



# Forthcoming EU Regulations on Veterinary Medicinal Products & Medicated Feed

**Fighting Antimicrobial Resistance!**

**Julie SAINZ & Wolfgang TRUNK**  
DG Health and Food Safety

*AMR One-Health Network Meeting*  
*Brussels, 26 October 2018*



# Forthcoming EU Regulation on Veterinary Medicinal Products (VMP)

## Fighting Antimicrobial Resistance!

Julie SAINZ, PhD  
DG Health and Food Safety  
*Animal Nutrition, Veterinary Medicines*

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# Current EU Legislation for VMPPs

## *2 major Legal Acts*



**DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 6 November 2001**  
**on the Community code relating to veterinary medicinal products**



**REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 31 March 2004**  
**laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**

# Supporting the EU Legislation for VMPs

## *EU Guidelines*

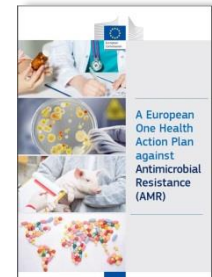


**COMMISSION NOTICE**  
**Guidelines for the prudent use of antimicrobials in veterinary medicine**  
(2015/C 299/04)

## *European One Health Action Plan against AMR*

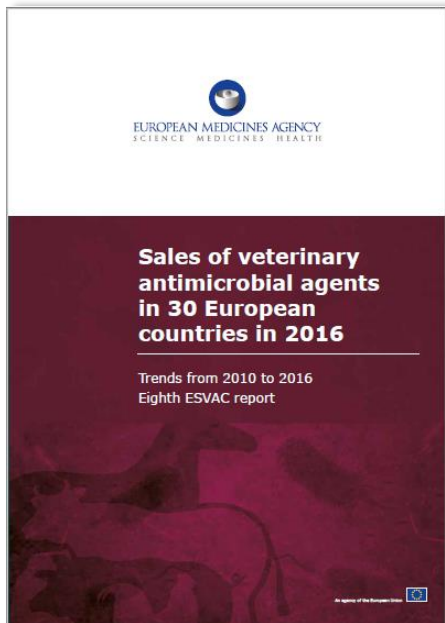


**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**  
**A European One Health Action Plan against Antimicrobial Resistance (AMR)**  
{SWD(2017) 240 final}



# Progress is being made against AMR ***BUT*** there is still much to achieve!

*Oct.2018*



## ***8<sup>th</sup> European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report***

- ***20% ↘ overall sales across Europe (2011-2016),***
- ***BUT heterogeneous situation among European Countries.***

# Forthcoming EU Regulation for VMPs

## - Objectives -

- Guarantee a **high level of public health protection**
  - Ensure **high quality & safety standards**
  - Enhance the **availability of VMPs**
  - Support an **optimal functioning of the internal market**
  - Put in place an **up-to-date legal framework, tailored to VMPs**
  - **Simplify procedures** for obtaining a **marketing authorisation**
  - Review **incentives for breakthrough medicines**
- ⇒ Strengthen the **fight against AMR**

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# Forthcoming EU Regulation for VMPs

## Concrete Measures strengthening the fight against AMR

ban on preventive use of antibiotics in groups of animals

restrictions on metaphylactic use

possibility to reserve certain antimicrobials for humans only

ban on the use of antimicrobials for promoting growth

compulsory data collection on sales and use of antimicrobials

various measures aiming at prudent and responsible use



# Forthcoming EU Regulation for VMPs

## On the way to Application...

### 25 Legal Acts to support/complement

#### **8 Delegated Acts**

⇒ **3 directly impact the fight vs. AMR**

#### **17 Implementing Acts**

⇒ **2 directly impact the fight vs. AMR**

**Requirements and methods for gathering data** on AMR (sale and use of antimicrobials)

**Complete format for the collection of data** on antimicrobials

**Criteria** for the designation of antimicrobials reserved for human use

**List** of antimicrobials reserved for human use

Rules on **exports from third countries**

# AMR has no borders...

## How does antibiotic resistance spread?

Antibiotic resistance is the ability of bacteria to combat the action of one or more antibiotics. Humans and animals do not become resistant to antibiotic treatments, but bacteria carried by humans and animals can.



1 Animals may be treated with antibiotics and they can therefore carry antibiotic-resistant bacteria. 2 Vegetables may be contaminated with antibiotic-resistant bacteria from animal manure used as fertilizer. 3 Antibiotic-resistant bacteria can spread to humans through food and direct contact with animals.

In animal farming

4 Humans sometimes receive antibiotics prescribed to treat infections. However, bacteria develop resistance to antibiotics as a natural, adaptive reaction. Antibiotic-resistant bacteria can then spread from the treated patient to other persons.

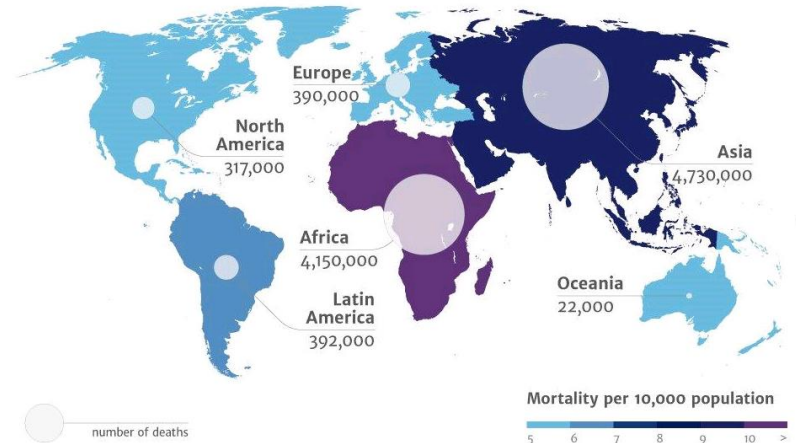
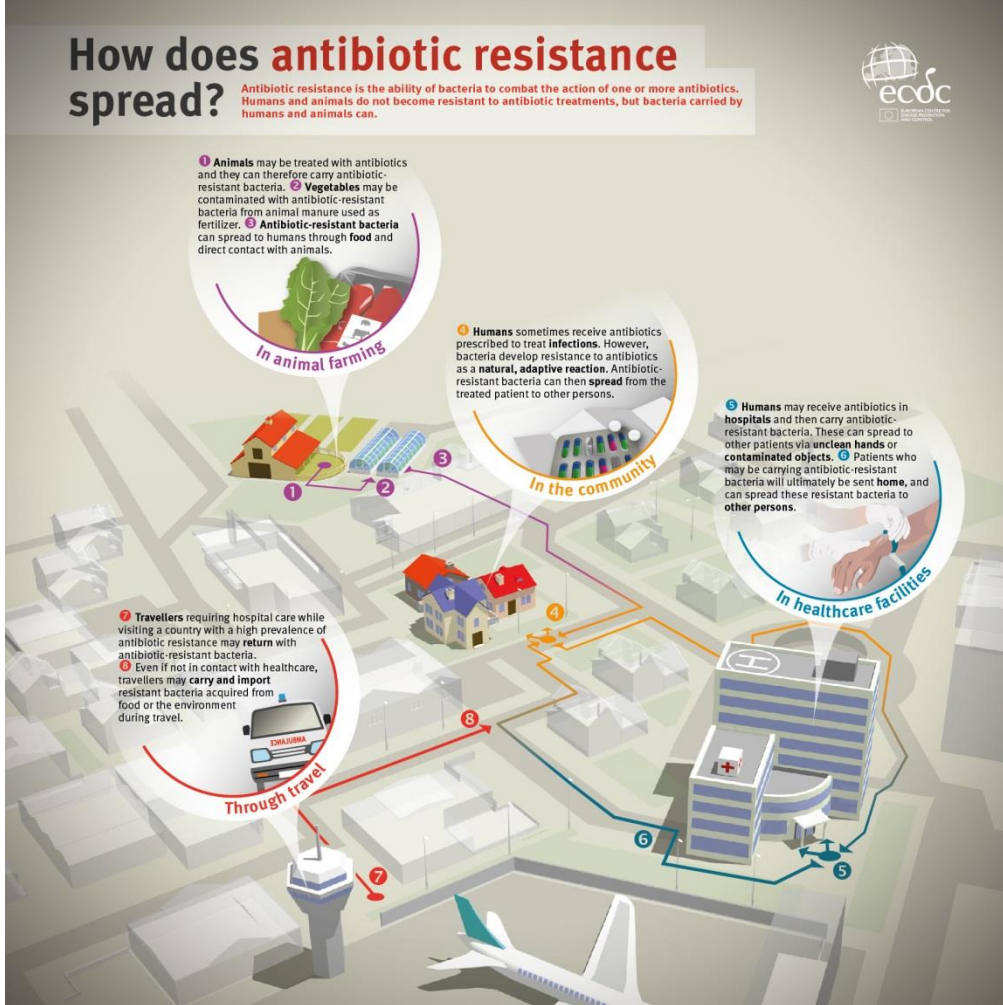
In the community

5 Humans may receive antibiotics in hospitals and then carry antibiotic-resistant bacteria. These can spread to other patients via unclean hands or contaminated objects. 6 Patients who may be carrying antibiotic-resistant bacteria will ultimately be sent home, and can spread these resistant bacteria to other persons.

In healthcare facilities

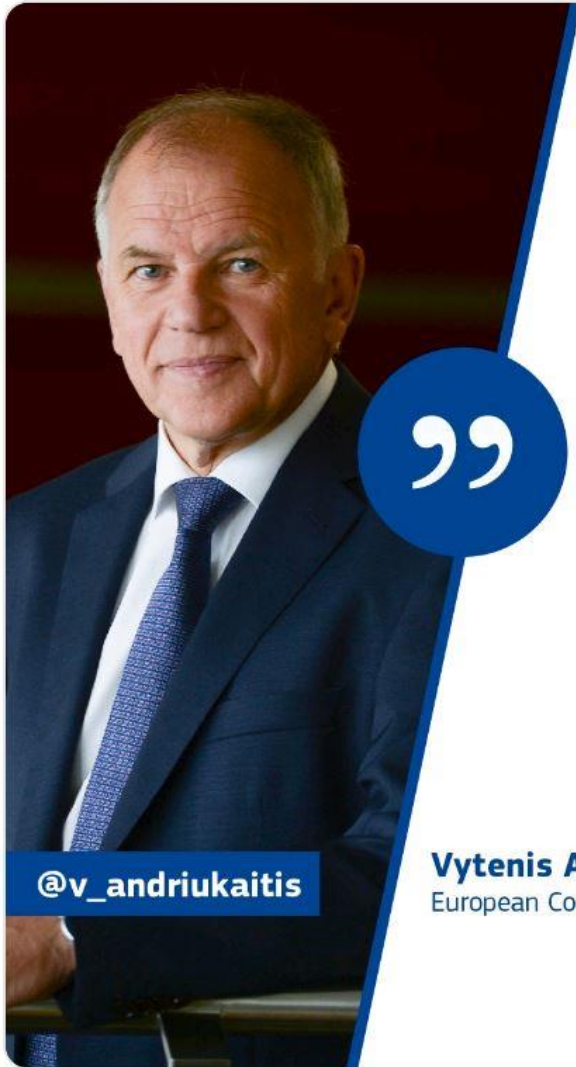
7 Travellers requiring hospital care while visiting a country with a high prevalence of antibiotic resistance may return with antibiotic-resistant bacteria. 8 Even if not in contact with healthcare, travellers may carry and import resistant bacteria acquired from food or the environment during travel.

Through travel



[https://amr-review.org/sites/default/files/World\\_Map.jpg](https://amr-review.org/sites/default/files/World_Map.jpg)

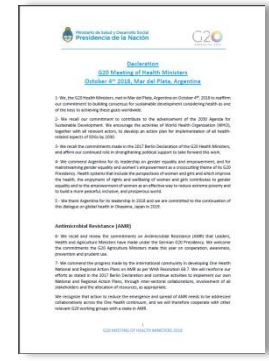
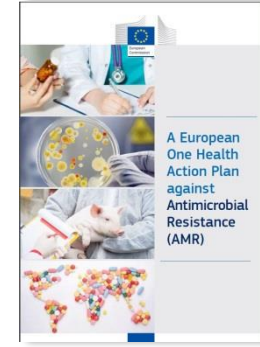
# Keeping the political momentum at EU and Global level



*Excessive or inappropriate use of antimicrobials has made of antimicrobial resistance one of the biggest threats to global health. It is our duty to take effective, coordinated measures at all levels and in all sectors – regional, national, European and global – so that we fight antimicrobial resistance from all angles. Therefore, I welcome the Parliament's report adopted today. Together we make sure that the EU remains a global leader on AMR.*

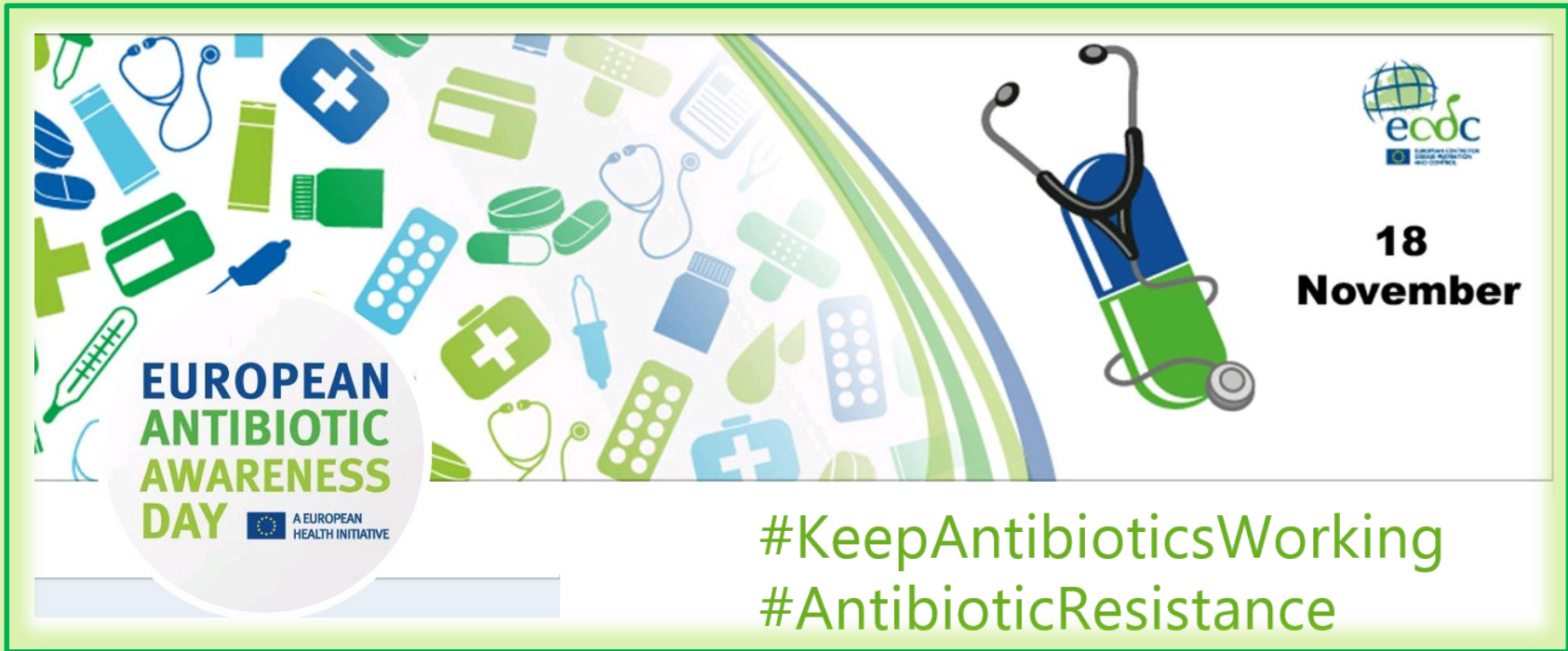
@v\_andriukaitis

**Vytenis Andriukaitis**  
European Commissioner for Health and Food Safety




(...)





The banner features a background of various medical icons in shades of green and blue, including a stethoscope, pills, syringes, and band-aids. A large, stylized graphic of a stethoscope is positioned on the right side. The text is arranged as follows:

**EUROPEAN  
ANTIBIOTIC  
AWARENESS  
DAY**  A EUROPEAN  
HEALTH INITIATIVE

**18  
November**

**#KeepAntibioticsWorking  
#AntibioticResistance**



**World Antibiotic Awareness Week, 12-18 November 2018**





# Forthcoming EU Regulation on Medicated Feed

**Fighting Antimicrobial Resistance!**

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DG Health and Food Safety  
*Animal Nutrition, Veterinary Medicines*

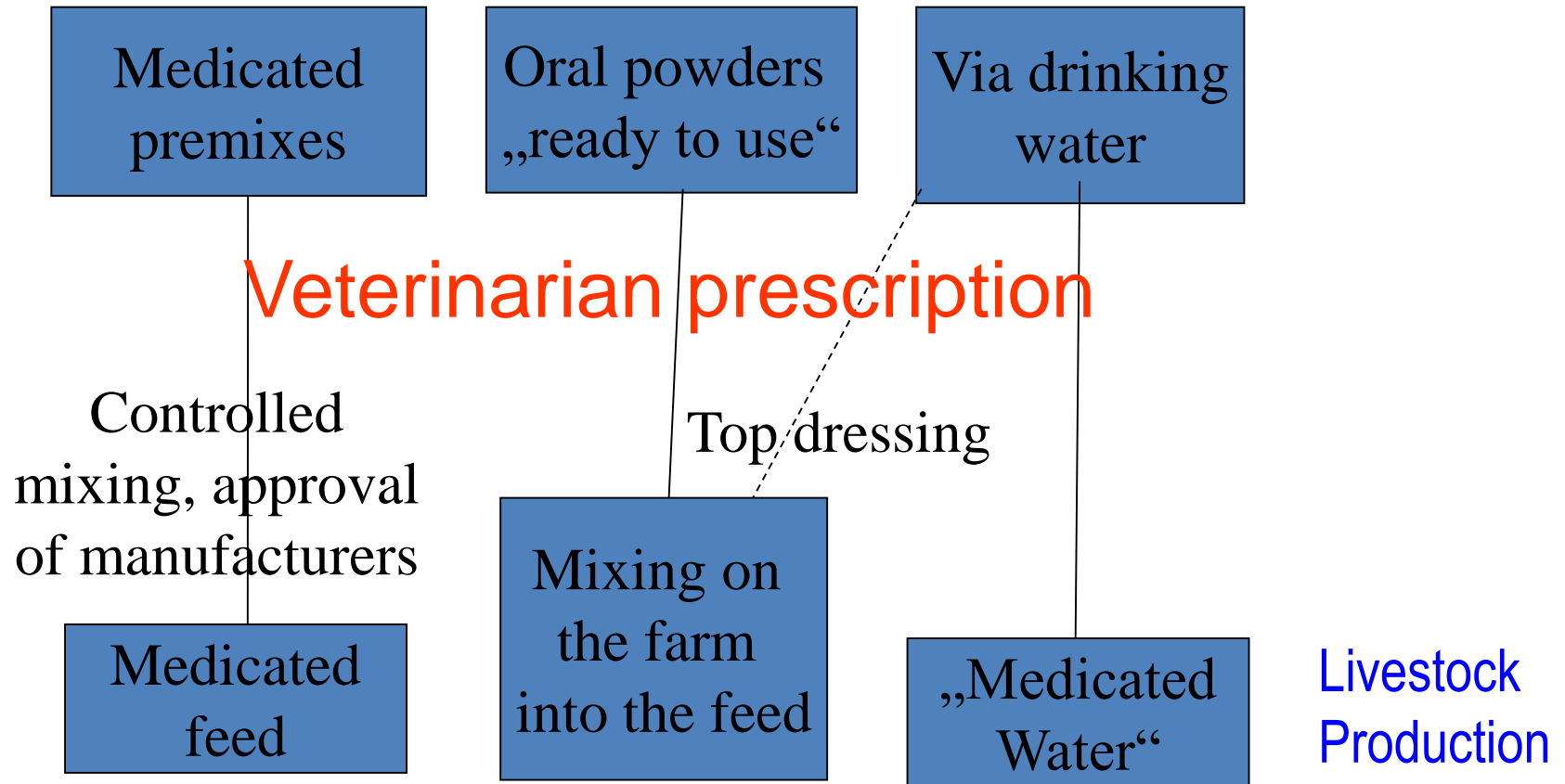
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# Why a revision?

- Directive 90/167/EEC on Medicated Feed has been established before the creation of the internal market and it has never been adapted in substance.
- The national transposition of this legal instrument has given freedom to Member States regarding interpretation and implementation of the legal provisions, but this flexibility has contributed to some problems.
- Need for a holistic approach at EU level to address antimicrobial resistance (AMR) => project launched 2008 - external report - IA

# Oral administration of VMPs



# Medication via drinking water ?





# “oral powders”



# Medicated Feed



# AMR measures (1)

## 1. Carry over limits of veterinary medicines in feed:

*Commission mandate for DA with science based residue limits for 24 antimicrobials in ordinary feed one year after date of application of the Regulation, i.e. 4 years after publication. This deadline is already a big challenge for the Commission as the procedure crucially depends on the European Food Safety Authority (EFSA), for which this will be a new task requiring close cooperation with the European Medicines Agency.*

# AMR measures (2)

2. Restrictions for veterinary prescriptions of VMPs
  - *The validity of veterinary prescriptions for medicated feed with antimicrobials is 5 days.*
  - *Duration of treatments with antibiotics max two weeks if not specified differently in SPC.*
  
3. Use of antimicrobials in medicated feed for prophylaxis and growth promotion banned:  
*In addition to the use restrictions for antimicrobials established for VMPs (reference to Article 107), ban of antimicrobials via MF for prophylaxis (for antiparasitics and immunological VMPs reference to VMP Regulation).*



# Questions ?

For more information on the revision of the legislation on medicated feed:  
[https://ec.europa.eu/food/safety/animal-feed/medicated-feed\\_en](https://ec.europa.eu/food/safety/animal-feed/medicated-feed_en)