Ref. Ares(2011)1067562 - 07/10/2011

EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2011)

Opinion

Title **Impact assessment on health security in the European Union**

(draft version of 7 September 2011)

(A) Context

The Lisbon Treaty gives the Union a mandate to encourage cooperation between Member States with regard to "monitoring, early warning of and combating serious cross-border threats to health" and to lend support to their actions where necessary. This report discusses how best to manage various threats arising from communicable diseases, other biological sources (e.g. the toxin ricin), chemicals and events with an unknown or environmental cause (e.g. heat waves). Health threats of radiological or nuclear origin are not covered because their management is governed by the EURATOM treaty. As communicable diseases have been governed by EU rules since 1988 (Decision 2119/98/EC), the report focuses on managing other relevant threats and on the future of the Council's Health Security Committee. One specific communicable disease issue is covered, namely joint procurement of medical counter-measures especially pandemic influenza vaccines and anti-viral drugs. Both the European Parliament and the Council have requested a review of the legal basis of the Health Security Committee, and the Council has requested an analysis of procurement options.

(B) Overall assessment

This impact assessment should be strengthened in several respects. First, the report should provide a better description of the general context for this initiative, clearly describing the existing legal framework and the links with related EU mechanisms for disaster prevention and control. Second, the form of the proposed measures, legal or otherwise, that the Impact Assessment is intended to support should be much clearer. Third, the extent of the problem, particularly in terms of Member States' preparedness should be clarified and supported by more concrete evidence and examples. Fourth, the content and workings of the options should be better explained, particularly in relation to vaccine procurement. Fifth, the costs and benefits of the proposed measures should be elaborated, particularly in relation to potential price advantages, efficiency gains, and avoidance of duplication and administrative costs. A more concrete plan for monitoring and evaluation should be included.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BERL 6/29. Telephone: direct line (32-2) 2981898. Fax: (32-2) 2965960.

E-mail: impact-assessment-board@ec.europa.eu

(C) Main recommendations for improvements

(1) Clarify the intended purpose of the Impact Assessment and better describe the problem. The report should put the initiative more clearly into context by better explaining the existing legal framework for the current policies in this field and by stating clearly the nature of the proposed changes to that structure that this Impact Assessment is intended to support. In particular, the report should clearly describe the extent to which the initiative either builds on an existing framework or presents new measures and should distinguish the elements of the new proposals that are legislative, clearly identifying the preferred form of legal instrument. The report should much better describe the scope of the initiative, identifying the sectors that are affected (in line with WHO definitions) e.g. non-health sectors that have an impact on health, and should provide a clearer explanation of the wider context, in particular the links with related EU mechanisms for disaster prevention and control. To strengthen the argument that EU action is needed, the report should better describe the differences in pandemic preparedness in more concrete terms and should better explain the respective competences of Member States and the EU in this area.

(2) Better describe the content of the options. In general the report should present the content of the alternative options in a much clearer manner, clarifying the level of ambition and precisely identifying the individual measures making up each option. It should be clear whether the measures proposed are legislative or non-legislative. The report should be considerably clearer on what an EU stockpile (virtual or otherwise) of medical countermeasures would involve, clearly describing the respective roles/obligations and liabilities of the EU and Member States in terms of purchasing and specifying how contract negotiation and payment arrangements would work in practice. Member States' views on this point should be fully outlined. The report should particularly describe how far Member States might be affected by binding rules about emergency actions and should clarify the role of the Health Security Committee under the preferred option.

(3) Improve the assessment of impacts. The report should better clarify and assess the impact of the proposed measures, particularly in Member States where gaps in the levels of preparedness, including for example, in relation to risk assessment, have been identified. The analysis of financial implications should be deepened and the report should be clear about which stakeholders might need to spend more or less. The extent to which the proposed measures will increase efficiency and avoid duplication of existing activities should be better explained. The report should make more use of practical examples to support its analysis for instance by providing more information on the similarities, realised price advantages and efficiencies gained in comparable joint procurement initiatives. It should also be clarified whether cooperating on cross-sectoral preparedness could impose costs on private companies in 'critical sectors' other than health. The level of any administrative costs arising from information obligations or costs for meeting preparedness rules should be clear and the assessment of administrative burden and governance aspects should be separate from that of social impacts.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation
The IA should be more concise and should avoid repetition. It should provide a more operational plan for monitoring and evaluation, identifying robust progress indicators and timing that are clearly linked to future decision-making needs.

(E) IAB scrutiny process	
Reference number	2011/SANCO/021
External expertise used	No
Date of IAB meeting	5 October 2011