EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Contribution from the veterinary side of the EMA and EU Regulatory Network on Antimicrobial resistance (AMR)

EMA Working Parties with PCWP and HCPWP joint meeting, 19 Sep 2017, London

Presented by Helen Jukes

CVMP vice-chair, chair of the CVMP's Antimicrobials Working Party

Antimicrobial consumption in humans and animals in EU

EU data from 2014 mg/kg estimated biomass, JIACRA 2 (2017)		
	Humans	**Food-producing Animals**
Total consumption	124	152
Median of EU countries	118	67
Range across EU countries	50 – 182	3 - 419
3/4G Cephalosporins	3.8	0.2
(Fluoro)quinolones	8.0	2.9
Polymyxins (colistin)	0.03	10.0
Macrolides	7.8	11.4

2006 – use of AM growth promoters prohibited

‘One Health’ approach

WHO Global Action Plan on AMR 2015,
adopted by the World Animal Health Organisation (OIE) and Food and Agriculture Organisation (FAO)

European Commission’s (EC) One Health Action Plan against AMR 2017

This presentation will cover…

- **Two reports/ ‘opinions’ originating from the EC’s Action Plan on AMR**
- **The CVMP’s Strategy on Antimicrobials**

EC request for advice on the **impact on public and animal health of the use of antibiotics in animals – 'AMEG'**

Antimicrobials Expert Group (AMEG): EMA/EFSA/ECDC

Published 2013-2016

AMEG opinion addressed 4 questions:

Q.1: Advice on 'old' antibiotics that have new use to treat multi-resistant bacteria in humans: tigecycline, colistin

Q.2: Categorisation of the WHO's critically important antimicrobials according to the **risk that their use in animals** poses to **human health**

Q.3: Advice on **the need to restrict or ban the use of new antimicrobial classes** from use in animals

Q.4: Advice on **risk management options for the use of CIAs** in animals

AMEG's advice on **Colistin**

Background

- In some EU member states colistin has become a **last resort** treatment for **MDR Gram-negative infections**

- **In animals, colistin has been used for > 50 years** to treat colibacillosis (*E coli*) a serious disease in pigs, poultry and veal calves

- **Prevalence of colistin resistance in isolates from food animals in the EU appears to be low**
- *E coli* from broilers 0.9%, pigs 0.4% (EFSA, 2015 & 2016 resp.)

[

….Nov 2015

***mcr-1* gene** encoding **colistin resistance** identified on a **transferable plasmid** in isolates from animals and humans in China (Liu et al, 2015):

- By April 2016: several EU member states had identified *mcr-1* in isolates from **human clinical cases** and **pigs, cattle, and poultry**
- *mcr-1* gene is located on **similar plasmids in same bacterial spp** from animals, food, humans, environment

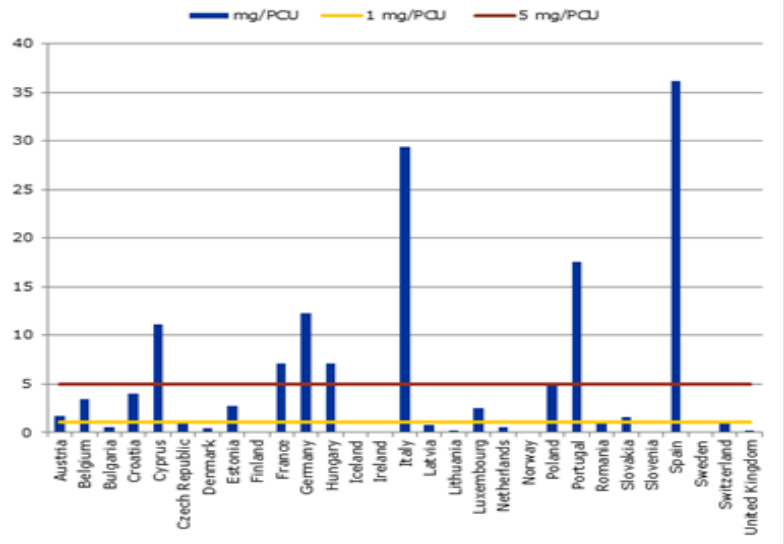
→ **Increased potential for transfer of colistin resistance** between animals and humans

(2016) AMEG's **risk management recommendations** for use of colistin in **animals**

- **No ban** on use
- Colistin added to **higher risk category 2 of the AMEG's classification** of CIAs

Category 2 should be **reserved for use** in conditions which have or are expected to respond poorly to other classes of AM

- Set an **EU target to ↓ consumption of colistin** to 5 mg/kg PCU* within 3 – 4 years
- equivalent to **65% reduction** in use across the EU



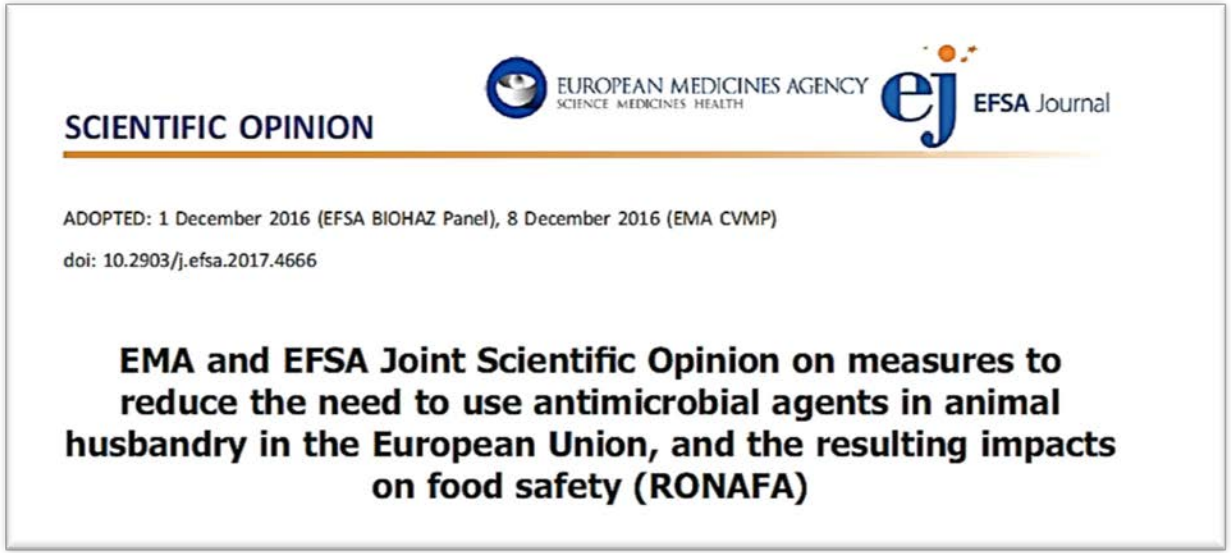
*1 Population Correction Unit (PCU) = 1 kg livestock, live + slaughtered)

EC request for an opinion on **measures to reduce the need to use antimicrobials in animal husbandry** in the EU, and the **impact on food safety - 'RONAFA'**

In 24 EU countries,

AM sales ↓ **12 %**

from 2011 to 2014



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EFSA Journal

SCIENTIFIC OPINION

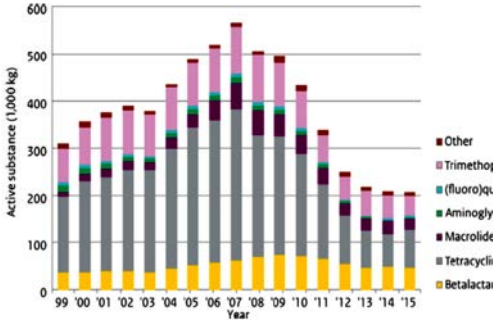
ADOPTED: 1 December 2016 (EFSA BIOHAZ Panel), 8 December 2016 (EMA CVMP)

doi: 10.2903/j.efsa.2017.4666

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)

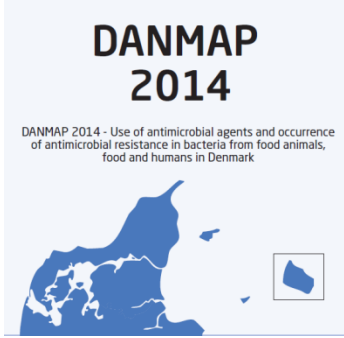
Terms of reference for the RONAFA

Review the **measures that have been taken by MSs to reduce the use of antimicrobials in food-producing animals**



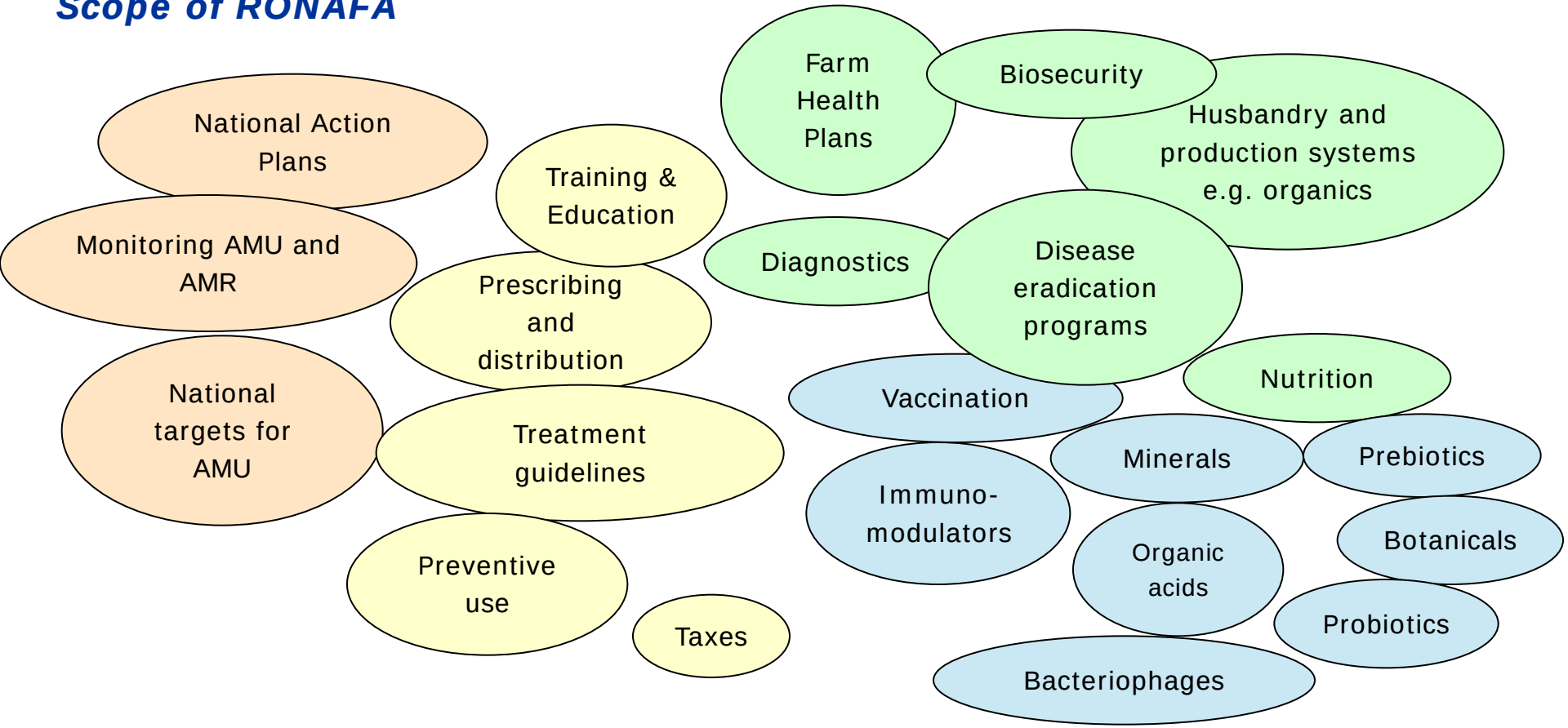
Review **'alternatives'** to the use of antimicrobials

Assess the **impacts** of the measures and alternatives on the **occurrence of AMR**

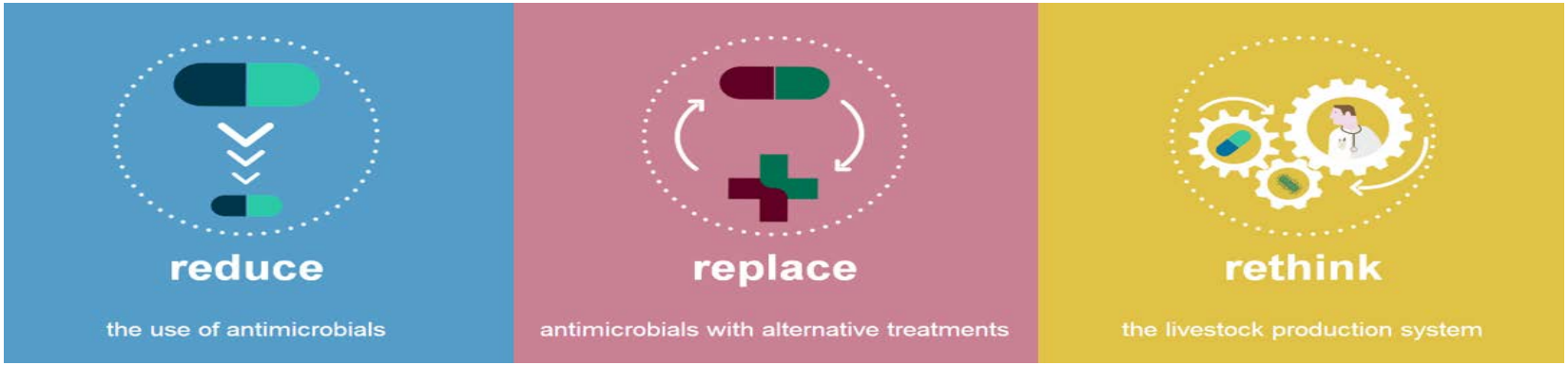


Recommend options to reduce antimicrobial use and for responsible use

Scope of RONAFA



Options to reduce use



Setting targets

Increase responsibility of veterinarians

Preventive use should be phased out

Consider alternatives to antimicrobials

Research new alternatives

Develop an EU legal framework for alternatives

Improve disease prevention and control

Consider alternative farming systems

Education and awareness

Committee for Medicinal Products for Veterinary Use **(CVMP) - Strategy on Antimicrobials 2016 - 2020**

CVMP's vision for antimicrobials: "*... the availability of* ***effective antimicrobial medicines for the treatment of infectious diseases of animals****, whilst* ***minimising the risks to animals or humans*** *arising from their use*."

Six aims of CVMP's strategy on Antimicrobials

1. Support authorisation of effective antimicrobial veterinary medicines

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21 January 2016
EMA/CVMP/627/2001-Rev.1
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances

2. Advise on risks to public health from antimicrobial use in animals

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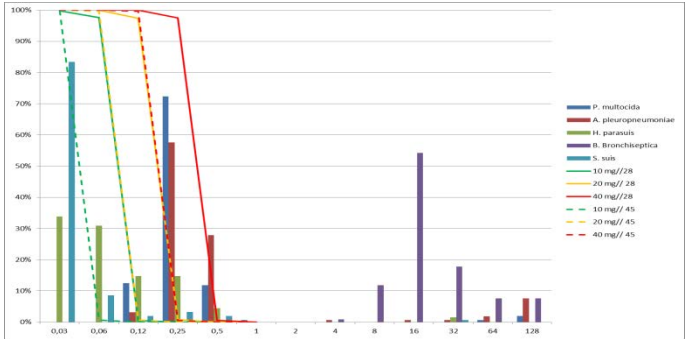
18 December 2014
EMA/381884/2014
Veterinary Medicines Division/CVMP/CHMP

Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

3. Maintaining the effectiveness of existing antimicrobials

- Revising product information through ‘referrals’ of veterinary medicines
- Pilot project on dose optimisation



4. Encouraging the development of antimicrobials and ‘alternatives’

- Scientific advice to pharmaceutical companies
- CVMP ad hoc group on vaccine availability “CADVVA”

5. Supporting responsible use

- Reflection paper on Off-label Use (draft at public consultation)
- Aim to reduce overall AMU - RONAFA


SCIENTIFIC OPINION

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6. Collaboration with other EU agencies and international organisations to tackle AMR

- AMEG, RONAFA, JIACRA, TATFAR

efsa European Food Safety Authority

TATFAR

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Key messages

- There is a need for a **One Health approach**: collaboration across animal and human sectors and EU agencies
- The impact of antimicrobial use in animals on **public health** is a high priority for the **veterinary sector**
- EMA/CVMP strategy strongly supports more **responsible antimicrobial use** in the interests of both animal and public health
- The veterinary sector is taking positive action to **reduce use** both of human CIAs and antimicrobial use overall

References

EMA and EFSA Joint Scientific opinion on measures to reduce the need to use antimicrobial agents in animals husbandry in the European Union, and the resulting impacts on food safety (RONAFA). EFSA Journal 2017;15(1):4666, 245 pp.

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Liu et al, 2016. Emergence of plasmid-mediated colistin resistance mechanism MCR-1 in animals and human beings in China: microbiological and molecular biological study. Lancet Infect Dis 2016;16:161-68

CVMP strategy on antimicrobials 2016-2020. EMA/CVMP/209189/2015

Draft reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union EMA/CVMP/AWP/237294/2017

Joint EMA/HMA Veterinary Vaccine Availability Action Plan EMA/239617/2016 (CADVVA)

Thank you for your attention

Further information

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