



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

EMA advice on use of colistin in animals to be updated

EMA acts upon request from European Commission following detection of colistin-resistant bacteria

The European Medicines Agency (EMA) has received a request from the European Commission to update its advice on the use in animals of colistin, which is one of the last-resort antibiotics to treat certain bacterial infections in humans. This follows the recent discovery of a gene (called *mcr-1*) that causes bacteria to become resistant to colistin, an antibiotic of the polymyxin class that can easily be transferred between different types of bacteria. The gene was first detected in bacteria (called Enterobacteriaceae) 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 defence against antimicrobial resistant bacteria, the Agency will consider if its 2013 advice on the responsible use of colistin in animals, particularly pigs, 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), who prepared the 2013 advice.

The AMEG is a multi-disciplinary group of experts with representatives from EMA's CVMP and Committee for Medicinal Products for Human Use (CHMP), the CVMP Antimicrobials Working Party (AWP) 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 2013 advice recommended maintaining the use of colistin in veterinary medicine but only for the treatment of infected animals and those in contact with them, and removing all indications for preventive (or prophylactic) use, in line with the principles of responsible use. It also recommended strengthening the systems for surveillance of antimicrobial resistance to colistin and carrying out a new review in case of a substantial increase of colistin resistance in animal bacteria or other new relevant information with a potential impact for public health.



AMEG will evaluate all available information and assess whether in the light of new evidence there is any impact on the 2013 advice for the use of colistin in animals within the EU. The update will take into account the importance of colistin to human and veterinary medicine, the impact of resistance, the availability of alternative treatments and the effectiveness of possible risk management measures for the protection of public and animal health in Europe.

The conclusions of the AMEG will be submitted to the CVMP and the CHMP for review and formal adoption before the updated advice is submitted to the European Commission. The Agency expects to finalise the update over the next six months.

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, 'Evidence of plasmid-mediated colistin resistance mechanism mcr-1 in animals and human beings in China', Lancet Infectious Diseases, November 2015.
3. Hasman H. et al, 'Detection of mcr-1 encoding plasmid-mediated colistin-resistant Escherichia coli isolates from human bloodstream infection and imported chicken meat, Denmark 2015 ' Eurosurveillance, Vol. 20 (49), 10 December 2015.
4. Woodmansey D., 'Scientists find mcr-1 gene in food and human isolates (England and Wales)', vet times, 11 December 2015. At <http://www.vettimes.co.uk/news/scientists-find-mcr-1-gene-in-food-and-human-isolates/>
5. 'New type of colistin resistance also found in the Netherlands', Wageningen UR, 17 December, 2015. At <http://www.wageningenur.nl/en/Expertise-Services/Research-Institutes/Central-Veterinary-Institute/show/New-type-of-colistin-resistance-also-found-in-the-Netherlands.htm>
6. Webb H.E., Granier S.A., Marault M., Millemann Y., den Bakker H.C., Nightingale K.K., Bugarel M., Ison S.A., Scott H.M., Loneragan G.H., 'Dissemination of the mcr-1 colistin resistance gene', Lancet Infectious Diseases, 2015.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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