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Press release

Countries should reduce use of colistin in animals to decrease the risk of antimicrobial resistance

Goal is to cut colistin sales by 65%

The European Medicines Agency (EMA) has recommended that colistin-containing medicines should only be used as a second line treatment in animals and that their sales should be minimised across all European Union (EU) Member States to reduce the risk of antimicrobial resistance. The advice updates EMA guidance from 2013 and takes into account comments made by stakeholders during a public consultation that ended on 26 June 2016.

The European Commission asked for this update in response to the discovery of a new mechanism of resistance in bacteria to colistin (caused by the *mcr-1* gene). The gene can be transferred between different types of bacteria, potentially causing a rapid development of resistance. The gene was first identified in bacteria (*Enterobacteriaceae*) in South China, and since then has also been found in the EU and other regions.

In light of the new evidence, the Antimicrobial Advice Ad Hoc Expert Group (AMEG) had been asked to re-evaluate the impact of the use of colistin on human and animal health, the consequences of resistance and what alternative treatments are available. Moreover, the group was asked to consider adequate risk management measures. The advice was endorsed by both the Committee for Medicinal Products for Veterinary Use (CVMP) and the Committee for Medicinal Products for Human Use (CHMP).

Measures to reduce the risk of antimicrobial resistance of veterinary use of colistin

Over the course of the next three to four years, all Member States should reduce the use of colistin in animals at least to a target level of 5 mg colistin/population correction unit. PCU means the estimated weight of livestock and slaughtered animals). If successfully applied, this could result in an overall reduction of approximately 65% in the current sales of colistin for veterinary use at an EU level. This decrease should build on the decrease of colistin sales for veterinary use already seen between 2011 and 2013. Member States are also encouraged to set stricter national targets, ideally below 1 mg colistin/PCU as a desirable level.

In its advice, AMEG underlined that the reduction of colistin sales should not be compensated by increase in the use of other types of antimicrobials, but should be achieved through other measures

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such as improved farming conditions, biosecurity between production cycles, and vaccination of livestock.

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 Organization 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 bacterial infections resistant to other antibiotics. In veterinary medicine, colistin has been used to treat infections caused by *Enterobacteriaceae* in farm animals. Partly due to the 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

AMEG is a multi-disciplinary group of experts with representatives from the CVMP and the CHMP, the CVMP Antimicrobials Working Party and the CHMP Infectious Diseases Working Party, as well as experts from the European Food Safety Authority, the European Centre for Disease Prevention and Control and the Joint Interagency Antimicrobial Consumption and Resistance Analysis report. The multi-disciplinary composition of the expert group reinforces the commitment of the Agency with the One Health approach (a concept that recognises that the health of humans is connected to the health of animals and the environment).

About measuring consumption of antimicrobials in the EU

Sales of antimicrobials used in veterinary medicine, including colistin, are reported by Member States to the EMA and published in the annual European Surveillance of Veterinary Antimicrobial Consumption report. 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 EU 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

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