Holisitic approach-disease prevention,
improved husbandry

Commission Action Plan

- Actions to date:
 - 2006 ban on use of AM for growth promotion
 - Monitoring zoonotic AMR and use of antimicrobials
 - International activities – TATFAR, WHO, OIE CODEX
 - Research- scientific opinions

Commission Action Plan



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12 Concrete Actions – Key points

- (1) Promotion of appropriate use of AMs – CIAs –
3rd & 4TH gen. cephalosporins, flouoroquinolones
↓ in overall usage- use only when necessary CVMP
- (2) Strengthen Regulatory Framework- review
 - appropriate warnings on labels
 - Restrictions on regular or off-label use of new or CIAs for humans in veterinary sector

12 Concrete Actions – Key points

- (2) Strengthen Regulatory Framework → Review
 - Amending rules for advertising
 - Revisit authorisation requirements to address risks and benefits of antimicrobials
- (3) Recommendations for veterinary use
- (5) New Animal Health Law to focus on disease prevention

12 Concrete Actions – Key points

(7) Research & incentives for development of new Veterinary antimicrobial

(10) Strengthen surveillance of AMR & monitoring of consumption- Animal Health law AMR in animal disease, Harmonised data between MS, Harmonised between human & veterinary

- International cooperation, communication & education

Council Conclusions

- Calls on MS to develop strategy to address AMR
 - Guidelines on treatment-prudent use
 - Clinical sampling & diagnostic tests
 - legislation preventing illegal sales
 - Limit use of CIAs
 - Limit prophylactic use
 - Herd usage justified by vet

Council Conclusions

- Effective surveillance system to allow comparison
- Collection of data on sale & use of antimicrobials in animals
- Intersectoral coordination to monitor implementation of national strategy
- Co-ordinated action at international level
- Training & Education

Previous Experiences

- Denmark: 1995 Danmap, Vetstat
1994-2011 ↑ pig production 50%, ↓ AM 47%
- Risk Management- monitoring usage & AMR
- ↓ need for AM-vaccination, yellow card system
 - Prudent use- Vetprax-vet usage
 - Decoupling prescribing & supply
 - Treatment guidelines
 - Herd health agreement

Previous Experiences

- Denmark –
 - 2002 restrictions on fluoroquinolones
 - ↑ therapeutic usage until 2009
 - 2010 non voluntary herd health agreement
cattle & pigs
 - Establishment of threshold values for herd
levels AM usage & mortality



- July 2010 pig industry voluntary ban
cephalosporins

Previous Experiences

- Netherlands: 1999 Nethmap
2006 AGP ban but therapeutic use ↑-usage static
MRSA – PUBLIC HEALTH ISSUE
Target 50% ↓ in 3 years by 2013
 - Guidelines to limit prescribing of CIAs
- Germany: Therapeutic use only
 - Legislative changes for vets
 - diagnostic tests- antibiogram
 - Cascade not permitted for CIAs

Previous Experiences

- France: 1999 ANSES

Antibiotic Usage ↑ 28% 1999-2009

Target : 25% in 5 years

Strategy – promotion of good practice, awareness

Development of alternatives to AM usage

Re-inforce controls

Consolidation of monitoring system

Promotion of European approach & international

activities

Resistance Stats – NRL 2011

- *Salmonella* spp. – 78% resistance (DT104 98%)
(500 SAMPLES) Highest in pigs and cattle
-5% resistance fluoroquinolones
Poultry resistance highest to CIAs
- *Campylobacter* spp – poultry
C. jejuni 64.7%
C. coli 59% 40% resistance to flouoroquinolones
15% 2008 → 57% 2010

Resistance Stats – NRL 2011

- Commensal *E. coli* & *Enterococcus* spp.
- Indicators of selective pressure that spread horizontally to zoonotic or other bacteria thru food chain or environment

E. coli (poultry) – 85% resistant to 1 ab, 40% 5 +

50% resistant to amp, oxytet, sulp

Enterococcus spp. poultry resistance levels varied

80% tetracyclines

68% erythromycin

0.07% vancomycin

EFSA & ECDC Joint Report

- Occurrence of resistance in animals & food remained similar to previous years
- Humans- campylobacter (200,000 cases)
- high resistance to ciprofloxacin, ampicillin & teracyclines
- Salmonellosis – 100,000 cases 2012, low resistance to CIAs
- Direct comparison between resistance findings in humans & animals cannot be made as different definition for resistance- harmonisation required



Healthy Animals → Premium Food

- Agri-food Exports - € 8.85 billion (12% ↑ 2011)
- 25% of rise in total export revenue
- Export orientated industry □ Improved Market Access & Volume Growth (25% ↑ exports)
- Food Harvest 2020 Target : ↑ Exports to 11.16 bill(42%)

To Conclude

- ‘..the current review provides a massive opportunity – an opportunity for all to engage in a fundamental rethink of the whole system of veterinary medicines ..It is an opportunity to re-mould the model; to modernise and to improve it.’ Commissioner Dalli

Thank you for your attention!



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