



European Antibiotic Awareness Day Is 18 November 2014



EMA supports innovative approaches to facilitate development of new antibiotics

The European Medicines Agency (EMA) supports European Antibiotic Awareness Day (EAAD), which is taking place on Tuesday 18 November. EAAD is organised every year by the European Centre for Disease Prevention and Control (ECDC). It aims to raise awareness of the threat to public and animal health of antimicrobial resistance and the importance of prudent use of antibiotics.

The emergence of antimicrobial resistance is a major public health concern. Infections by multidrug-resistant bacteria have been estimated to cause 25,000 deaths in the European Union every year.

New antibiotics are urgently needed to treat patients with serious infections caused by pathogenic bacterial strains. A central pillar in EMA's strategy to fight antimicrobial resistance is to offer an environment that stimulates and facilitates development of innovative antibiotics.

The Agency issued new guidance in November 2013 that allows for a flexible approach in the development of new antibiotics for human use, targeting multidrug resistant pathogens in areas where patients have very limited or no remaining treatment options.

Applications for marketing authorisation for five new antibiotics have recently been submitted to EMA. These are currently under evaluation by EMA's Committee for Medicinal Products for Human Use (CHMP).

In addition, over the past year, EMA has received more than 15 requests for scientific advice from several companies developing new antibiotics. "The multiple requests for scientific advice for antibiotics recently received indicate that we may see more promising medicines reaching patients in the next years, explains Spiros Vamvakas, Head of EMA's Scientific Advice Service. We strongly encourage medicines developers to approach us as early as possible during the development of their medicines. Scientific advice is an excellent platform to discuss approaches which can facilitate the rapid development and authorisation of new antibiotics."

Promoting responsible use of medicines

Responsible use of antibiotics, both in humans and in animals, is a key factor to minimise the risk of selecting resistant bacteria and help keep antibiotics effective for future generations.

The Agency works with the European Commission and Member States in the framework of the European

Commission's action plan against antimicrobial resistance. In line with the action plan, the EMA has produced multiple recommendations on responsible use of antibiotics for animal use, especially for those that are critically important for human medicine. This has been undertaken for fluoroquinolones, third and fourth generation cephalosporins, macrolides and polymyxins.

The Agency also monitors consumption of antibiotics used in animals in EU Members States as part of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. Between 2010 and 2012, consumption fell overall by 15% in Europe. This decline suggests a positive trend towards more responsible use of antibiotics in animals in Europe. It results from measures taken at various levels, including national campaigns on the responsible use of antimicrobials, restrictions on the use of certain antimicrobials and setting of reduction targets for the use of antimicrobials in animal production at national level. These actions need to continue to ensure that antibiotics are used according to the product information so that development of antimicrobial resistance can be reduced to a minimum.

Recent activities to fight antimicrobial resistance

- October 2014: publication of third report on sales of veterinary antimicrobials from the ESVAC project. A total of 26 European Union (EU) and European Economic Area (EEA) countries submitted data on 2011 sales to the Agency.
- August 2014: release for public consultation of draft advice on the impact on public health and animal health of the use of antibiotics in animals in response to a request from the European Commission; report makes a number of recommendations to minimise the risk of transmission of resistance from animals to humans.
- July 2014: Concept paper on the use of aminoglycosides in animals in the EU and the development of resistance and impact on human and animal health; this is the latest of a series of concept papers addressing the impact of use of certain classes of antibiotics in animals on public and animal health.
- November 2013: workshop on regulatory options in the fight against antimicrobial resistance; a set of recommendations is published in the workshop report in December 2013.

EMA also contributes to international initiatives to combat antibiotic resistance, such as the Trans-Atlantic Task Force on Antimicrobial Resistance (TATFAR). The EMA welcomes the initiative by the World Health Organization to develop a global action plan against AMR, recognising that global cooperation is key to tackling this international problem.

[Source: European Medicines Agency](#)

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