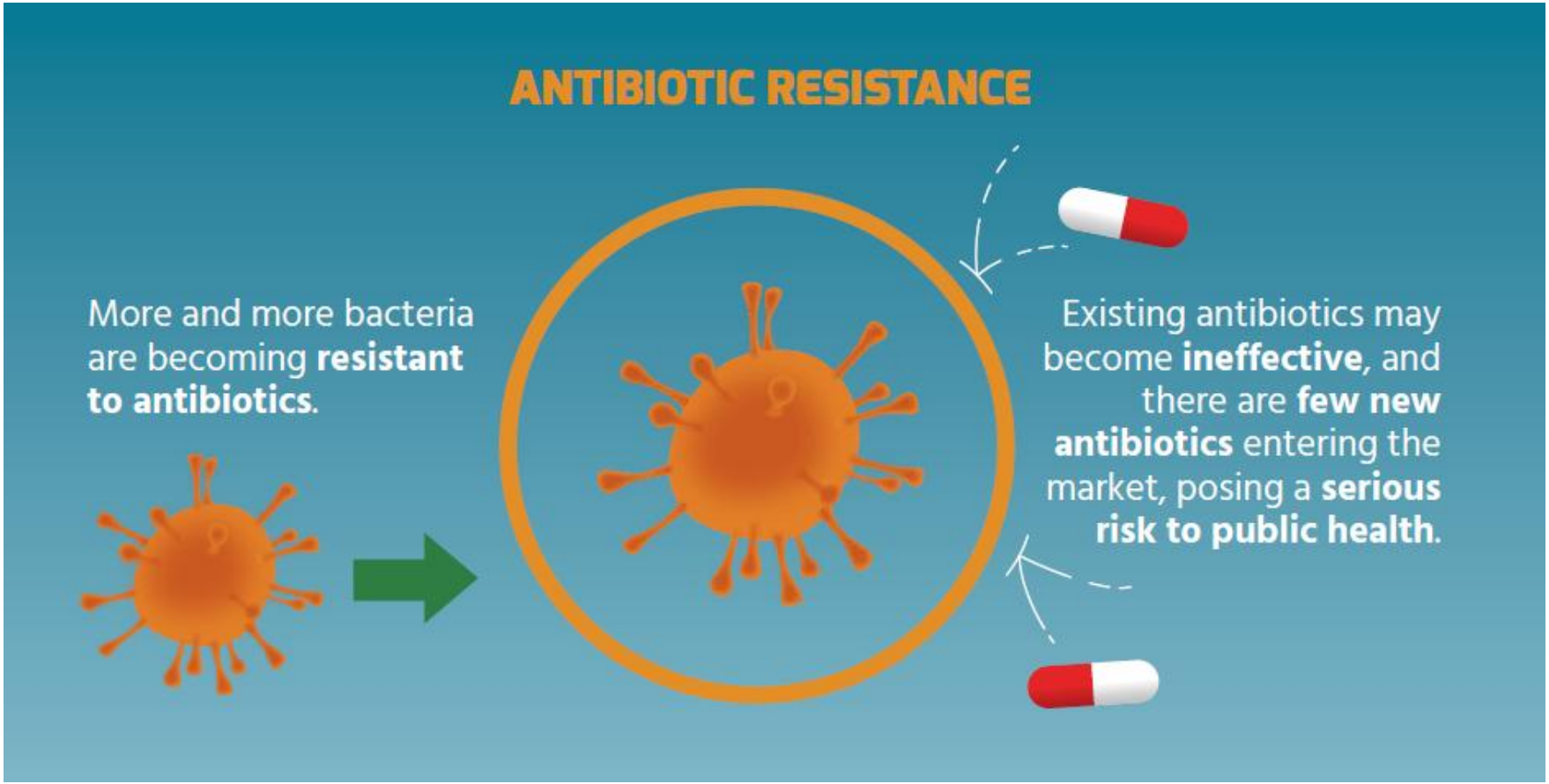
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Consumo y venta de antibióticos para uso en animales en Europa

Jornada sobre Transmisión de Resistencia entre Humanos y Animales
Plan Nacional frente a la Resistencia a los Antibióticos (PRAN)
Fundación Ramón Areces

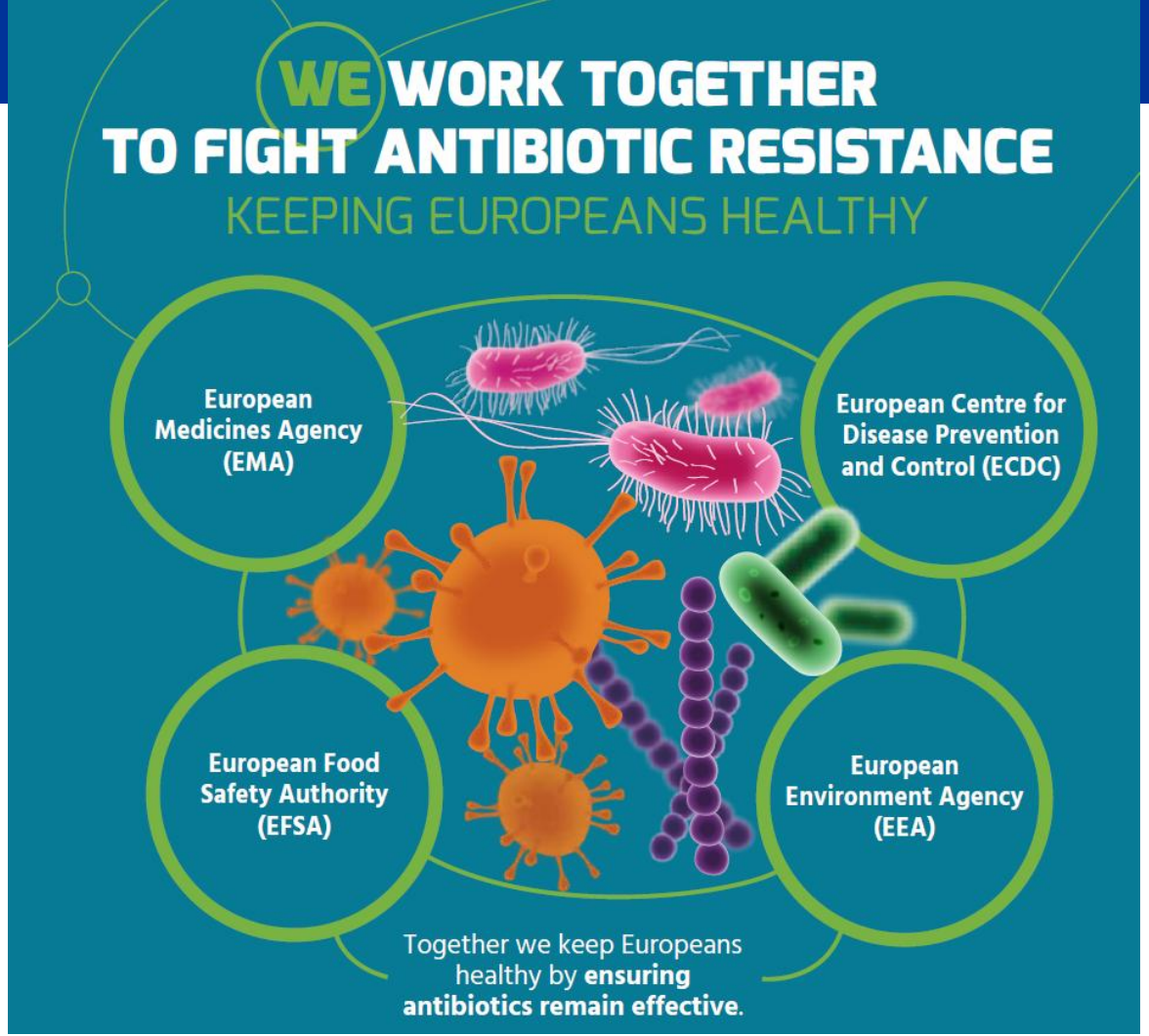
Presentado por Jordi Torren, Madrid, 5 de junio de 2018
Head of Service of Veterinary Risk and Surveillance (V-VM-SUR), Veterinary Medicines Department

An agency of the European Union


ANTIBIOTIC RESISTANCE
More and more bacteria are becoming **resistant to antibiotics**.
Existing antibiotics may become **ineffective**, and there are **few new antibiotics** entering the market, posing a **serious risk to public health**.

Cost of AMR

- 25 000 patients die annually in the EU alone as a result of infections caused by resistant bacteria.
- Globally this number could be as high as 700,000.
- 10 million deaths per year are projected between 2015 and 2050


WE WORK TOGETHER
TO FIGHT ANTIBIOTIC RESISTANCE
KEEPING EUROPEANS HEALTHY
European Medicines Agency (EMA)
European Centre for Disease Prevention and Control (ECDC)
European Food Safety Authority (EFSA)
European Environment Agency (EEA)
Together we keep Europeans healthy by ensuring antibiotics remain effective.

The fight against AMR

- "One health approach"; veterinarians, environment and human sectors
- Close cooperation with EC and sister Agencies, ECDC and EFSA, on the AMR strategy
- Cooperation with international partners, e.g. Transatlantic Taskforce on Antimicrobial Resistance, WHO, OIE, FAO, Codex Alimentarius

The global fight against AMR

The EU is not alone in recognising the threat of AMR and in addressing this issue at the highest political level. Many countries outside of the EU, as well as international organisations, are tackling this issue. International cooperation is a key element of the AMR action plan.

EU DECISION-MAKERS

European Parliament

European Commission

Council of the European Union

SCIENTIFIC ADVICE

European Medicines Agency

efsa European Food Safety Authority

ecdc

Scientific committes

Committees

CHMP

CVMP

ESVAC

Networks

EARS-Net

ESAC-Net

SCENIHR

INTERNATIONAL ORGANISATIONS

World Health Organization

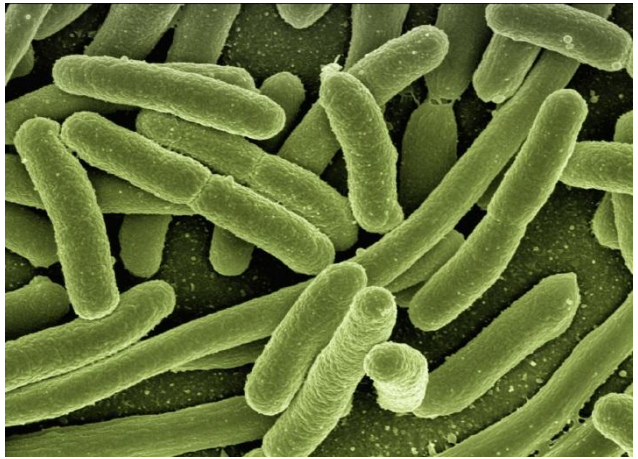
Food and Agriculture Organization of the United Nations

Oie World Organisation for Animal Health

codex Alimentarius

Current challenges and policy options

- To tackle AMR we need a sustainable pipeline of antimicrobials and alternatives.
- R&D scientifically challenging with low success rate.
- New Antibiotics are not profitable.
- New antibiotics will be kept in reserve.
- More infection control, prudent use and surveillance happening/expected.

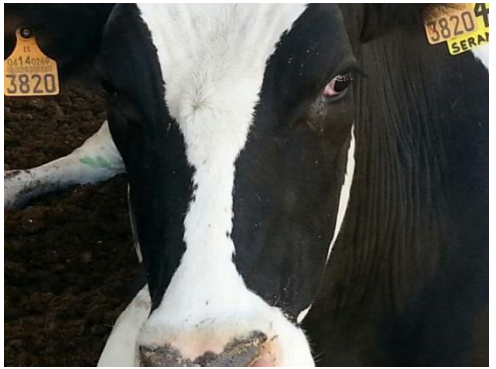


Current challenges and policy options (2)

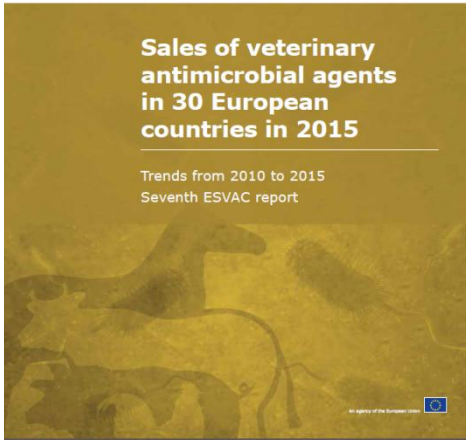
- New business models for antibiotics necessary to reward innovation.
- Alternatives to antibiotics to be explored, e.g. phages, vaccines.
- Key role of rapid-diagnostic tests to foster rational use.

Antimicrobials in the veterinary sector

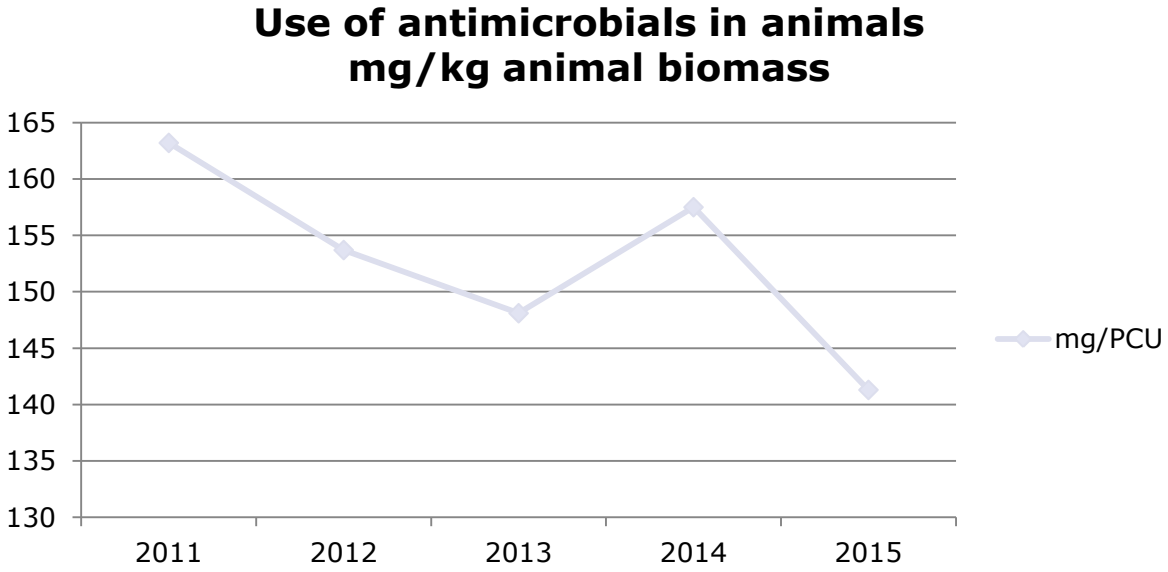
- No truly new antimicrobial classes have been introduced in recent years.
- Responsible use of antimicrobials is regarded a cornerstone to contain resistance for benefit of both animal and human health.
- Improved livestock management, including biosecurity.
- Reduction of antimicrobial use in animals is a target.
- EU: no growth promoters since 2006.
- Need for effective antimicrobial treatment of animals.



Sales of all antimicrobials for food-producing animals, in mg/kg animal biomass, for 30 countries, for 2015



Overall reduction of use of antimicrobials in animals in the EU



- Overall reduction of antimicrobials used in animals in the EU (ESVAC)
- Some countries massive reduction (France, Netherlands, Germany…)
- Setting targets works

Indicators

SCIENTIFIC OPINION

ADOPTED: 22 September 2017 (ECDC Advisory Forum), 14 September 2017 (EFSA BIOHAZ Panel), 6 September 2017 (EMA CVMP)

doi: 10.2903/j.efsa.2017.5017

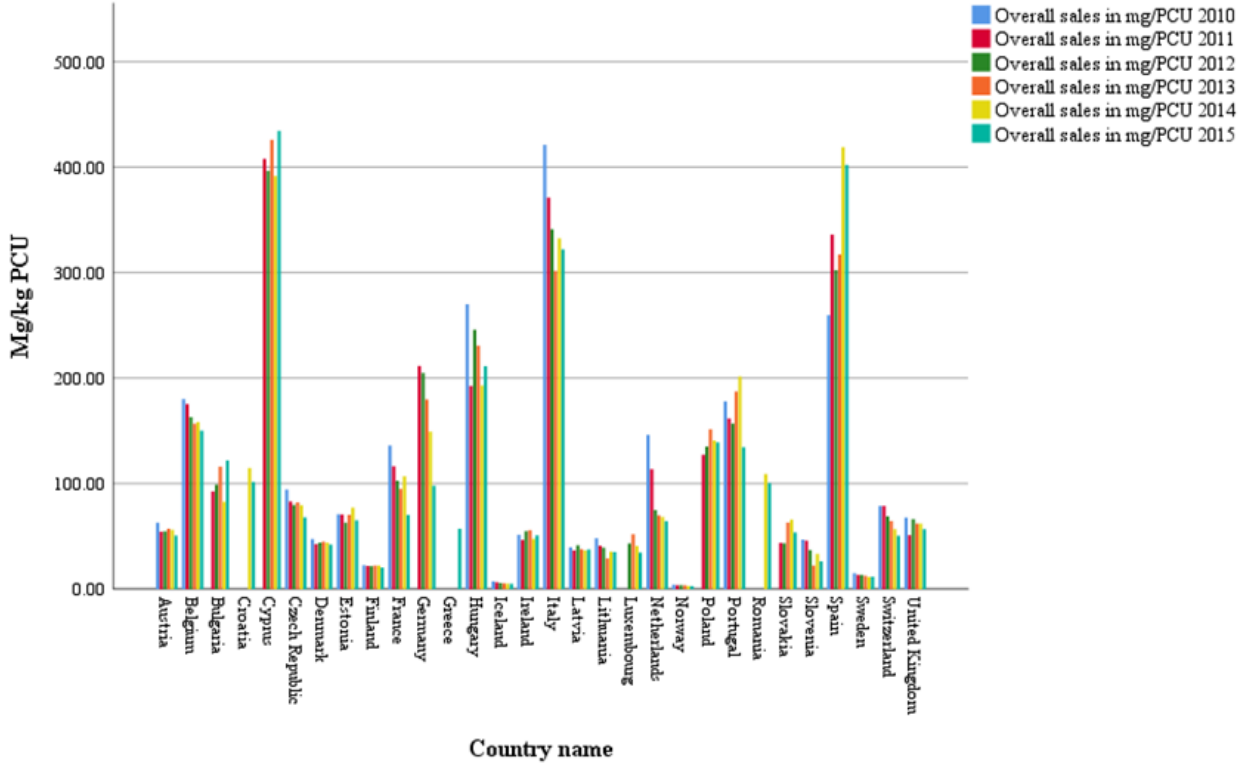
ECDC, EFSA and EMA Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals

ECDC, EFSA Panel on Biological Hazards (BIOHAZ) and
EMA Committee for Medicinal Products for Veterinary Use (CVMP)*

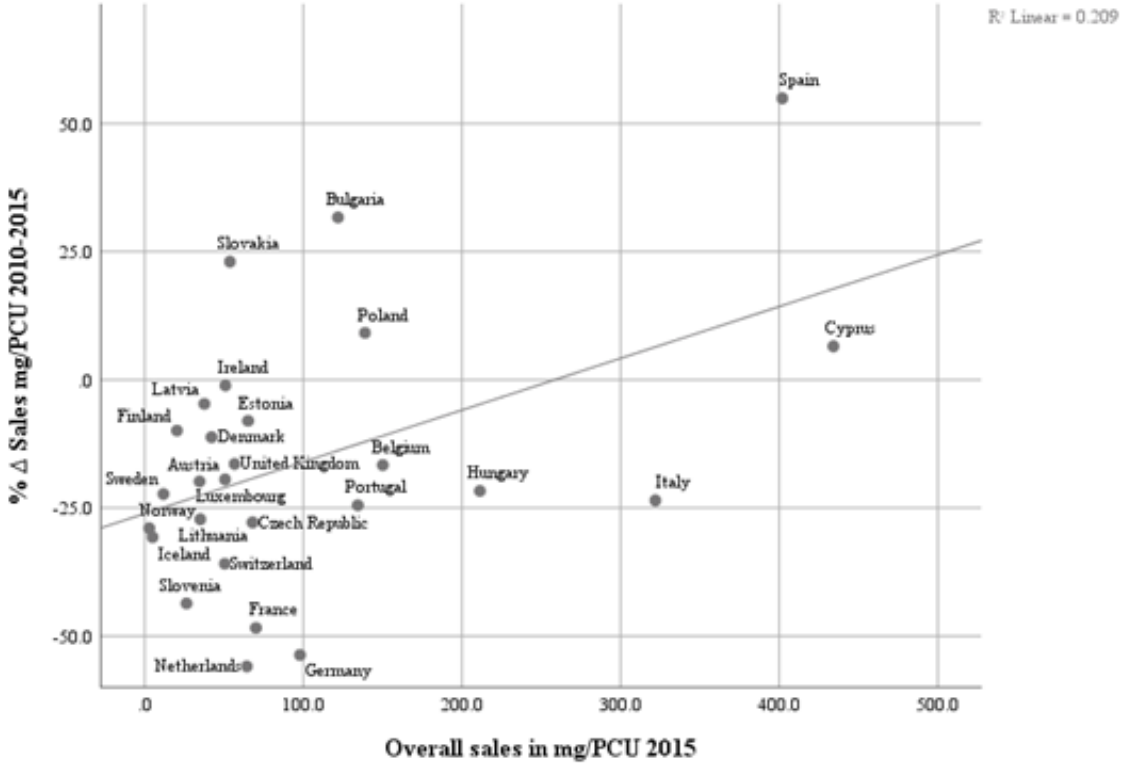
	Sales in mg per PCU				Proportion %
Country	Overall sales	3-4 gen. cephalosporins	Polymyxins	All Quinolones (fluoroquinolones + other quinolones)	Fluoroquinolones vs all quinolones
Austria	50.7	0.2	1.6	0.5	100%
Belgium	150.1	0.4	2.7	2.3	45%
Bulgaria	121.9	0.2	3.6	5.7	94%
Croatia	100.0	0.2	2.5	4.2	82%
Cyprus	434.2	0.3	12.3	1.5	74%
Czech Republic	68.1	0.4	< 1mg/PCU	1.7	97%
Denmark	42.2	0.0	< 1mg/PCU	0.4	1%
Estonia	65.2	0.6	1.3	1.8	100%
Finland	20.4	0.0		0.1	100%
France	70.2	0.2	4	0.7	47%
Germany	97.9	0.4	9.1	1.1	100%
Greece	57.2	0.1	3.3	4.3	39%
Hungary	211.4	0.4	9.6	9.7	97%
Iceland	5.0	0.0		0.0	100%
Ireland	51.0	0.1	< 1mg/PCU	0.4	100%
Italy	322.0	0.4	26.1	6.2	47%
Latvia	37.6	0.4	< 1mg/PCU	1.1	99%
Lithuania	35.1	0.1	< 1mg/PCU	1.9	90%
Luxembourg	34.6	0.6	1.4	0.9	84%
Netherlands	64.4	0.0	< 1mg/PCU	1.3	9%
Norway	2.9	0.0		0.0	12%
Poland	138.9	0.1	5.9	8.6	100%
Portugal	134.4	0.4	12.1	8.1	98%
Romania	100.5	0.0	7.4	6.3	97%
Slovakia	51.0	0.3	1.1	2.9	99%
Slovenia	26.4	0.2	< 1mg/PCU	3.1	100%
Spain	402.0	0.3	34.9	9.7	92%
Sweden	11.8	0.0	< 1mg/PCU	0.0	100%
Switzerland	50.6	0.2	< 1mg/PCU	0.5	100%
United Kingdom	56.7	0.2	< 1mg/PCU	0.3	100%

Refresh - Print

Sales in mg/kg PCU (Population Correction Unit) 2010-2015

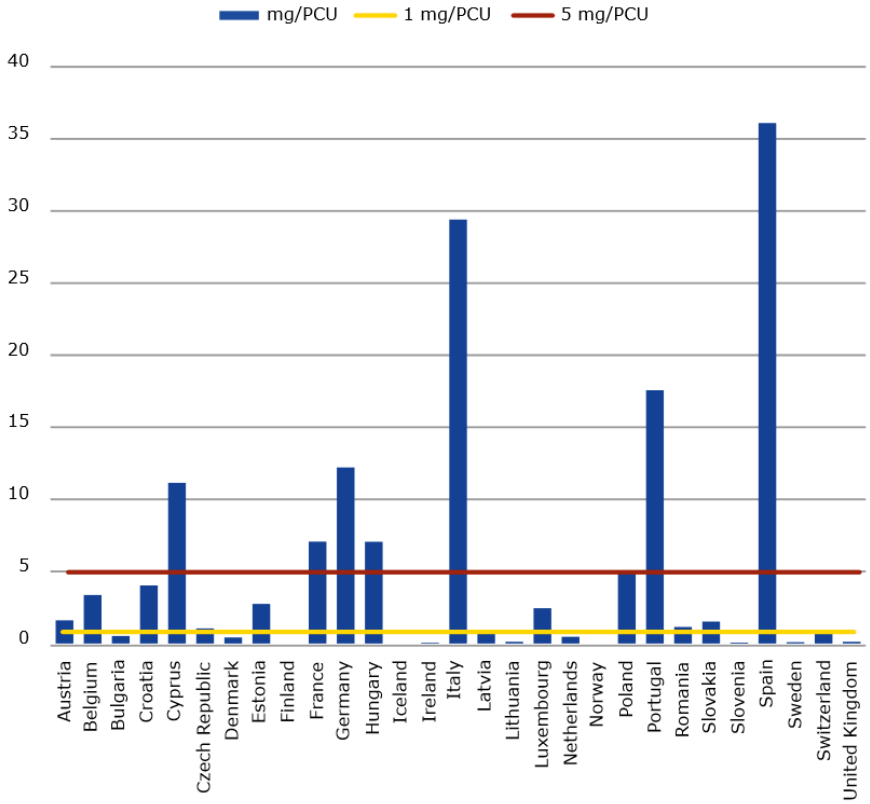


Total sales vs increase/decrease of antimicrobial use



Colistin

Mcr-1 gen
Targets set on
reduction
of use of colistin



ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) Population Correction Unit (PCU)

The main indicator is mg active ingredient normalised by the population correction unit (mg/PCU)

Estimated animal population data from Eurostat, TRACES and national statistics

PCU domestic

- Number of animals slaughtered x estimated weight at treatment
- Number of livestock x estimated weight at treatment

PCU export

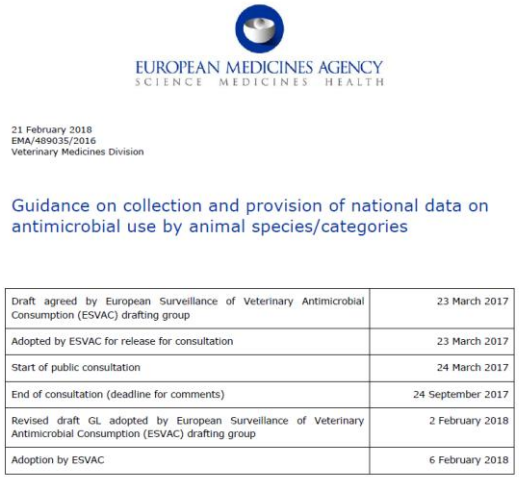
PCU import

Importance of the "denominator" ESVAC PCU and OIE animal biomass

ESVAC PCU	OIE animal biomass
Weight at treatment	Weight at slaughter
Produced in the country + Import and export	Indigenous
Mg/PCU **141** (30 EU/EEA)	Mg/kg **90** (31 Europe)

Collection of use data by animal species

- Guidance published
- Waiting for new veterinary medicines regulation (art. 54)
- No immediate project to start collecting data by animal species

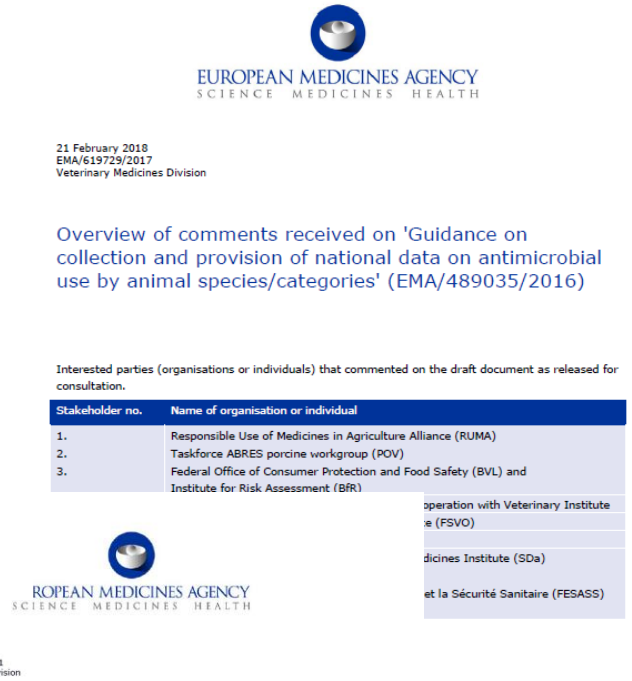


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2018
EMA/489035/2016
Veterinary Medicines Division

Guidance on collection and provision of national data on antimicrobial use by animal species/categories

Draft agreed by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) drafting group	23 March 2017
Adopted by ESVAC for release for consultation	23 March 2017
Start of public consultation	24 March 2017
End of consultation (deadline for comments)	24 September 2017
Revised draft GL adopted by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) drafting group	2 February 2018
Adoption by ESVAC	6 February 2018



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2018
EMA/619729/2017
Veterinary Medicines Division

Overview of comments received on 'Guidance on collection and provision of national data on antimicrobial use by animal species/categories' (EMA/489035/2016)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1.	Responsible Use of Medicines in Agriculture Alliance (RUMA)
2.	Taskforce ABRES porcine workgroup (POV)
3.	Federal Office of Consumer Protection and Food Safety (BVL) and Institute for Risk Assessment (BfR)

ROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2018
EMA/716249/2016-Rev.1
Veterinary Medicines Division

Questions and answers for the guidance on collection and provision of national data on antimicrobial use by animal species/categories (EMA/489035/2016-Rev.1)

Collection of antimicrobial use by animal species in Europe

- In eleven countries data collection systems are in place for one or more species.
- In five more countries data collection system is under development.

Variation in:

→ Included species/categories.

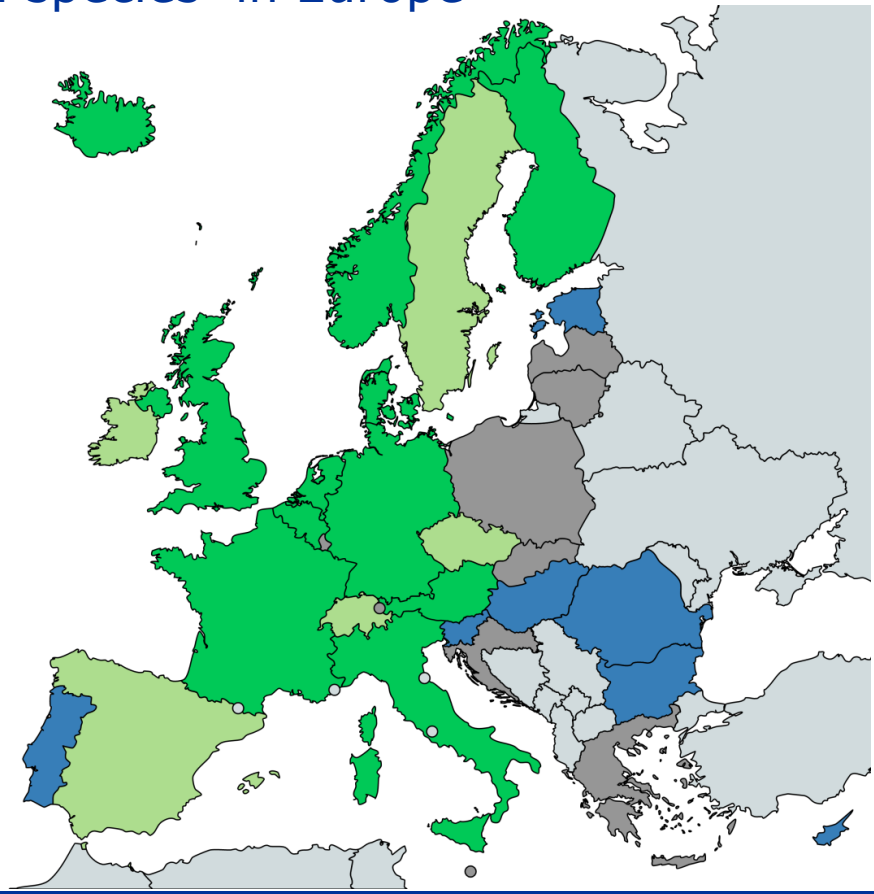
→ Coverage per species.

→ Initiator (e.g. government, industry).

→ Data sources.

→ Variables.

→ Indicators.



Targets and animal biomass

Supply Chain	2016 Industry data	Waitrose 2016 Antibiotic usage (Mg/PCU)	RUMA/ Industry Target 2020 (Mg/PCU)
Beef, Veal, Venison	N/A	<10	10
Lamb	N/A	<10	10
Pigs	183	50-75	99
Dairy	26.2	15-25	21
Chicken	17	<5	25
Duck	3	<5	25
Turkey	86	10-15	50
Salmon	N/A	<10	5
Trout	N/A	<5	<20
Egg *	0.73	<0.5	<1

*NB. No mg/PCU is available for eggs so the number of days hens are medicated are counted (%)

Understanding mg/PCU

xx mg divided by xx kg = xx mg/PCU

1 PCU = 1 kg. For example a 50 mg/PCU figure for food producing animals would mean that on average, and over the course of a year, 50 mg of antibiotic active ingredient was used for every kg of bodyweight at time of treatment.

Stratification of sales data

- Project launched
- Start of pilot (Austria, Czech Republic, Denmark, France, the Netherlands and **Spain**)
- FDA/Health Canada

Units of measurement

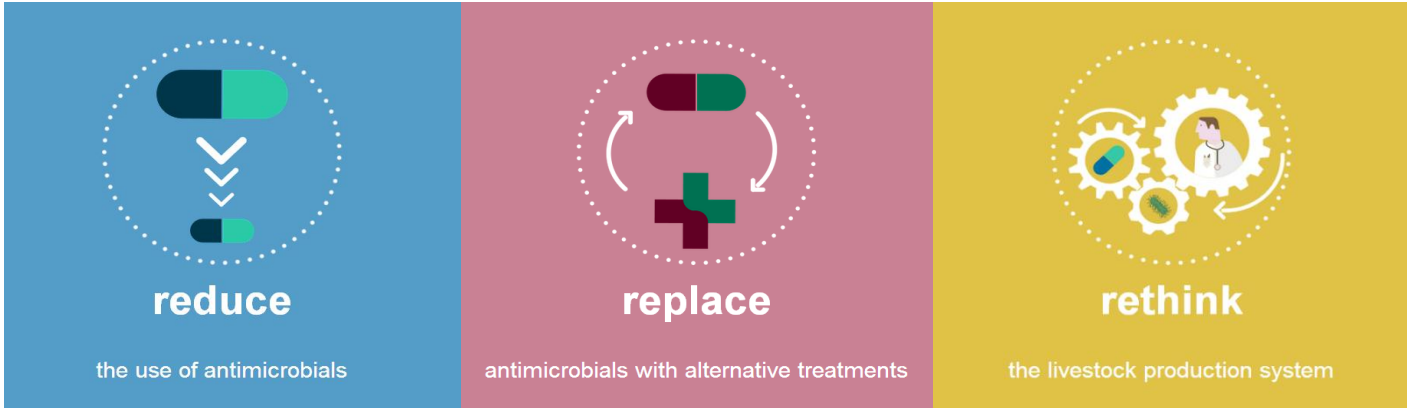
- DDDvet and DCDvet produced
- 3 Long acting substances still missing
- Possible transfer to WHO Collaborating Centre for Drug Statistics Methodology

28 April 2016
EMA/224954/2016
Veterinary Medicines Division

Defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet)

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

EMA/EFSA Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU (RONAFA)



New Veterinary Regulation

New tools to

fight AMR:

Already decreasing sales!

EUROPEAN
COMMISSION

Brussels, 10.9.2014
COM(2014) 558 final

2014/0257 (COD)

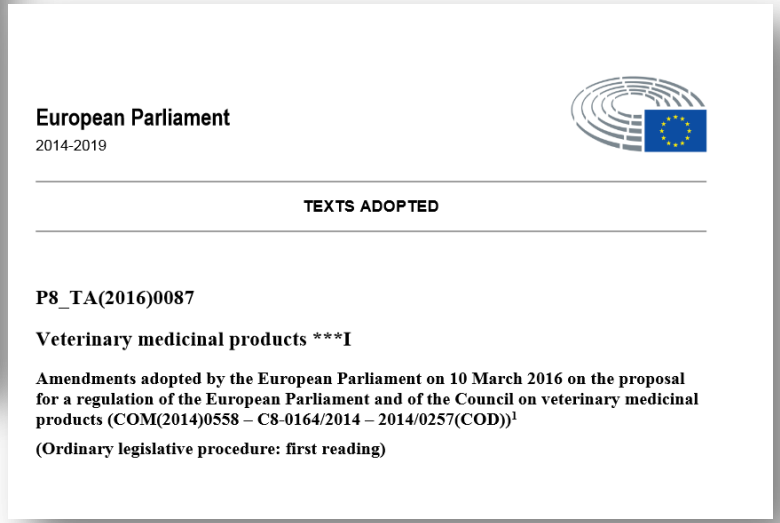
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on veterinary medicinal products

(Text with EEA relevance)

{SWD(2014) 273 final}
{SWD(2014) 274 final}



European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2016)0087

Veterinary medicinal products ***I

Amendments adopted by the European Parliament on 10 March 2016 on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products (COM(2014)0558 – C8-0164/2014 – 2014/0257(COD))[1]

(Ordinary legislative procedure: first reading)

Conclusions and further reflections

- Overall reduction on sales of antimicrobials for use in animals.
- The action taken on specific groups of substances; colistin, fluoroquinolones, 3rd and 4th generation of cephalosporins has resulted on reductions on some countries of those substances.
- No new antimicrobials.
- The need to reduce unnecessary use of antimicrobials in all areas as part of a One Health approach is now a well defined objective in the EU, with many countries setting specific targets for antimicrobial use reduction.
- Future review of veterinary medicines -> tools to reduce AMR

Any questions?

Further information

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