Regulatory Policy Committee	**Opinion**	
Impact Assessment (IA)	EU Directive on Patients' Rights in Cross-border Healthcare	
Lead Department/Agency	Department for Health	
Stage	Final	
IA number	6013	
Origin	European	
Expected date of implementation (and SNR number)	1 October 2013 (SNR 6.)	
Date submitted to RPC	25/07/2013	
RPC Opinion date and reference	08/08/2013	RPC12-DH-1548(2)
Overall Assessment	**GREEN**	

RPC comments

The IA is fit for purpose. The IA confirms that it is concerned with only one aspect of the Directive on Patients' Rights, namely the establishment of a National Contact Point (NCP). On this basis, there is no evidence that the proposal has a direct impact on business.

Background (extracts from IA)

What is the problem under consideration? Why is government intervention necessary?

On 24 April 2011, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, came into force. Member States are responsible for ensuring that their national legislation is consistent with European law. Where it is not, they must amend existing provisions, and introduce new law as necessary. The Government is obliged to transpose the Directive's requirements into national law by 25 October 2013.

What are the policy objectives and the intended effects?

Transposition aims to ensure the application in UK law of the legally binding provisions of the Directive:
- Clarification of established case law on patients' right to access health care elsewhere in the EEA;
- Setting out the grounds on which patients can claim reimbursement, from their home health system, for the costs related to such care;
- Equal application of patients' rights for all EU citizens;
- Improved information and better clarity on the rules that apply.

Comments on the robustness of the OITO assessment

As the proposal is to establish a National Contact Point (NCP) in the UK, which has resource implications for the department and the National Health Service (NHS), but not for business, (page 3) the assessment that there is no direct impact on business appears robust.

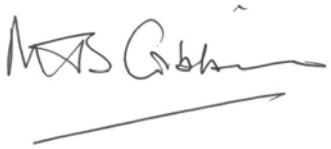
Comments on the robustness of the Small & Micro Business Assessment (SMBA)

The proposals do not regulate business and therefore the SMBA is not applicable.

Quality of the analysis and evidence presented in the IA

Costs and Benefits. The IA estimates the costs and benefits of implementing this Directive in terms of establishing a National Contact Point (NCP) in the UK as required by the Directive. The IA justifies this approach because it says that in terms of patient rights *"..this Directive and its transposition do not grant any new rights, nor does it extend eligibility."* (page 4). Further to this, the IA says that *"..the Directive does not create any new entitlements to cross border healthcare."* (paragraph 51).

On this basis, the IA appears fit for purpose. However the IA says, " ..*we have so little evidence about the likely scale of behaviour change*", (paragraph 125); and that ".. *despite specific appeals for information, no new information was made available*", (paragraph 126). The IA should explain more clearly where, any wider direct and indirect effects of the Directive (in terms of promoting cross border healthcare) will be assessed in terms of the costs and benefits for health and business in the UK.

Signed  **Michael Gibbons,** Chairman