

Resistance rages but antibiotic pipeline is dry

New alarming report from ECDC, EMEA and ReAct presented at EU expert conference

In Europe alone, multi drug-resistant bacteria cause some 25,000 deaths annually while extra costs for healthcare and productivity losses add up to at least €1,5 billion per year. Nevertheless, the R&D pipeline for new drugs is more or less empty. There is, thus, an untenable gap between the burden of antibiotic resistance and the development of new drugs to tackle the problem.

Antibiotic resistance is one of the greatest global health challenges of our time. In the European Union alone, multi drug-resistant bacteria cause some 25,000 deaths annually while extra costs for healthcare and productivity losses add up to at least €1,5 billion per year.

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– These findings are more serious than I could ever have imagined. The need for new drugs targeting multiresistant Gram-negative bacteria is extremely acute, for which the treatment options are already very limited, says Professor Otto Cars, director of ReAct - Action on Antibiotic Resistance.

On the 17th of September, the Swedish EU Presidency hosted an expert conference on how to bring about urgently needed research and development of new antibacterial agents.

This conference targeted an audience of EU policy-makers, executive officers and experts from the public health sector and also industry trade associations.

A report, entitled *The bacterial challenge – time to react*, was commissioned as background material for the conference. The report has been produced by The European Centre for Disease Prevention and Control (ECDC) and the European medicines Agency (EMA) with the assistance of the international network Action on Antibiotic Resistance (ReAct).

– The report shows clearly that the market system has not worked in the case of antibacterials, says Professor Cars.

The reasons for the unfortunate lack of R&D are manifold. In addition to the scientific barriers, there is a lack of relative profitability. Industry analysis shows that, compared to the returns expected for drugs for chronic diseases, there is little commercial incentive to develop antibiotics.

The gap between the disease burden of resistant bacteria and the insufficient development of new antibiotics has been known among experts for a long time, but it has never been thoroughly investigated up till now. ECDC and EMA have, with the assistance ReAct, worked out an analysis that will allow reasonable predictions for the coming years; these findings are being presented today, and their implications are grave.

Altogether, the antibacterial drug development pipeline contains 90 agents (which can be compared to some 860 cancer drugs currently in clinical trials) but only 27 that offer a potential benefit over existing antibiotics. The most troubling finding, however, regards drugs targeting Gram-negative bacteria, which account for two thirds of deaths in the EU; only two new agents are in the pipeline, both in early stages. Considering the fact that only a relatively small percentage of R&D projects actually make it to the market, the prospects for the coming years must be seen as bleak.

Just earlier this month, the Swedish media reported that three newborn babies in a Swedish hospital had died from infection with multi-resistant (Gram-negative) bacteria. Sad to say, this tragic event is by no means unique. In fact, the burden of resistance in the EU is already substantial, claiming more than 25 000 victims every year and imposing over €1,5 billion in excess costs. What is still worse, both these numbers are likely to increase.

In order to find ways to break the deadlock in antibacterial R&D, the Swedish EU presidency commissioned a second report which focuses on creating incentives to spur R&D of much needed drugs. The report, entitled "Policies and incentives for Promoting Innovation in Antibiotic Research", was written by experts at the London School of Economics.

The two reports as well as the results of expert workshops held prior to the conference will now lay the foundation for what hopefully turns into EU council conclusions.

ReAct considers the efforts of the European Union and particularly the Swedish presidency a promising sign of commitment to fight antibiotic resistance and an example of the global leadership that is needed. We now hope this is the start of a process that can actually spur the development of new antibacterials that will benefit not only the EU and other wealthy countries, but also those where the burden of antibiotic resistance is greatest.

Find out more at

http://www.se2009.eu/en/meetings_news/2009/9/17/conference_innovative_incentives_for_effective_antibacterials, where you can also download documents and presentations from the conference.