Better Training for Safer Food
Initiative

EU LEGISLATION

BTSF

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Food safety

Malaga, Spain – 25-28 November 2019

EU legislative framework: in what areas can the EU legislate?

- Only if competences are conferred upon the Union in Treaties **Treaty of Lisbon; Art. 5 of the Treaty on the EU**
  - Exclusive Competence (i.e. agricultural, fisheries policy)
  - Shared Competence (environment, contribution to achieve health protection)
- Competences not conferred upon the Union in the Treaties remain with the MS (i.e. health policies)
- The use of Union competences is governed by the principles of:

  Subsidiarity: *in areas which do not fall within its exclusive competence, the Union shall act only if the objectives of the proposed action cannot be sufficiently achieved by the MS and can therefore be better achieved by the EU*

  Proportionality: *the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties*.
- **Art. 168 of the TFEU:** health protection, improvement public health; cross border threats

EU legislative framework: Human sector

- Directive 2001/83/EC of the EP and Council (6 November 2001) on **medicinal products for human use**
- Regulation (EC) No 726/2004 of the EP and Council (31 March 2004) laying down Community **procedures for the authorization and supervision of medicinal products** for human and veterinary use and establishing a **European Medicines Agency**
- Decision No 1082/2013/EU of the EP and Council (22 Oct 2013) on **serious cross-border threats to health:**
  - rules to coordinate/complement national policies on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, preparedness and response planning
  - methods of cooperation/coordination on serious cross-border threats to health: (a) threats of biological origin:
    (i) communicable diseases;
    (ii) AMR and HIA related to communicable diseases.

EU legislative framework: Human sector

- [**Council Recommendation** of 9 June 2009 on **patient safety**, including the prevention and control of healthcare associated infections (2009/C 151/01)]
- [**Council Recommendation** of 15 November 2001 on the **prudent use** of antimicrobial agents in human medicine (2002/77/EC)]
- [**Council Conclusions** on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a "One Health" perspective (June 2012)]
- [**Council Conclusions** on the next step under the "One Health" approach to combat antimicrobial resistance (June 2016)]
- [**Commission Notice**: EU **Guidelines** for the prudent use of antimicrobials in human health (2017/C 212/01)]

EU legislative framework: Human sector

- Regulation (EU) No 282/2014 of the EP and Council (11 March 2014) on the establishment of a third **Programme** for the **Union's action in the field of health** (2014-2020)
  - Activities of the Union to complement/support national health policies, encourage cooperation and promote the coordination between MS
  - Thematic priorities:
    1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle
    2. Protect Union citizens from serious cross-border health threats
    3. Contribute to innovative, efficient and sustainable health systems
    4. Facilitate access to better and safer healthcare for Union citizens

Revision of the regulatory framework – background related to AMR

- Directive 2001/82/EC on **veterinary medicinal products**
  - Annex I: Application file for marketing authorization - data on the potential emergence of resistance are necessary
- Regulation (EC) No 1831/2003 on **additives** for use in animal nutrition
  - Medicated feed containing AM: use no allowed to prevent diseases
  - Ban on authorization of antibiotics as feed additives
- Council Directive 90/167/EEC (26 March 1990) on the conditions governing the preparation, placing on the market and use of medicated feedingstuffs.
- Regulation (EC) No 470/2009 on procedures for the **establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin**

New Regulation (EU) 2019/6 on veterinary medicinal products and 2019/4 on the manufacture, placing on the market and use of medicated feed.

Entry into force: **28 January 2019**
Entry into application: **28 January 2022**

2019 EN Official Journal of the European Union L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

(Text with EEA relevance)

EU legislative framework: Veterinary sector

New Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMP) and 2019/4

Lays down **a wide range of CONCRETE MEASURES TO FIGHT AMR** and to **promote a PRUDENT AND RESPONSIBLE USE of antimicrobials**, such as:

- **REINFORCED BAN** on the use of antimicrobials for **promoting growth and increasing yield** (in addition to the 2006 prohibition of using antibiotics as growth promoters in feed)
- **BAN** on the **preventive use of antibiotics** in groups of animals,
- **RESTRICTIONS** on **metaphylactic use** of antimicrobials
- possibility to **RESERVE certain antimicrobials for humans only**,
- **OBLIGATION** for Member States to **collect data on the sale and use** of antimicrobials.
- For animals and products of animal origin **IMPORTED from NON-EU COUNTRIES to the EU**: **BAN** on antimicrobials for promoting growth & **RESTRICTIONS** on antimicrobials reserved for human use in the EU

EU legislative framework: Veterinary sector

New Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMP)

Lays down **a wide range of CONCRETE MEASURES TO FIGHT AMR** and to **promote a PRUDENT AND RESPONSIBLE USE of antimicrobials**, such as:

- **REQUIREMENTS** for prescription
- **RESTRICTION** off-label use
- **SUPPLY AND ADVERTISING**
- **FORBIDDANCE** of use of AM as AGP (antibiotic growth promoter)

EU legislative framework: Veterinary sector

New Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMP)

Lays down **a wide range of CONCRETE MEASURES TO FIGHT AMR** and to **promote a PRUDENT AND RESPONSIBLE USE of antimicrobials**, such as:

- Comprehensive evaluation of new marketing authorisation applications
- Ensuring that risk-benefit balance is positive for authorised antimicrobials: post authorisation requirements for AM
- Providing legal tools for preserving critical antimicrobials for the treatment of human infections
- Establishing an effective and harmonised compulsory monitoring system on sales and use of veterinary antimicrobials
- Incentives for development/marketing new AB (by extension protection to 14 years)

EU legislative framework: Feed sector

Lays down **a wide range of CONCRETE MEASURES TO FIGHT AMR** and to **promote a PRUDENT AND RESPONSIBLE USE of antimicrobials**, such as:

- ✓ Ban on the use of MF with antimicrobials for preventive treatment or growth promoter;
- ✓ Requirement for diagnosis of disease prior to the mandatory prescription for MF;
- ✓ Limitation of the duration of a treatment and validity of prescription;
- ✓ Establishment of EU wide, science based limits for residual levels of the major antimicrobials in ordinary compound feed;
- ✓ Measures to increase the quality of medicated feed production (more precise dosage) to avoid sub-therapeutic exposure and carry-over of antimicrobials into non-target feed.

European Commission

➢ OJ publication:

VMP: http://data.europa.eu/eli/reg/2019/6/oj

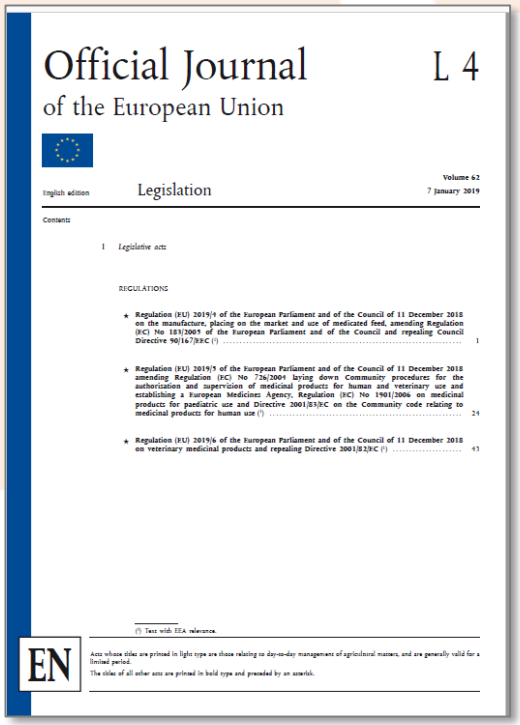
MF: http://data.europa.eu/eli/reg/2019/4/oj

➢ Factsheet infographic (VMP & MF)

https://ec.europa.eu/food/sites/food/files/animals/docs/ah_vet_med_feed_factsheet_2018_en.pdf

➢ Q&A (VMP & MF)

http://europa.eu/rapid/press-release_MEMO-18-6562_en.htm



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English edition — Legislation — Volume 62 — 7 January 2019

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★ Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (1) ... 1

★ Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (1) ... 24

★ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (1) ... 43

(1) Text with EEA relevance.

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

European Commission

NEW EU RULES ON VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEED

VETERINARY MEDICINAL PRODUCTS: WHAT'S NEW?

FIGHTING ANTIMICROBIAL RESISTANCE

BAN on preventive use of antibiotics in groups of animals

REINFORCED BAN on the use of antimicrobials for promoting growth and increasing yield

RESTRICTIONS on metaphylactic use of antimicrobials (control treatment preventing a further spread of infection)

Possibility to RESERVE certain antimicrobials for humans only

OBLIGATION for Member States to collect data on the sale and use of antimicrobials

For IMPORTED ANIMALS and products from OUTSIDE THE EU: ban on antimicrobials for promoting growth and restrictions on antimicrobials reserved for human use

PROMOTING AVAILABILITY OF VETERINARY MEDICINAL PRODUCTS BY STIMULATING INNOVATION AND COMPETITIVENESS

ESTABLISHING A MODERN, INNOVATIVE, FIT-FOR-PURPOSE LEGAL FRAMEWORK

MEDICATED FEED: WHAT'S NEW?

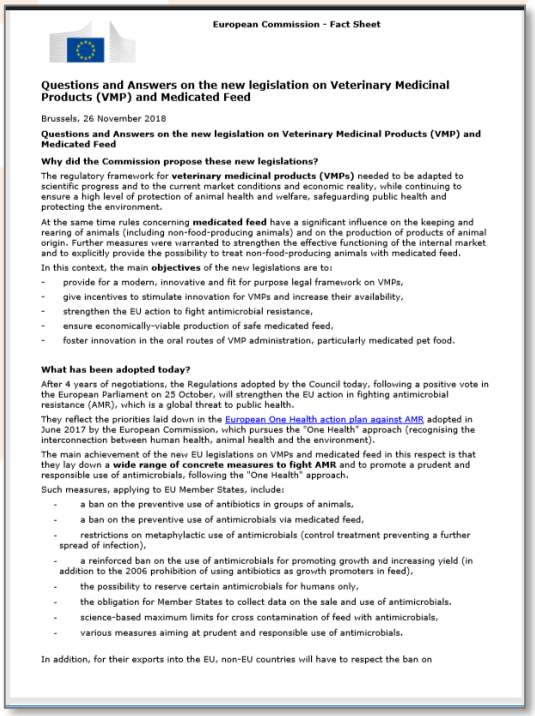
FIGHTING ANTIMICROBIAL RESISTANCE

BAN on preventive use of antimicrobials via medicated feed, on top of the use restrictions for veterinary medicines

RESTRICTIONS on the prescription of antimicrobials in medicated feed

EU-WIDE RULES FOR THE ECONOMICALLY VIABLE PRODUCTION OF SAFE MEDICATED FEED

Health and Food Safety



European Commission - Fact Sheet

Questions and Answers on the new legislation on Veterinary Medicinal Products (VMP) and Medicated Feed

Brussels, 26 November 2018

Questions and Answers on the new legislation on Veterinary Medicinal Products (VMP) and Medicated Feed

Why did the Commission propose these new legislations?

The regulatory framework for **veterinary medicinal products (VMPs)** needed to be adapted to scientific progress and to the current market conditions and economic reality, while continuing to ensure a high level of protection of animal health and welfare, safeguarding public health and protecting the environment.

At the same time rules concerning **medicated feed** have a significant influence on the keeping and rearing of animals (including non-food-producing animals) and on the production of products of animal origin. Further measures were warranted to strengthen the effective functioning of the internal market and to explicitly provide the possibility to treat non-food-producing animals with medicated feed.

In this context, the main **objectives** of the new legislations are to:

- provide for a modern, innovative and fit for purpose legal framework on VMPs,
- give incentives to stimulate innovation for VMPs and increase their availability,
- strengthen the EU action to fight antimicrobial resistance,
- ensure economically-viable production of safe medicated feed,
- foster innovation in the oral routes of VMP administration, particularly medicated pet food.

What has been adopted today?

After 4 years of negotiations, the Regulations adopted by the Council today, following a positive vote in the European Parliament on 25 October, will strengthen the EU action in fighting antimicrobial resistance (AMR), which is a global threat to public health.

They reflect the priorities laid down in the European One Health action plan against AMR adopted in June 2017 by the European Commission, which pursues the "One Health" approach (recognising the interconnection between human health, animal health and the environment).

The main achievement of the new EU legislations on VMPs and medicated feed in this respect is that they lay down a **wide range of concrete measures to fight AMR** and to promote a prudent and responsible use of antimicrobials, following the "One Health" approach.

Such measures, applying to EU Member States, include:

- a ban on the preventive use of antibiotics in groups of animals,
- a ban on the preventive use of antimicrobials via medicated feed,
- restrictions on metaphylactic use of antimicrobials (control treatment preventing a further spread of infection),
- a reinforced ban on the use of antimicrobials for promoting growth and increasing yield (in addition to the 2006 prohibition of using antibiotics as growth promoters in feed),
- the possibility to reserve certain antimicrobials for humans only,
- the obligation for Member States to collect data on the sale and use of antimicrobials.
- science-based maximum limits for cross contamination of feed with antimicrobials,
- various measures aiming at prudent and responsible use of antimicrobials.

In addition, for their exports into the EU, non-EU countries will have to respect the ban on

EU legislative framework: Veterinary sector

FOOD – ZOONOTIC AGENTS

- Directive 2003/99/EC on the **monitoring of zoonoses** and zoonotic agents;

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

Review EU implementing legislation on monitoring AMR in zoonotic and commensal bacteria in farm animals and food.

- Mandate to EFSA for technical advice 2017
- EFSA opinión 2019
- Adoption of the new legislation 2021

Animal Health Law: Regulation (EU) 2016/429 of the EP and the Council (9 March 2016) on transmissible animal diseases "Prevention is better than cure"

- **Preventive** driven **approach**: improvement animal health and biosecurity measures, good farming practices
- Clear **responsibility** for all players for animal health
  - Operators → ensure level of animal health and biosecurity
  - Vets → prevention spread pathogens and to raise awareness
  - CA → protect animal health, human health and environment
- **Prioritising** EU intervention,
  - Regulatory tools/interventions for resistant pathogens: "disease agents"
  - Disease preventive and control measures may apply (surveillance, eradication etc.)
  - Legal basis monitoring AMR in animal pathogens

Referrals on VMP

A referral is a procedure used to resolve concerns over the safety or benefit-risk balance of a medicine or a class of medicines.

- The VMPs is 'referred' to the EMA-CVMP
- Recommendations to ensue harmonisation across EU
- Referral (CVMP recommendation) transformed in Decision by the EC (voted by MS) + implementation by MS

Legal basis: Directive 2001/82/EC (Regulation (EU) 2019/6 on veterinary medicinal products)

Comparison of legal basis under Directive 2001/82/EC

	Article 33(4)	Article 34	Article 35
Basis	Failure to agree at CMDv level on the basis of potential serious risk to human or animal health or for the environment	Divergent decisions between Member States on authorisation	Community interest
Referred to CVMP	By default	Optional	Optional
Who can trigger	Reference Member State on basis of ground provided by the objecting Concerned Member State(s)	Member State Commission MAH	Member State Commission MAH
Scope (size)	One application/product	One product authorised in more than one MS	One product or a class of products
Evidence required	Scientific justification for potential serious risk concern based on Commission guideline (2006)	Different SPCs in Member States Refusal of application by one MS of product authorised in another	Scientific justification for Community interest
Timetable	60 days	Up to 150 days	Up to 150 days
Outcome	Granting or refusal of the marketing authorisation	Harmonised SPC	Maintenance, variation or suspension of the marketing authorisation(s)

Referrals under Directive 2001/82/EC & Regulation 2019/6/EU

Directive 2001/82/EC	Regulation 2019/6
Article 33 MRP/DCP referral	Article 54 Review procedure
Article 34 SPC harmonisation	Article 69 SPC harmonisation
Article 35 Union interest referral	Article 82 Union interest referral
Article 78 Urgent Union procedure	Article 130 Suspending, revoking, or varying the terms, of MAs

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Food safety