EMA contribution to a One Health approach addressing antimicrobial resistance

The veterinary perspective

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Content

1. AMR in the European context
2. Sales data
3. Better regulation
5. International collaboration

Europe is on the right track to fight antibiotic resistance...

2011-2018
Sales of antibiotics for veterinary use are declining

↓ 34%
overall sales in 25 of the 31 countries in the ESVAC network

↓ -50%
in some countries
AMR in the European context – a One Health Approach

EU One Health Action Plan against AMR –

EU Guidelines on prudent use of antimicrobials in human health

EMA: - human and veterinary medicines authorisation
  - surveillance of veterinary antimicrobial consumption (ESVAC)
  - better regulation of human & veterinary medicines

ECDC: - EARS-Net – EU antimicrobial resistance surveillance (human),
  - ESAC-Net – EU surveillance of a consumption (human)
  - FWD-Net – EU Food- & Waterborne Diseases & Zoonoses net

EFSA: - resistance monitoring in zoonotic bacteria (veterinary)
  - Scientific Network for Zoonosis Monitoring Data

EMA-ECDC-EFSA together: JIACRA reports (joint inter-agency antimicrobial consumption and resistance analysis)
European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

- Launched in 09/2009 by the EMA as a project mandated by the EC with 9 countries
- 2020: 10th report, 31 countries (EU 27 plus CH, IS, NO, UK)
- Between 2011 and 2018, sales have reduced by:
  - ↓ 34% for overall sales;
  - ↓ 24% for third and fourth generation cephalosporins;
  - ↓ 70% for polymyxins;
  - ↓ 4% for fluoroquinolones;
  - ↓ 74% for other quinolones.
- Mixed picture across the EU, even increase over time in a few countries
3. Better regulation of veterinary medicines

The Committee’s for Veterinary Medicinal Products CVMP strategy on antimicrobials (2021-2025 in development)

CVMP guidelines on
- Efficacy of antimicrobial VMPs
- AMR public health risk assessment
- SPC of antimicrobial VMPs

Additional resources:
- EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA)
- Updated AMEG categorisation of antibiotics
- CVMP Reflection paper on authorisation of Alternatives to Antibiotics
- AMEG advice on preliminary risk profiling for new veterinary antimicrobials
4. Regulation (EU) 2019/6 on veterinary medicinal products

Replaces Directive 2001/82/EC within the overall aim of achieving ‘Better Regulation’ in the EU

- provides for a modern, innovative and fit for purpose legal framework
- gives incentives to stimulate innovation
- gives incentives to increase the availability of veterinary medicines
- strengthens the EU action to fight antimicrobial resistance
4. Regulation (EU) 2019/6 on VMPs

Timeline

Approved on 11 December 2018

Published on 7 January 2019; effective since 27 January 2019

Becomes applicable in January 2022

3-year implementation period
20 Implementing or Delegated Acts foreseen to be developed during the implementation period
We must increase awareness of the social and economic relevance of the activities related to veterinary medicines – most of what we do has an effect on people.
Specific actions for AMR

- Extended collection of antimicrobial sales data
- Collection of data on use of antimicrobials in animals (stepwise approach)
- List of antimicrobials reserved for human use based on specific criteria (under development)
- Restriction of legally allowed use outside the terms of the marketing authorisation for certain antimicrobials
5. International collaboration

[Limited during the implementation for Regulation (EU) 2019/6]

- VICH
- Codex Alimentarius TFAMR
- TATFAR
- OIE Antimicrobials Working Group
Any questions?

Further information

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