Regulatory Policy Committee	**OPINION**	
Impact Assessment (IA)	Consolidation of UK medicines legislation	
Lead Department/Agency	Medicines and Healthcare products Regulatory Agency / Department of Health	
Stage	Final	
Origin	Domestic	
Date submitted to RPC	20/03/2012	
RPC Opinion date and reference	23/03/2012	RPC11-DH-0940
Overall Assessment	**AMBER**	

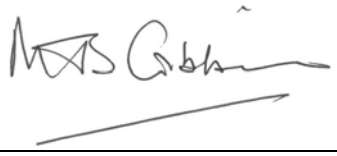
The IA is fit for purpose. However, the IA should set out more clearly the specific pieces of regulation and rules that are being removed and/or consolidated to explain better the estimated benefits.

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

Changes in legislation. The IA says that the proposal will "*bring together the 200 or so legislative instruments into one statutory instrument that sets out for the first time almost all of the regulatory requirements for medicines in a single text*" (page 5). The department says the proposed consolidation in legislation will deliver savings to various players in the private sector in terms of understanding regulations in the range of £0.12m - £2.67m per annum. However, the IA should set out more clearly the specific pieces of regulation and rules that are being removed and/or consolidated to explain better the benefits.

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

The IA says the proposal is a deregulatory measure that has a direct net benefit to business ('an OUT') with an Equivalent Annual Net Cost to Business (EANCB) of -£0.940m. This is consistent with the One-in, One-out Methodology and provides a reasonable assessment of the likely impacts.

Signed  **Michael Gibbons,** Chairman