Revision of the legal framework on veterinary medicines: main provisions linked to AMR and state of play

EC workshop with EMA: Data collection on consumption of veterinary antimicrobials in Europe – achievements, challenges and way forward

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Dean Bosnjak
Unit E5 - Animal nutrition, veterinary medicines
Directorate General for Health and Food Safety
European Commission

Current EU legislation

- **Regulation (EC) No 1831/2003 on additives for use in animal nutrition**
  - *Ban on authorisation of antibiotics as feed additives*
  - *Ban on the use of antibiotics as growth promoting agents in feed (since 01.01.2006)*

Current EU legislation

- **Directive 2001/82/EC on the Community code relating to veterinary medicinal products**
  - *Annex I: Application file for marketing authorisation - data on the potential emergence of resistance are necessary*

Current EU legislation

- **Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin,** **repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council**

  - *Assessment of the risk of microbiological effects in human beings*

Current EU legislation

- **Guidelines supporting the basic pharmaceutical legislation - more detailed requirements**

  - *Volume 6 - Notice to Applicants and Regulatory Guidelines for Medicinal products for Veterinary use (Volume 6B)*
  - *Volume 8 - Maximum residue limits guidelines (MRL)*

Current EU legislation

- **Commission Decisions based on EMA/CVMP opinions following referral procedures under Article 35 of Directive 2001/82/EC**
  - *Critically important antimicrobials (quinolones, third and fourth generation cephalosporins, colistin)*

Current EU legislation

- Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

- Commission Implementing Decision 2013/652/EU on the **monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria**

EU soft law and non-legislative tools

- **Commission Guidelines for the prudent use of antimicrobials in veterinary medicine + practical examples (*September 2015*)**

- **EMA guidelines/recommendations (opinions)/scientific advice/joint reports with other EU agencies**

Revision of the regulatory framework – background related to AMR

- **November 2011: Commission launched a five-year Action Plan against the rising threats from AMR**
  - *Action 2: Strenghten the regulatory framework on veterinary medicines and medicated feed (package)*
  - *Proposals on veterinary medicines and on medicated feed adopted by the Commission in September 2014*

Proposal for a Regulation on veterinary medicinal products (VMPs)

Main objectives

1. Increase the availability of veterinary medicinal products
2. Reduce administrative burden
3. Stimulate competitiveness and innovation
4. Improve the functioning of the internal market
5. **Address the public health risk of AMR**

While safeguarding public and animal health and protection of the environment

Provisions addressing AMR

- **Directive 2001/82/EC barely mentions AMR, the new proposal contains a comprehensive package of specific provisions**

- **Recitals** (33-40, 75, 77, 79)

- **Definitions**
  - *AMR (Art. 4(8))*
  - *benefit-risk balance (Art. 4(11)(c))*

Provisions addressing AMR

Marketing authorisation (antimicrobial VMPs)

- ***Documentation/information to be submitted by applicants on direct or indirect risks to public/animal health from the use, and on risk mitigation measures to limit AMR development***
  (Art. 7(2); Annex II, Part 1 - 1.1., 1.3.1., 1.3.2., 1.4.2.)

- ***Possibility to require post-authorisation studies from marketing authorisation holders*** *(Art. 28(3))*

Provisions addressing AMR

Marketing authorisation (antimicrobial VMPs)

- ***All antimicrobial products shall be subject to veterinary prescription*** *(Art. 29(1)(c))*

- ***Specific information (conditions/restrictions on the use) to be included in the SPC*** *(Art. 30(1)(c))*

Provisions addressing AMR

Marketing authorisation (antimicrobial VMPs)

- ***Refusal of marketing authorisation if:***
  - ***the product is presented as growth promotor*** *(Art. 32(1)(d))*
  - ***risk to public health due to AMR development outweighs the benefits to animal health***

    (Art. 32(1)(g))
  - ***the antimicrobial is reserved for treatment of certain infections in humans***

    (Art. 32(2))

Provisions addressing AMR

Marketing authorisation (antimicrobial VMPs)

- ***The Commission shall be empowered to establish rules for designation and designate antimicrobials reserved for humans*** *(Art. 32(3)(4))*

- ***Extended protection of technical documentation (14 years) for new antimicrobials*** *(Art. 34(1)(b))*

Provisions addressing AMR

Post marketing authorisation measures

- ***Collection of data on sales and use*** *(Art. 54)*
  - ***Relevant and comparable data to be collected and sent to the Agency***
  - ***The Agency to analyse the data and publish annual reports***
  - ***The Commission to establish detailed rules on methods of gathering data and of their transfer to the Agency***
  - ***The Commission may set up the format and the requirements for the data***

Provisions addressing AMR

Supply and use

- ***Prescribers shall retail antimicrobial products only for animals under their care, and only in the amount required for the treatment concerned*** *(Art. 107(2))*

- ***Advertising*** *(Arts. 123, 124) – not specific for antimicrobial VMPs*
  - ***should not lead to overconsumption***
  - ***banned for prescription-only products*** *(except to prescribers and suppliers)*

Provisions addressing AMR

Supply and use

- ***Off-label use*** *(Art. 118, also Art. 116(4)(b-c))*

  - ***the Commission may establish a list of products which cannot be used off-label or can only be used subject to certain conditions***

  (scientific advice of the Agency and prescribed criteria to be taken into account)

State of play

European Parliament

- COM ENVI - lead committee
- Finalisation of negotiations in Committees:
  - **COM AGRI adopted its opinion in July 2015**
  - **COM ENVI adopted its report on 17 February 2016**
  - **ENVI report put on the plenary in March 2016 - mandate to start inter-institutional negotiations**
  - **Proposed amendments generally in line with the core objectives of the proposal**

State of play

Council

- Council WP meetings started in October 2014
- Negotiations in Council WP started in January 2016
  - **All articles have been discussed, most of them being on the basis of a second draft**
  - **Work is now progressing on a "package" basis**

Proposal for a Regulation on medicated feed

Main objectives

1. **AMR – measures to fight the misuse of antimicrobials**
2. Effective Internal Market
3. Fostering innovation

Provisions addressing AMR

Measures to fight the misuse of antimicrobials:

- ***Ban on the use in medicated feed for preventive treatment or as a growth promoter***
- ***Requirement for diagnosis of a disease prior to the mandatory prescription for medicated feed***
- ***Limitation of the duration of a treatment and of the validity of the prescription***
- ***EU-wide residue limit for veterinary medicines in ordinary feed***

State of play

European Parliament

- COM AGRI - lead committee
- COM AGRI report adopted in March 2016 - mandate to start inter-institutional negotiations

State of play

Council

- The proposal was discussed entirely in the Council WP
- Revised draft presented by the Presidency is almost finalised
- The draft now awaiting progress on the VMPs proposal (to finalise the text regarding interfaces)

Regulation (EU) 2016/429 on transmissible animal diseases ("Animal Health Law")

Provisions related to AMR

- **Background: Actions 5 and 10 of the previous Commission Action Plan against AMR**
- **Complements the measures in proposals on veterinary medicines and medicated feed**
- **Follows the EU Animal Health strategy principle "*Prevention is better than cure*"**

Provisions related to AMR

- **General preventive measures/behaviour contributing to reduced use of antibiotics**
  - *biosecurity, some rules on use of VMPs (vaccines, prudent use) etc.*
  - *responsibilities, knowledge, awareness of operators, veterinarians etc.*
- **Possible specific measures**
  - *AMR pathogens considered as "disease" (resistance to treatments is a disease listing/categorisation criterion)*
  - *AMR monitoring in animal pathogens*
  - *other disease prevention and control measures*

Timelines

- Publication in OJ: 31 March 2016

- Delegated and implementing acts
  - transitional period (5 years)
  - application: 21 April 2021
  - "key" delegated and implementing acts to be adopted by 20 April 2019


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