EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 December 2014
EMA/787672/2014
Press Office

Press release

Mitigating risks due to the use of antibiotics in animals

European experts propose measures to minimise antimicrobial resistance arising from the use of antibiotics in veterinary medicines

The European Medicines Agency (EMA) has published recommendations to limit the development of antimicrobial resistance (AMR) linked to the use of antibiotics in animals, thereby minimising at source the risk of transmission of resistance from animals to humans.

The proposed measures focus in particular on promoting the responsible use in veterinary medicine of antibiotics that are critically important in human medicine such as fluoroquinolones and third and fourth generation cephalosporins.

The advice was developed by an interdisciplinary group of experts coordinated by EMA and has been sent to the European Commission to inform their action plan against the rising threats from antimicrobial resistance.

The emergence and steady increase of bacteria that are resistant to several antibiotics has become a global public health threat. It is a priority for public health authorities worldwide to strengthen measures for the prevention and control of antimicrobial resistance to keep antibiotics effective for future generations.

The recommendations include:

- Reinforcing the existing risk assessment of new veterinary antimicrobial substances by identifying the main potential risks to public health at a very early stage of authorisation;
- Monitoring the development of resistance in specific bacteria according to plans agreed between regulators and companies when a new antimicrobial substance is first approved in veterinary medicine;
- Introducing legal tools to restrict the use of antibiotics in animals if a significant risk to public health is identified;
- Monitoring changes in the use of antimicrobials in animals as part of the Agency's European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project to measure the impact of

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20
Send a question via our website www.ema.europa.eu/contact

the actions implemented; in particular, fluoroquinolones and cephalosporins should be monitored as these two classes of antibiotics are critically important for human medicine.

A number of recommendations relate to the off-label use of veterinary medicines. The advice proposes the introduction of flexible tools as part of the on-going review of the veterinary legislation to allow banning or limiting the off-label use in animals of certain antimicrobials authorised only in human medicine following a specific risk assessment of the potential risks arising from such off-label use. It is also suggests that prescribers should keep records of all off-label use and that authorities should be encouraged to collect data on off-label use of antibiotics used in animals.

The advice will act as valuable input into the discussions that have now started in the European Council and the European Parliament on the proposal for revision of the legislation covering veterinary medicines.

This advice was released for public consultation earlier in 2014. Thirteen comments were received as part of this consultation, these comments were taken into account in the final version of the advice.

About the expert group

In April 2013, the European Commission requested scientific advice from EMA on the impact of the use of antibiotics in animals on public health and animal health and measures to manage the possible risk to humans. The European Commission made the four-part request for advice as part of its action plan against the rising threats from AMR. EMA advice on the first question was sent to the Commission and published on the EMA website in July 2013.

The advice, published today, relates to the other three questions. It includes the classification of antibiotics according to their importance for human medicine, risk mitigation measures for antibiotics that are currently used in animals, including those that are critically important in human medicine, and recommendations regarding the authorisation of new veterinary antibiotics.

For the preparation of its advice, EMA sought the views of experts across the European Union on the development and use of antimicrobials. These experts, who formed the Antimicrobial Advice Ad Hoc Expert Group (AMEG), include representatives from EMA's Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Medicinal Products for Human Use (CHMP) as well as the CVMP Antimicrobials Working Party and the CHMP Infectious Diseases Working Party, the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC).

Notes

- This press release, together with all related documents, is available on the Agency's website.
- Link to advice: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/07/WC500170253.pdf
- European Commissions's action plan against the rising threats from antimicrobial resistance: http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf
- Advice on the first question from the European Commission: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/08/news_detail_002152.jsp&mid=WC0b01ac058004d5c1
- European Surveillance of Veterinary Antimicrobial Consumption (ESVAC): http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

- More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu