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Press release

European Antibiotic Awareness Day 2015

EMA reinforces commitment to help combat antimicrobial resistance

Speed up development of new treatments, promote responsible use of antimicrobials and collect data to advise policy and research - the European Medicines Agency (EMA) confirms its three-pronged approach to fight antimicrobial resistance in support of European Antibiotic Awareness Day (EAAD) observed on Wednesday 18 November. Antimicrobial resistance is one of the most serious public health threats globally. In Europe alone, infections caused by multidrug-resistant bacteria are estimated to kill 25,000 people every year. To ensure that treatments continue to be available for common and emerging infectious diseases, it is important to both protect available effective medicines and develop new treatments.

Speeding up development of new treatments

A central pillar of EMA's strategy to tackle antimicrobial resistance in human medicine is to create an environment that stimulates and facilitates the development of innovative antimicrobials, especially those that target multidrug-resistant pathogens. EMA also provides guidance and scientific advice to companies on the most appropriate clinical trial designs to study these new medicines. In particular, in 2015, the Agency released a draft new guidance and organised a workshop on the use of pharmacokinetic and pharmacodynamic data analyses to speed up the development of new antimicrobials. In addition, in both the human and veterinary domains the Agency encourages the development of alternatives to antimicrobials. One example is the organisation in June 2015 of a workshop on the therapeutic use of bacteriophages, naturally occurring viruses that kill bacteria.

Promoting responsible use

Responsible use of existing antimicrobials both in humans and animals is also essential to limit the development of resistance and preserve the efficacy of medicines for future generations.

Therefore, EMA devotes considerable efforts to ensuring that the approved conditions of use for human and veterinary antimicrobials in the European Union (EU) incorporate principles of prudent and responsible use. For example, in 2015, the conditions of use of colistin in veterinary medicine were

¹ On page 2, "fourth report on sales of veterinary antimicrobials from the ESVAC project" was corrected by "fifth report on sales of veterinary antimicrobials from the ESVAC project".



amended and the prescribing information for the widely used antibiotic amoxicillin in human medicine were harmonised across the EU. In this way, EMA ensures that doctors, pharmacists, patients, veterinarians and animal owners have the best possible information on how to use antimicrobials in a way that minimises the risks from antimicrobial resistance.

Collecting robust data to inform public health policies

To advise policy makers on the best way to tackle antimicrobial resistance, robust scientific data on how antimicrobials are used across the EU and how resistance emerges and transfers are needed. This requires close cooperation between the various European agencies that have responsibilities in this area.

In January 2015, EMA, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) provided the first integrated analysis of data on antimicrobial use and resistance in Europe. This report provides unique information on the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans, food and food-producing animals.

EMA is also monitoring the consumption of antimicrobials used in animals in EU Members States as part of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. In 2015, a new interactive database was launched to allow users to access the specific ESVAC data they are interested in, e.g. data for a specific country or sales of a particular class of antibiotic, and create charts, maps or graphs tailored to their needs. Over the past years, an overall decrease in the consumption of antimicrobials has been observed in the EU. As the data collected through ESVAC are becoming increasingly robust, they are an important tool for European countries to promote and monitor the success of policies intended to promote the responsible use of antimicrobials in animals.

EAAD is organised on 18 November every year by ECDC. It aims to raise awareness of the threat of antimicrobial resistance to public and animal health and the importance of prudent use of antimicrobials.

Recent EMA activities to fight antimicrobial resistance

November 2015: New strategy on antimicrobials for 2016-2020 released for public consultation. The strategy was adopted by EMA's Committee for Veterinary Medicinal Products (CVMP) and aims to help combat the threat of antimicrobial resistance in animals and humans, which may arise from the use of antimicrobials in animals.

October 2015: Fifth report on sales of veterinary antimicrobials from the ESVAC project together with a new interactive database published. The report shows that sales of antimicrobials in animals in Europe decreased by approximately 8% between 2011 and 2013.

September 2015: <u>Draft guideline</u> on the use of pharmacokinetic and pharmacodynamic data analyses released for public consultation. The guideline aims to facilitate and speed up the development of new antimicrobials, in particular those targeting multidrug-resistant bacteria. On 12-13 November a <u>workshop</u> took place to discuss the proposed approach with stakeholders.

June 2015: A <u>workshop</u> on bacteriophages was organised. Experts from academia, industry and regulatory bodies discussed key issues related to the potential therapeutic use of bacteriophages as anti-bacterial agents.

March 2015: EMA started working with EFSA on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU, and the resulting impacts on food safety, at the request of the European Commission. The <u>scientific opinion</u> is expected at the end of 2016.

January 2015: Together with ECDC and EFSA, EMA published a <u>joint integrated analysis</u> of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals. This analysis combines data from humans, animals and food from five European monitoring networks.

December 2014: EMA published <u>scientific advice</u> on the impact on public and animal health of the use of antibiotics in animals in response to a request from the European Commission; the advice makes a number of recommendations to minimise the risk of transmission of resistance from animals to humans and addresses the need for new antimicrobials in veterinary medicine. These recommendations are part of the <u>European Commission's guidelines on the prudent use of antimicrobials in veterinary medicine</u> published in September 2015.

Notes

- 1. This press release, together with all related documents, is available on the Agency's website.
- 2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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