Regulatory Policy Committee	**OPINION**	
Impact Assessment (IA)	Falsified Medicines Directive 2011/62/EU	
Lead Department/Agency	Department for Health/ Medicines and Healthcare Products Regulatory Agency	
Stage	Final	
Origin	European	
IA number	4024	
Date submitted to RPC	05/04/2013	
RPC Opinion date and reference	16/05/2013	RPC12-DH-1467(3)
OITO Assessment	**GREEN**	

Overall comments on the robustness of the OITO assessment.
The IA says that the proposal implements the European Directive without going beyond the EU minima and is out of scope of OITO (paragraph 63)**.** This appears to be a reasonable assessment and is consistent with the current One-in, Two-out Methodology (paragraph 2.9.8 ii of the Better Regulation Framework Manual). This measure provides an EANCB of £1.891m net cost to business.

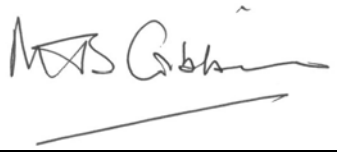
Overall quality of the analysis and evidence presented in the IA

The issues raised in our previous Opinion (01/03/2013) have now been addressed. In particular, the IA now provides clearer explanations to support the cost and benefit assumptions including how many companies exporting medicines will be affected by the new measures. The IA also provides detailed explanations as to the apparently disproportionate effect of the Directive upon small firms (paragraphs 200 to 204).
EU Directive. We note that the IA explains the difference between the Department's estimates and evidence for the underlying EU Directive (paragraph 42). On the basis of the examples given, the Department's own estimates appear to be more reasonable assumptions. In this the evidence suggests that the costs on UK businesses appear to outweigh the benefits substantially.

New safety features. The IA explains that discussion on this issue is still at an early stage with the Commission (paragraph 65) and the Department are unable provide detail of the impact on business. We note therefore that safety features are outside of the scope of the current IA.

Adjustments to the potential lost profits. We note that the IA makes 3 specific adjustments to the potential lost profits of businesses operating in the UK as a consequence of falsified medicines (paragraph 30). Two of these (an adjustment for the percentage of UK shareholders and an adjustment for advertising expenditure) are not obviously compatible with the HM Treasury's 'Green Book'. The IA acknowledges that there is no agreement between the Department and the RPC on these issues.

The paragraph also adjusts potential losses to businesses by distributional weighting. However, the IA does not appear to use such an adjustment in calculating other costs or benefits from the Directive. Moreover, this approach is

rarely used and it is not apparent to the RPC why it is justified in this case.
Signed  **Michael Gibbons,** Chairman