Regulatory Policy Committee	**OPINION**	
Impact Assessment (IA)	Transposition of Pharmacovigilance Directive 2010/84/EU	
Lead Department/Agency	Department of Health	
Stage	Final	
Origin	European	
Date submitted to RPC	23/05/2012	
RPC Opinion date and reference	01/06/2012	RPC11-DH-1042(2)
Overall Assessment	**AMBER**	

The IA is fit for purpose. The costs and benefits have been adequately assessed. However, we have reservations regarding the methodology used to apportion UK costs and benefits.

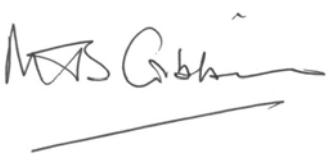
Identification of costs and benefits, and the impacts on small firms, public and third sector organisations, individuals and community groups and reflection of these in the choice of options

Costs to UK. In line with Government methodology for assessing costs and benefits, as set out in the HM Treasury Green Book, the IA attempts to separate out the costs and benefits to the UK of transposing the pharmacovigilance regulations. As these costs will fall on multinational firms it is difficult to accurately assess what portion of costs will fall on the UK. The IA has assumed that all of the costs will be passed on to shareholders and therefore the UK cost is estimated based on the proportion of shareholders believed to be UK residents.

While this approach is explained in the IA, we have serious reservations regarding how it has been applied. We accept it would be disproportionate to resolve these wider methodological issues within this individual IA. However, we would expect to see work undertaken to produce an agreed methodology across Whitehall to help Departments assess the UK and non-UK costs and benefits of regulations in a consistent way within and across departments.

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

As the measure is of European origin, with no evidence of going beyond the minimum requirements, it is out of scope of One-in, One-out.

Signed  **Michael Gibbons,** Chairman