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The bacterial challenge - time to react A call to narrow the gap between multidrug-resistant bacteria in the EU and development of new antibacterial agents

There is a need for more development of antibiotics that are effective against multidrug-resistant bacteria. That is the conclusion of a new report prepared jointly by the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMEA) with contributions from the international network Action on Antibiotic Resistance (ReAct). The report is being discussed today in Stockholm by experts at a conference on "Innovative Incentives for Effective Antibacterials", as part of the Swedish Presidency of the European Union.

Bo Aronsson MD, responsible for the EMEA part of the study said: "Industry's pipeline contains very few new antibiotics active against multidrug-resistant bacteria. Without stimulating research and development into new antibiotics, an increasing number of infected patients will be without effective treatment".

Dominique Monnet, responsible for the ECDC part of the study said: "A future without effective antibiotics will exacerbate a situation where already at least 25,000 patients in the EU each year die from infections due to multidrug-resistant bacteria. Patients suffering from healthcare-associated infections will be particularly hard hit".

In 2007, the ECDC, the EMEA and the international network Action on Antibiotic Resistance entered into a discussion on the need to produce a report that reviewed and documented the gap between infections caused by multidrug-resistant bacteria in the EU and the development of new antibiotics to treat them. An ECDC-EMEA joint Working Group was established in 2008 to prepare this report called "The bacterial challenge - time to react. A call to narrow the gap between multi-drug resistant bacteria in the EU and development of new antibacterial agents".

The objective of this report is to give an account of facts and figures that would allow reasonable predictions of the gap between bacterial resistance in the EU and the likely availability of new treatments that would be effective against multidrug-resistant bacteria in the near future. As such, this technical report is made available to the European Commission for consideration. The report also serves as a basis for discussions at today's expert conference on "Innovative Incentives for Effective Antibacterials", as part of the Swedish EU Presidency.

Main findings

The general finding of the report is that there is a gap between the burden of infections due to multidrug-resistant bacteria and the development of new antibiotics to tackle the problem. Specifically, the report finds that:

• Resistance to antibiotics is high among Gram-positive and Gram-negative bacteria that cause serious infections in humans and reaches 25% or more in several EU Member States.

- Resistance is increasing in the EU among certain Gram-negative bacteria such as recently observed for *Escherichia coli*.
- Each year, about 25,000 patients die in the EU from an infection with the selected multidrugresistant bacteria.
- Infections due to these selected multidrug-resistant bacteria in the EU result in extra healthcare costs and productivity losses of at least €1.5 billion each year.
- Fifteen systemically administered antibacterial agents, with a new mechanism of action or directed against a new bacterial target, were identified as being under development with a potential to meet the challenge of multidrug resistance. Most of these were in early phases of development and were primarily developed against bacteria for which treatment options are already available.
- There is a particular lack of new agents with new targets or mechanisms of action against multidrug-resistant Gram-negative bacteria. Two such agents with new or possibly new targets and documented activity were identified, both in early phases of development.
- A European and global strategy to address this gap is urgently needed.

Background information on EMEA

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Background information on ECDC

The European Centre for Disease Prevention and Control (ECDC) is an EU agency tasked with identifying assessing and communicating threats to human health posed by infectious diseases. It supports the work of public health authorities in the EU and EEA/EFTA Member States.

Further information

See the full joint report here

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