



EUROPEAN COMMISSION

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COMMISSION RECOMMENDATION

of 27.10.2011

on the research Joint Programming Initiative "The Microbial Challenge – An Emerging Threat to Human Health"

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 181 and Article 292 thereof,

Whereas:

- (1) The microbial challenge, due to the increasing resistance to antimicrobial drugs, represents one of the major emerging threats to human health in the 21st century¹. More than 25,000 patients die in the Union each year from infections caused by bacteria that are resistant to multiple antibiotics, so-called multidrug-resistant bacteria². Resistance rates to a single antibiotic exceed 40-50% in some European countries³, and resistance to multiple antibiotics is a common and growing problem.
- (2) Infectious diseases caused by resistant bacteria lead to additional healthcare costs and indirect costs, such as sick-leave and lost output due to premature death. The overall direct costs to society in terms of extra healthcare costs and productivity losses total €1.5 billion each year in Europe⁴; and the indirect costs to European countries are likely to be several times higher⁵.
- (3) The problem of drug resistance is a natural and unavoidable consequence of treating infectious diseases with antimicrobial drugs. However, this is exacerbated by indiscriminate use of antimicrobials and the dissemination of antibiotic-resistant bacteria in the environment. The dynamics of human populations, including travel and worldwide distribution of food, contribute significantly to the rapid spread of resistant infectious microorganisms⁶. Moreover, the misuse of antibiotics in livestock is increasing the risk of spread of resistant microorganisms to humans through food

¹ Priority Medicines for Europe and the World, Kaplan W, Laing R. Geneva: World Health Organization (2004).

² The bacterial challenge: time to react. ECDC/EMA joint technical report (September 2009).

³ Goldstein FW. Penicillin-resistant *Streptococcus pneumoniae*: selection by both beta lactam and non-beta lactam antibiotics. J Antimicrob Chemother 44:141-144 (1999).

⁴ The bacterial challenge: time to react. ECDC/EMA joint technical report (September 2009).

⁵ Conference report; Innovative Incentives for Effective Antibacterials (2009).

⁶ World health report 2007. A safer future: global public health security in the 21st century. WHO (2007).

consumption⁷. At the same time, the development of new antimicrobials is declining dramatically.

- (4) A comprehensive solution to the problem requires measures to be taken by many sectors of society: policy-makers, healthcare, education, industry, environmental agencies, agriculture, veterinary medicine, research and other areas.
- (5) Cross-border collaboration is essential given that the increasing resistance of microorganisms to antibiotics is not confined to individual countries, but poses a real threat to public health on a global scale. Sharing the burden in order to efficiently handle the challenges ahead will yield benefits for all countries involved and will enable better management and treatment of infectious diseases in the future.
- (6) While excellent research is being carried out throughout Europe, the current European landscape for antimicrobial resistance research appears to be rather complex and fragmented. Many research networks and organisations at European and national level define antimicrobial resistance research agendas in isolation, leading to overlaps or competing research activities that often lack critical mass.
- (7) The Commission staff working paper of 18 November 2009 on antimicrobial resistance⁸ summarised the initiatives in this field at Union level. Several actions were proposed and followed up, including the improved monitoring of antimicrobial resistance and usage, and also risk management measures.
- (8) At its meeting of 1 December 2009⁹, the Council of the European Union called 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*" on innovative incentives for effective antibiotics.
- (9) At its meeting of 26 May 2010¹⁰, the Competitiveness Council identified and substantiated a set of potential Joint Programming Initiatives (hereinafter referred to as JPIs), including "The Microbial Challenge - An Emerging Threat to Human Health" as areas where joint research programming would provide major added value to the fragmented efforts currently being made by Member States. It therefore adopted conclusions recognising the need to launch a JPI on the subject and inviting the Commission to contribute to the preparation of that JPI.
- (10) Member States have confirmed their participation in this JPI by the sending of formal letters of commitment.
- (11) Joint programming in research in the area of antimicrobial resistance, as in the proposed initiative "The Microbial Challenge - An Emerging Threat to Human

⁷ Joint opinion on antimicrobial resistance (AMR) focused on zoonotic infections. EFSA Journal 7(11):1372 (2009).

⁸ SANCO/6867/2009r6.

⁹ Council of the European Union. Council Conclusions on innovative incentives for effective antibiotics. Adopted at 2980th Employment, Social Policy, Health and Consumer Affairs Council Meeting in Brussels, 1 December 2009.

¹⁰ 10246/10.

Health", will contribute to tackling the fragmentation of research efforts by Member States and will step up the mobilisation of skills, knowledge and resources, with a view to advancing and strengthening Europe's leadership and research competitiveness in this field. In addition, by tackling a major societal challenge, it complements the Europe 2020 strategy¹¹ and the Innovation Union¹².

- (12) In order to achieve the goals set out in this Recommendation, Member States should ensure cooperation and synergy with major related initiatives such as: the Innovative Medicines Initiative; research, development and innovation supported by the Framework Programme, including in the fields of health, food, agriculture and environment, where necessary enabled by information technology, as well as other initiatives, such as relevant ERA-NETs.
- (13) In order for the Commission to be able to report to the European Parliament and to the Council, Member States should report regularly to the Commission on the progress made on this JPI,

HAS ADOPTED THIS RECOMMENDATION:

1. Member States are encouraged to develop a common vision, based on a multidisciplinary approach, on how cooperation and coordination in the field of research at European level can improve, addressing the challenges of antimicrobial resistance and capitalising on the opportunities it presents, in order to ensure the efficiency of the joint efforts of the Member States.
2. Member States are encouraged to develop a common Strategic Research Agenda (SRA) establishing medium to long-term research needs and objectives in the area of antimicrobial resistance. The SRA should be further developed towards an implementation plan, establishing priorities and timelines and specifying the actions, instruments and resources required for its implementation.
3. Member States are encouraged to include the following actions, as part of the SRA and of the implementation plan:
 - (a) identifying and exchanging information on relevant national programmes and research activities;
 - (b) strengthening joint foresight exercises and technology assessment capacities;
 - (c) exchanging information, resources, best practices, methodologies and guidelines;
 - (d) identifying areas or research activities that would benefit from coordination or joint calls for proposals or pooling of resources;
 - (e) defining the detailed procedures for research to be undertaken jointly in the areas referred to in point (d);

¹¹ COM(2010) 2020.

¹² COM(2010) 546.

- (f) considering the needs for patient treatment and of healthcare systems when defining the objectives for research programmes on antimicrobial resistance;
 - (g) sharing, where appropriate, existing research infrastructures or developing new facilities, such as coordinated databanks or the development of models for studying antimicrobial resistance processes;
 - (h) encouraging better collaboration between public and private sectors, as well as open innovation between different research activities and business sectors related to antimicrobial resistance;
 - (i) exporting and disseminating knowledge, innovation and interdisciplinary methodological approaches, as well as identifying and addressing obstacles in the research and innovation system that prevent innovative solutions with a societal benefit from getting to the market quicker;
 - (j) creating networks between centres dedicated to antimicrobial resistance research.
4. Member States are encouraged to maintain an efficient common management structure in the field of research on antimicrobial resistance, with a mandate to establish appropriate conditions, rules and procedures for cooperation and coordination, and to monitor the implementation of the SRA. This management structure should be lean, efficient and flexible, and should take account of the Voluntary Guidelines on Framework Conditions for Joint Programming in Research developed by the High Level Group on Joint Programming (GPC).
 5. Member States are encouraged to jointly implement the common SRA, including via their national research programmes in accordance with the Voluntary Guidelines on Framework Conditions for Joint Programming in Research developed by the GPC or other national research activities.
 6. Member States are encouraged to build on the existing expertise within the Commission and take the Voluntary Guidelines on Framework Conditions into account when developing and implementing the SRA, and with a view to coordinating the JPIs with other programmes and initiatives in this field.
 7. Member States are encouraged to report regularly to the Council and to the Commission on the progress and results of this JPI, including lessons learned on achieving optimal efficiency.

Done at Brussels, 27.10.2011

*For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission*