29 February 2016
EMA/103285/2016
Veterinary Medicines Division

Advice on the impact on public health and animal health of the use of antibiotics in animals (colistin) following the recent discovery of the first mobile colistin resistance gene (*mcr-1*)

Call for scientific data for the update of advice

Submission period: 29 February – 15 March 2016

The European Medicines Agency (EMA) has received a request from the European Commission to update its advice on the use of colistin in animals, which is one of the last-resort antibiotics to treat certain bacterial infections in humans. This follows the recent discovery of the mobile colistin resistance gene *mcr-1* that causes bacteria to become resistant to colistin, an antibiotic of the polymyxin class. All earlier colistin resistance genes were not mobile, meaning that they were not horizontally transferable between different types of bacteria. The gene was first detected in Enterobacteriaceae bacteria that were isolated from pigs, pork and chicken products and from a small number of humans in South China. Since the gene was first detected it has subsequently been found also in the European Union (EU).

Colistin or colistimethate sodium has been used for over 50 years in both humans and animals. In human medicines it is now used as a last resort medicine for the treatment of people suffering from different kinds of infections caused by multidrug-resistant bacteria. Because of its important role as a last defense against antimicrobial resistant bacteria in humans, the Agency will consider if its 2013 advice on the responsible use of colistin in animals needs to be updated in light of the recent discovery.

To undertake this work, EMA's Committee for Veterinary Medicinal Products (CVMP) requested to re-convene the Antimicrobial Advice Ad Hoc Expert Group (AMEG) that prepared the 2013 advice. AMEG will evaluate all available information and assess if there is a need to update the 2013 advice on the use of colistin in animals within the EU in the light of the new evidence.

The CVMP and CHMP invites all interested parties such as pharmaceutical industry associations, animal and public health care professional groups, learned societies, consumers and patients' associations, governmental institutions as well as EU and EEA-EFTA Member States to submit any scientific data that might have an impact on public and animal health that the CVMP and CHMP should consider when updating the 2013 advice.

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Scientific contributions should be relevant to the purpose of the assessment, and their scope should address either:

- **The importance of colistin to human and veterinary medicine (e.g. estimated frequency of use, target indications, including selective digestive tract decontamination, estimation of the use per animal species).**
- **Any information on colistin resistance mediated by the *mcr-1* gene in isolates from humans and animals, including animal pathogens.**
- **The effectiveness and availability of alternative treatments to the use of colistin in human and animals especially if restrictions on the use of colistin would be applied.**
- **Experiences on colistin resistance risk management measures such as changes in indications, restrictions of use, husbandry practices or controls of imported food for the protection of public and animal health in Europe.**

Scientific contributions should be sent by email to: vet-guidelines@ema.europa.eu

A list of all scientific contributions and their references should be enclosed.

The name and contact details of the interested party providing the scientific contributions is required.

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The CVMP and CHMP will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should highlight any data of confidential nature in the data submitted.

Time permitting, a short period of consultation on the draft opinion will be arranged which should allow contributors to evaluate the use of the information provided.

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