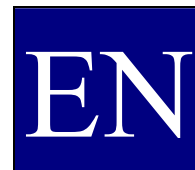




COUNCIL OF
THE EUROPEAN UNION



Council Conclusions on innovative incentives for effective antibiotics

*2980th EMPLOYMENT, SOCIAL POLICY, HEALTH AND
CONSUMER AFFAIRS Council meeting*

Brussels, 1 December 2009

"The Council adopted the following conclusions:

Nota bene: In this document, the term "antibiotics" encompasses medicinal products produced either synthetically or naturally used to kill or inhibit the growth of bacteria as well as those with alternative mechanisms of action e.g. effect on bacterial virulence. In this context, alternative methods for prevention and control of infections should also be taken into account.

1. **RECALLS** the Community Strategy against antimicrobial resistance (COM(2001) 0333).
2. **RECALLS** the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine¹.
3. **RECALLS** the Council Conclusions on antimicrobial resistance of 10 June 2008².
4. **RECALLS** the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections³.
5. **RECALLS** the WHO report (2004) Priority Medicines for Europe and the World⁴

¹ OJ L 34, 5.2.2002, p. 13.

² 9637/08.

³ OJ C 151, 3.7.2009, p. 1.

⁴ http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf.

P R E S S

6. **RECALLS** the ECDC/EMA joint technical report (2009) "*The bacterial challenge: time to react*" on the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents⁵.
7. **RECOGNISES** that the spread of antibiotic resistance is a major threat to public health security worldwide which requires action at all levels. The disease burden related to antibiotic resistant bacteria that cannot be effectively treated with first- or even second-line medicinal products, is rapidly increasing in the world.
8. **RECOGNISES** that antibiotic resistance could be the final consequence of several inadequacies occurring in the healthcare system and in animal husbandry, including those related to the prevention, management and treatment of infections.
9. **RECOGNISES** that access to effective and rationally used antibiotics is essential to ensure a high level of public health and effective healthcare in both the developed and the developing countries. Without access to effective antibiotics, common infectious diseases may again become lethal threats and many medical and therapeutic procedures, such as cancer treatments and transplantations, will carry high risks.
10. **RECOGNISES** that a wide range of measures is needed to ensure that currently available antibiotics remain effective for as long as possible, such as effective vaccines to prevent infections, new diagnostic methods and greater awareness among the public, healthcare and veterinary professionals of the importance of rational use of antibiotics to prevent the spread of antibiotic resistance, in both the human and animal sector.
11. **RECOGNISES** that adequately resourced prevention and control of antibiotic resistance and healthcare associated infections is a cost-effective strategy which contributes to the overall financial sustainability of healthcare systems and ensures continuous quality and patient safety improvements.
12. **RECOGNISES** that research into and development of new effective antibiotics has significantly declined and probably will not provide sufficient new therapeutic alternatives to meet medical needs within the next 5-10 years. There is therefore an urgent need to create incentives for research and development of new antibiotics, especially in those areas where the need is greatest.
13. **WELCOMES** the outcome of the Conference on Innovative Incentives for Effective Antibacterials in Stockholm on 17 September 2009, which provided valuable input for further action to promote research and development of new effective antibiotic medicinal products and methods.
14. **CALLS UPON THE MEMBER STATES TO**
 - develop and implement strategies to ensure awareness among the public and health professionals of the threat of antibiotic resistance and of the measures available to counter the problem;

⁵ <http://www.nelm.nhs.uk/en/NeLM-Area/News/2009---September/17/ECDC/EMA-joint-technical-report-The-bacterial-challenge--time-to-react/>

- ensure the development and use of integrated strategies to diminish the development and spread of antibiotic resistance as well as healthcare-associated infections and their consequences, encourage healthcare institutions to have structures in place as well as ensuring effective coordination of programmes focusing on diagnosis, antibiotic stewardship and infection control;
- review and consider options to strengthen incentives to conduct research and development of new effective antibiotics within the academic as well as the pharmaceutical sector as a whole, taking into account the situation of small and medium-sized enterprises. These options and methods could include cost-effective push mechanisms to remove bottlenecks in the early stages of research and development of new antibiotics and pull mechanisms to promote the successful introduction of new products.

15. CALLS UPON THE MEMBER STATES AND THE COMMISSION TO

- support the sharing of research infrastructures, recruitment of researchers, stimulation of and support for global research cooperation, increasing the spread of research results and knowledge through information exchange structures and considering existing and new financial instruments;
- explore ways to promote further public-private partnerships between industry, academia, non-profit organisations and the healthcare system to facilitate research into new antibiotics, strategies for use of currently available antibiotics and diagnostic methods;
- within the legal framework for market authorization of medicines, facilitate development of new antibiotics for which a particular medical need exists and when only limited clinical data can be submitted by the applicant for objective reasons, take full advantage of additional means of assessing safety and efficacy such as the utilization of preclinical assessment tools and pharmacokinetic data analyses;
- identify appropriate regulatory instruments to facilitate early approval for new antibiotics for which a particular medical need exists, in terms of providing continuous EMEA and national competent-authorities-assisted scientific advice, including strategies for adequate post-authorisation follow-up with an emphasis on safety aspects, including monitoring of antibiotic resistance;
- examine how to keep effective antibiotics on the market;
- while facilitating the development of new effective antibiotics, ensure prevention of healthcare-associated and other infections as well as the rational use of existing and new medicines;
- ensure that all actions are appropriately co-ordinated between different stakeholders from the sectors involved, such as health, finance, economic, legal and research.

16. CALLS UPON THE COMMISSION TO

- within 24 months, develop a comprehensive action-plan, with concrete proposals concerning incentives to develop new effective antibiotics, including ways to secure their rational use; and ensure that these proposals take account of the economic impact on the financial sustainability of healthcare systems.
 - consider using experience regarding relevant procedures from previous specific EU legislation on orphan drugs and drugs for paediatric use to stimulate the development of new antibiotics for which a particular medical need exists;
 - monitor and regularly report back to the Council on the public health need for new antibiotics, based on the emergence of antibiotic resistance, the characterisation of new resistant pathogens and new antibiotic medicinal products and other methods to treat and prevent infectious disease in development as well as to propose further action when appropriate."
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