



Brussels, 11-07-2008  
D(2008) 5885

## Opinion

**Title**                    **Impact Assessment on a proposal for a Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare-associated infections**

**(draft version of 12 June 2008)**

**Lead DG**                **DG SANCO**

### **1) Impact Assessment Board Opinion**

#### **(A) Context**

Even though the problem of patient safety is primarily the responsibility of the Member States, the Community can take actions that facilitate the exchange of good practice in order to improve the situations of the patients all over Europe. Article 152, on public health, gives the Community the right to act in order to encourage cooperation between the Member States. Article 153, on consumer protection, underlines consumers' right to information. Both Articles define shared Community and Member State competences and provide a basis to address systemic patient safety as well as on HAIs (hospital acquired infections).

#### **(B) Positive aspects**

The report provides a comprehensive overview of problems concerning patient safety, and especially hospital acquired infections. It provides an overview of actions previously taken and currently underway at Community level and in Member States to improve the way in which these infections are dealt with and to promote patient safety in general.

#### **(C) Main recommendations for improvements**

*The recommendations below are listed in order of descending importance. 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.*

**General recommendation: The IA report should provide a clear explanation (in the section on problem description) of what the current level of patient exposure to HAIs is in different Member States. It should also provide clearer examples of best practices at Member State level. The report should analyse further the issue of**

**subsidiarity by setting out more clearly the baseline scenario on the basis of identified problems associated with the existing situation and identifying to what extent Community action could lead to improvement in comparison with this baseline. The options section should be reorganised accordingly.**

**(1) Strengthen the baseline scenario and provide more clarity on existing policies.** More clarity should be provided on the present framework, including actions currently undertaken by Member States, to strengthen the assessment of the necessity and value added of EU action. The temporary ('project') character of a number of current actions should be explained, with more precise information about the time at which they are expected to expire.

**(2) Refine the description of the problems in the problem definition section.** Clarify to what extent these problems have a significant 'EU component', by indicating whether these problems are especially significant in some Member States rather than in the entire EU, and to what extent they can be considered to have 'cross-border aspects' (link to goods or persons movements, etc.). Distinguish between situations in which national authorities are not able to address these problems adequately, and cases in which it is a policy choice to provide a lower level of protection than others. Explain to what extent this may have consequences for other Member States. This applies for instance to issues such as lack of awareness, commitment, information in healthcare systems or institutions.

**(3) Restructure the objectives and options sections.** The report should be more explicit in its objectives and clarify what the overall aim of the policies should be. For instance, it is not clear what the operational objectives are concerning redress or interoperability. The links with other health policies - existing or in preparation - should be further clarified, especially those that are related to the pharmaceutical sector and medical R&D. The policy options section should be reorganised to make the comparison of the options more transparent.

**(D) Procedure and presentation**

It appears that all procedural requirements have been complied with.

The executive summary should provide an overview of the quantified impacts of the options.

**IAB scrutiny process**

Reference number	2008/SANCO/003 (CLWP / 2008 / Strategic Initiative)
Author DG	SANCO
External expertise used	No
Date of Board Meeting	Written procedure
Date of adoption of Opinion	11-07-2008