EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2016
EMA/355125/2016
Press Office

Press release

European expert group proposes reduction of use in animals of last resort antibiotic colistin to manage risk of resistance

Updated advice is released for public consultation

The European Medicines Agency (EMA) has today launched a public consultation on the advice drafted by its Antimicrobial Advice Ad Hoc Expert Group (AMEG), and endorsed by the Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Medicinal Products for Human Use (CHMP), to minimise sales of colistin for use in animals and restrict its use in animals to last resort treatment only. The deadline to provide comments is 26 June 2016.

The new advice is an update to AMEG's 2013 opinion, which was requested by the European Commission following the recent discovery of a new mechanism of resistance in bacteria to colistin (caused by the *mcr*-1 gene), which has the potential for rapid spread. The gene can easily be transferred between different types of bacteria, potentially leading to rapid development of resistance. While the gene was first detected in bacteria (*Enterobacteriaceae*) in South China, it has subsequently been found also in the EU.

In light of the new evidence, EMA reconvened the AMEG to assess the importance of colistin for human and animal health, the impact of resistance and the availability of alternative treatments. In addition, the group was asked to propose suitable risk management measures.

Risk management measures

In its updated advice, AMEG recommends that Member States should reduce the use of colistin to a maximum level of 5 mg colistin/PCU (population correction unit) and consider setting stricter national targets, ideally lower than 5 mg/PCU of colistin, e.g. below 1 mg/PCU as a desirable level. The AMEG emphasises that reduction of colistin use should not be compensated for by increasing the use of other types of antimicrobials. Instead, the use of this antibiotic should be reduced through other measures such as improved farming conditions, biosecurity in between production cycles, and vaccination.

In addition, colistin should be reclassified and added to Category 2 of the AMEG classification system, which includes medicines reserved for treating infections in animals for which no effective alternative treatments exist. This category includes certain classes of antimicrobials listed by the World Health

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Organization (WHO) as critically important to human health. Because of the risk posed to public health by their veterinary use, these medicines are subject to specific restrictions.

About colistin

Colistin or colistimethate sodium has been used for over 50 years in both humans and animals. In human medicines it is a last resort medicine to treat people who have bacterial infections resistant to other antibiotics.

In veterinary medicine colistin has been used for over 50 years to treat infections caused by *Enterobacteriaceae* in farm animals. Partly due to development of resistance to other classes of antibiotics, colistin consumption has increased in recent years. Today it is one of the five most commonly used antibiotics in animals within the EU.

About the expert group

The AMEG is a multi-disciplinary group of experts with representatives from EMA's Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Medicinal Products for Human Use (CHMP), the CVMP Antimicrobials Working Party and the CHMP Infectious Diseases Working Party, as well as experts from the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC) and the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report. The multi-disciplinary composition of the expert group reinforces the commitment of the Agency with the One Health approach.

About measuring consumption of antimicrobials in the EU

Sales of antimicrobials used in veterinary medicine, including colistin, are reported by Member States to the European Medicines Agency and published in the annual ESVAC report (European Surveillance of Veterinary Antimicrobial Consumption). Consumption is reported in terms of mg/PCU which is a measure of use standardised for the total amount (biomass) of animals within each country. This allows a single target to be set for consumption across the European Union as a whole.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The discovery of the *mcr-1* gene was published in a paper in Lancet Infectious Diseases on 18 November 2015: Liu Y-Y et al, 'Emergence of plasmid-mediated colistin resistance mechanism MCR-1 in animals and human beings in China: microbiological and molecular biological study', Lancet Infectious Diseases, November 2015.
3. 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

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