



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EFSA/EMA opinion to reduce overall need of use of antimicrobials (RONAFA)

Updates on JIACRA and AMEG





EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for the Food chain

Brussels,
SANTE/G4/RP/hh(2015)

Dear Mr Url and Mr Pott,

Subject: Request for a joint EFSA and EMA 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

In the context of the Action Plan against the rising threats from Antimicrobial Resistance, the European Commission has developed different initiatives to enhance the prudent use of veterinary antimicrobials and to reduce the overall use in animal husbandry. The measures include inter alia the development of "Guidelines for prudent use of antimicrobials in veterinary medicine". The guidelines present practical examples of different approaches to reduce the need to use antimicrobials and examples of alternatives.

However, the guidelines don't specify which the contribution is and which factors may impact on the success of these measures and alternatives to reduce the need of the use of antimicrobials.

Therefore, I would like to request EFSA and EMA to develop a joint scientific opinion in accordance with the terms of reference as included in the Annex to this letter.

The Commission needs this advice to be delivered by 20 December 2016.



Joint EFSA-EMA opinion on the reduction of the need to use antimicrobials in animal husbandry (RONAFA)

- Review the measures that have been, or are being taken, to reduce the use of antimicrobials in animal husbandry in the EU.
- Assess the impact of such measures regarding the occurrence of antimicrobial resistance in bacteria from food-producing animals and food.
- Review the recent scientific developments in the area of possible alternatives to the use of antimicrobials in animal husbandry in the EU.
- Assess the potential impact of such alternative measures on the occurrence of antimicrobial resistance in bacteria from food-producing animals and food.
- Recommend options to reduce antimicrobial usage in animal husbandry in the EU, including consideration of the advantages and disadvantages of the different alternatives. Where a continued need is identified to use antimicrobials in the interests of animal health and welfare, recommend how such use can continue with the minimum possible risk to human health.

Deadline: 20 December 2016



Joint EFSA-EMA WG

- EMA: Keith Baptiste, Boudewijn Catry, Cristian Friis, Helen Jukes (co-chair), Cristina Munoz Madero, Pascal Sanders
CVMP, AWP members
- EFSA: Els M. Broens, Pier Sandro Cocconcelli, Rob Davies, Christian Ducrot, Gregers Jungersen, Simon More, John Threlfall (co-chair)
Panel members (BIOHAZ, AHAW, FEEDAP), External experts
- Secretariat by EFSA and EMA



Structure of the opinion

The report is to be divided into 3 main parts:

- (1) Measures** that have been taken to **reduce the need for and use of** antimicrobials in animals and the **impact** of those measures. CVMP/AWP representatives are leading on this part. It mostly focuses on measures taken in the **EC's Prudent Use GLs**: prescribing, monitoring of use, controls on CIAs, treatment guidelines, training & education campaigns, etc
- (2) Possible alternatives** to use of antimicrobials – This part focuses on husbandry, disease eradication, vaccination programmes, alternative therapies. EFSA Biohaz and AHAW panels are leading.
- (3) Recommendations**; including how use can continue, where needed, with minimum impact on public health. Case examples may be included to demonstrate that a holistic approach is needed.



Additional resources for RONAFA

FVO Questionnaire to MSs on the implementation of measures from the prudent use GLs

Questions to:

• **Vet professionals** (via FVE)

For which livestock production systems and life stages are the most AMs used?

For which of these is it most difficult to implement measures to reduce AM use, and for which is it easiest?

• **To food producers/retailers** (AVEC, BEUC, COPA-COGECA, EUROCOMMERCE, EUROCOOP, FESASS, FOOD DRINK EUROPE, IFOAM-EU GROUP, INDEPENDENT RETAIL EUROPE)

To provide advice on guidance and controls that you have in place for food producers in regards to AM use?

Input from the IWP on use of vaccines (including autogenous vacc).



The requests from the EC for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

(AMEG - Antimicrobial Advice Ad Hoc Expert Group)

In April 2013, the European Commission requested advice from EMA on the impact of the use of antimicrobials in animals on public and animal health and measures to manage the possible risk to humans

The request was divided in four questions.



Questions

Question 1 (colistin and tigecycline): the response was published in July 2013

Question 2 (ranking of antibiotics)

Question 3 (new antibiotics)

Question 4 (risk mitigation options)

the responses were published in December 2014

Update of the AMEG advice

- Recent discovery of the mobile colistin resistance gene *mcr-1* that causes bacteria to become resistant to colistin
- EMA received a request from the European Commission to update its advice on the use of colistin in animals
- CVMP requested to re-convene the AMEG
- Public call for data: 29 February – 15 March 2016
- Consultation: 25 May – 2 June 2016
- Deadline for the finalisation of the advice: 30 June 2016

Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report

ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals.

Published by the 3 Agencies on their webs on January 2015.

First time 3 Agencies collaborate on analysis of the data available.



*EMA link: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/01/WC500181485.pdf



JIACRA: new mandate

New mandate from the EC for the second JIACRA (2013, 2014, 2015 data)

Deadline: 30 June 2017



Thank you for your attention

Further information

esvac@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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