Regulatory Policy Committee	**OPINION**	
Impact Assessment (IA)	Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation	
Lead Department/Agency	Department of Health	
Stage	Final	
Origin	European	
Date submitted to RPC	27/04/2012	
RPC Opinion date and reference	11/05/2012	RPC11-DH-1023(5)
Overall Assessment	**GREEN**	

The IA is fit for purpose. The issues raised in our previous Opinion (30/03/2012) have been addressed. In particular, the IA now provides the appropriate level of analysis and evidence for us to confirm that the estimated costs have been adequately assessed.

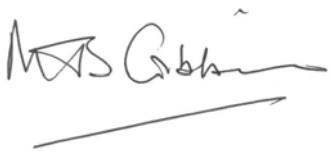
Identification of costs and benefits, and the impacts on small firms, public and third sector organisations, individuals and community groups and reflection of these in the choice of options

Estimates of costs. In our previous Opinion (30/03/2012) we noted that the IA failed to explain either the basis or the source of the data used in estimating the costs. This is now clearly explained in the revised IA.

Activity in private hospitals. We also noted that there was a risk that existing private hospitals might not be able to continue to operate in this area resulting in costs to business. The revised IA explains more clearly how the new licensing regime will impact on existing private hospitals post August 2012, and confirms that it will not result in existing private hospitals being forced to close. The RPC notes that consultees believed there would be little direct benefits for the UK from the Directive. A new licensing system, rather than using the existing UK regulator, remains unjustified but is required by the Directive.

Have the necessary burden reductions required by One-in, One-out been identified and are they robust?

As this proposal is of European origin, with no evidence of going beyond minimum requirements, it is out of scope of One-in, One-out (OIOO) in accordance with the current OIOO Methodology.

Signed  **Michael Gibbons,** Chairman