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Opinion

Title **Impact Assessment on: Improving Organ Donation and Transplantation in the European Union (revised draft version of 8 August 2008)**

Lead DG **DG SANCO**

1) Impact Assessment Board Opinion

(A) Context

The initiative finds its legal basis in Article 152 (4) (a) of the EC Treaty, which allows the European Community to adopt measures setting high standards of quality and safety of organs and substances of human origin. It follows an earlier Communication on Organ donation and Transplantation - COM(2007)275 – in which the main policy challenges were defined.

The IAB issued an Opinion on the previous version of the IA on 15 July 2008, in which it asked DG SANCO to submit a revised version to the Board.

(B) Positive aspects

Most of the IAB recommendations from the previous opinion have been addressed. In particular, the IA report now differentiates more clearly between organisational issues and cross-border aspects in the problem description; the role of the 'Spanish model' as a benchmark in setting the objectives is also better presented.

(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, subject to the discussions that took place in the meeting with the Board.

General recommendation: The IA has been improved and most of the IAB recommendations have been addressed. Nevertheless, the impact of the preferred option – an increase by 30% in organ availability – needs further substantiation. The baseline scenario is still too vague, especially as regards existing structures and arrangements and their expected evolution, to provide a clear and stable basis for comparison of the different options. The costs and benefits of the different options

still need to be presented more clearly to allow comparison of the envisaged net benefits of the different options.

(1) Further improve the baseline scenario, incorporating available information on the existing arrangements in Member States. The report now appears to use the 'Spanish model' as benchmark, rather than assessing the expected costs and benefits in comparison with a clear baseline scenario. Whereas it is clear that convergence to the 'Spanish model' can usefully be employed in the analysis as an illustration of the operational objectives, it should be understood that the main point of reference should be the status quo.

(2) Provide more solid arguments for the choice of the preferred option. Although the methodology underlying the scenarios developed for assessing the impacts of the different options is now better explained, the report still needs to clarify how adding a Framework Directive to the elements of the Action Plan would lead to the projected results. The presumed negative effects on donation rates of a strict regulatory approach (as in Option 4) should be better explained. It should also clarify why this would not apply to a Framework Directive (Option 3), as this would also lead to binding legislation. The budgetary implications (reimbursements, implementation costs) should be better quantified, to make a clearer comparison of costs and benefits possible, especially between Options 2 and 3.

(3) Improve the coherence between the different elements in the analysis, especially in view of subsidiarity, proportionality and EU value added. The report still needs to strengthen the arguments for dealing with specific aspects on an EU scale. As stated in the original Opinion, where the evidence shows that important best practices could be implemented even at a sub-national level, all options that suggest EU-level action should be screened more thoroughly on proportionality and value-added aspects.

(D) Procedure and presentation

It appears that all procedural requirements have been complied with.

2) IAB scrutiny process

Reference number	2008/SANCO/018 (priority initiative)
Author DG	SANCO
External expertise used	No
Date of Board Meeting	Written procedure (resubmission)
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