EUROPEAN MEDICINES AGENCY
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Press Office

Press release

Antimicrobial resistance - European Medicines Agency provides advice on use of colistin and tigecycline in animals

In a response published today, the European Medicines Agency (EMA) provided advice to the European Commission on the impact on public health and on animal health of the use of the antibiotics colistin and tigecycline in animals. This is the first response to a series of four questions raised by the European Commission in a request to the Agency related to the use of antimicrobials in animals and the potential impact of this use on human health and animal health.

The emergence and steady increase in the occurrence of bacteria that are resistant to multiple antibiotics has become a global public health threat due to the lack of therapeutic options to treat certain infections in man. Colistin and tigecycline are amongst the antibiotics that have become life-saving treatments for human patients suffering from different kinds of infections caused by multidrug-resistant bacteria.

Continue the responsible use of colistin to treat diseases in animals

Colistin has been used in veterinary medicine for over 50 years. There is no available evidence on the transfer of resistance to colistin from animals to man; however, the Agency's advice acknowledges there is limited information on the subject and more research and surveillance should be done.

The advice recommends maintaining the use of colistin in veterinary medicine but restricting its use to the treatment of infected animals and those in contact with them, and to remove all indications for preventive (or prophylactic) use. It mentions that the European Commission should determine the best way to amend the labelling and product literature for colistin-containing veterinary medicines to reflect this more restricted pattern of use which is aligned with the principles of responsible use. The advice also recommends strengthening the systems for surveillance for resistance to colistin in order to increase the likelihood of early detection of any rise. The benefit-risk balance for colistin would need to be re-evaluated should a substantial increase be detected in rates of resistance.

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No need identified for authorisation of tigecycline for use in animals

Tigecycline, an antibiotic of the glycylcycline class, is not currently approved for use in animals. The extent of off-label use of this antibiotic in veterinary medicine cannot currently be quantified, although there is some anecdotal evidence of the use in dogs and cats of tigecycline products authorised for human use.

The Agency advised that currently no need is foreseen for the authorisation of tigecycline for use in animals. If the need for an approval of tigecycline as a veterinary medicine should ever arise in the future, authorisations should only be considered on the basis of a positive benefit-risk assessment which would take into account the risk of transfer of resistance to humans.

However, based on the current situation, it is unlikely that a marketing authorisation could be granted in light of the need for this antibiotic in human medicine.

About the expert group

This answer to the first request from the Commission, which focused on colistin and tigecycline, has been prepared by the Antimicrobial Advice ad hoc Expert group (AMEG).

The AMEG is composed of representatives and experts from the 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, 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 Report (JIACRA). The advice produced by the AMEG has been endorsed by both the CVMP and CHMP at their respective meetings in July 2013.

The request was made by the European Commission as part of its 'Action Plan Against the rising threats from Antimicrobial Resistance (AMR)'. The scientific answer to this four-part request is expected to be finalised by the end of 2014.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: www.ema.europa.eu
2. The answer to the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals can be found here.
3. The request from the Commission with the detailed questions was published on the Agency's website in April 2013 and is available here.
4. The Action Plan against the rising threats from Antimicrobial Resistance (AMR) is available here: http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf
5. For ECDC's work on antimicrobial resistance, please see here: http://www.ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/Pages/index.aspx
6. For EFSA's work on antimicrobial resistance, please see here: http://www.efsa.europa.eu/en/topics/topic/amr.htm?wtrl=01
7. For EMA's work on antimicrobial resistance, please see here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000439.jsp&mid=WC0b01ac058002d4e9

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

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