Regulatory Policy Committee	**Opinion**	
Impact Assessment (IA)	Tobacco Products Directive	
Lead Department/Agency	Department of Health	
Stage	Consultation	
IA Number	3131	
Origin	European	
Expected date of implementation	May 2016	
Date submitted to RPC	30 January 2015	
RPC Opinion date and reference	18 February 2015	RPC14-DH-2303
Overall Assessment	**AMBER**	

RPC comments

The IA will be fit for purpose, provided the Department addresses the following point prior to going to consultation. The Department should ensure that its approach is fully consistent with that taken in the standardised packaging proposals. The Department must, therefore, revise the IA to make it clear that under the One-in Two-out rules the effect of the ban on e-cigarette advertising on the profits of electronic cigarettes (e-cigarettes) manufacturers is a direct impact on.

Background (extracts from IA)

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

"Tobacco use remains one of the most significant challenges to public health across the United Kingdom and is the leading cause of premature death in the UK. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Action is required to harmonize certain aspects of tobacco control policies across the European Union and update earlier legislation to account for newly developed products.
The UK is required to transpose the Tobacco Products Directive into domestic legislation by 20th May 2016".

What are the policy objectives and the intended effects?

"The Tobacco Products Directive was formulated with the intention to:
- *Update harmonised European Union tobacco control rules which has not been done since 2001*
- *Introduce harmonised rules for novel tobacco products, herbals products for smoking and electronic cigarettes (e-cigarettes)*
- *Prevent distortion of the market as Member States consider their implementation of the global Framework Convention on Tobacco Control*
- *Improve the function of the internal market whilst maintaining a high level of health protection*

Domestic legislation and enforcement provisions to implement the EU TPD must be put in place. We must also decide which optional national measures to adopt.

Option 1: Implement the TPD at a minimum cost to business (do minimum)
Option 2: Implement some selected optional elements of TPD (preferred option)".

Identification of costs and benefits, and the impacts on business, civil society organisations, the public sector and individuals, and reflection of these in the choice of options

The Department proposes to transpose the Tobacco Products Directive (TPD) and also implement some of the additional flexibilities available under the transposition. Specifically, the Directive aims to update the harmonised EU tobacco control rules covering ingredients, emissions, labelling and packaging. It will also introduce harmonised rules for novel tobacco products, herbals products for smoking and e-cigarettes. The additional elements under consideration include the adoption of transition periods to allow the "sell through" of old stock and less onerous labelling requirements for specialist tobacco producers such as cigars, cigarillos and pipe tobacco.

The Department is not taking up all the derogations allowed under the Directive. In particular, it proposes to go beyond the minimum requirements for the packaging of cigars and pipe tobacco and to charge the tobacco industry for the cost of the regulatory regime. This represents gold plating at an estimated equivalent annual cost of £0.02 million each year.

The IA explains that the impact on business will be through both one-off and on-going costs to meet the requirement of the Directive. We note that the Department intends to use the consultation to seek further evidence of the impacts on business.

The IA is not consistent in how it treats lost profits from restrictions on advertising and branding. In particular:

- Following discussions with the RPC on standardised packaging, on the issue of the loss of profit from the reduction in branding having a direct impact on business, the Department has resubmitted the IA on the basis that the loss of profits to manufacturers, wholesalers and retailers is a direct impact. In doing so, the Department has revised the business net present value from -£1.17 million to -£130 million. The Department should use the consultation to test the revised figure.
- The IA discusses the effect of a ban on e-cigarette advertising, and states that the impact on the profits of e-cigarette manufacturers is deemed to be indirect for OITO purposes (paragraph 151), but seeks guidance from the RPC. The Department should ensure that its approach is fully consistent with that taken in the standardised packaging proposals. Based on the evidence provided, the effect on profit of the ban on e-cigarette advertising is direct. The Department must, therefore, revise the IA, prior to going to consultation, to make it clear that the impact on the profits of e-cigarette manufacturers of the ban on e-cigarette advertising is a direct impact on business.

The IA quantifies the effect of the proposals taking into account an expected effect of the planned closures of the two remaining UK based tobacco manufacturers on production of tobacco products in the UK (paragraphs 168 to 172). More evidence on the closures should be obtained during consultation. Also, the IA acknowledges that detail relating to the level of UK manufacture of novel tobacco products, herbals products for smoking and e- cigarettes is sparse at this stage (paragraphs 178 to 180). The Department should use the consultation to provide more information on the production of these products within the UK.

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

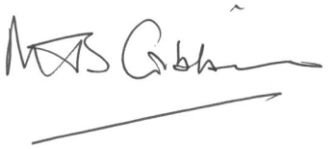
A SaMBA is not required because the proposal is of EU origin. However, the Department has provided a discussion on how the Directive will have an impact on small niche manufacturers, such as herbal-based products and e-cigarettes, and how it intends using the consultation to seek further information.

The IA highlights that small and micro advertising businesses may experience reduced business as a result of the ban on e-cigarette advertising (paragraph 243). The IA also indicates that small retailers account for a high proportion of sales of cigars, pipe tobacco and e-cigarettes (paragraph 245). The Department should use the consultation to gather more evidence on the effects of the proposals on smaller businesses.

Comments on the robustness of the OITO assessment.

The proposal is of European origin. However, the additional elements of option 2 lead to an increase in regulation beyond the minimum requirements of the transposition of the Directive. The IA says that these optional elements under the Directive are in scope of OITO and would impose a direct net cost on business (an 'IN'). Based on the evidence presented, the Department's assessment appears reasonable, and the OITO assessment is consistent with the current Better Regulation Framework Manual (paragraph 1.9.10).

The Department will need to refine its initial estimates to produce an equivalent annual net cost to business (EANCB) figure for the elements of the IA that constitute 'gold plating' and score in the Government's OITO account. The Department should also provide an EANCB figure covering the 'non-gold plated' EU elements of the proposal for RPC validation at the final stage, in order to support balanced reporting of overall EU burdens.

Signed  **Michael Gibbons,** Chairman