 Regulatory Policy Committee	Opinion	
Impact Assessment (IA)	Age of sale – Nicotine inhaling products	
Lead Department/Agency	Department of Health	
Stage	Final	
IA number	3132	
Origin	Domestic	
Expected date of implementation	April 2015	
Date submitted to RPC	18 February 2015	
RPC Opinion date and reference	6 March 2015	RPC14-DH-2195(4)
Departmental Assessment		
One-in, Two-out status	IN	
Estimate of the Equivalent Annual Net Cost to Business (EANCB)	£0.20 million	
RPC Overall Assessment	GREEN	
RPC comments		
<p>The IA is fit for purpose. The Department has taken note of consultation responses to assist in the calculation of the equivalent annual net cost to business (EANCB). In particular, the Department has provided an explanation of the percentage of manufacturing profits from business located in the UK (paragraphs 158 to 165). While the Department could have provided better evidence in some cases, the overall EANCB is unlikely to be significantly affected and therefore appears reasonable.</p> <p>The RPC notes that the Department has, not for the first time, requested an opinion from us to meet its very tight timetable to enable the legislation to be made during this Parliament. Under no circumstances should such requests be considered as forming a precedent.</p>		
Background (extracts from IA)		
What is the problem under consideration? Why is government intervention necessary?		
<p><i>“Nicotine is a potent pharmacological agent, is highly addictive and can permanently affect the development of the adolescent brain. The Government has concerns about young people becoming addicted to any substance before they are able to make informed, adult decisions. Also, as nicotine inhaling products (NIPs), such as electronic cigarettes, are currently legally available to under 18's, there is a risk that they could act as a gateway into tobacco smoking if young non-smokers become addicted to nicotine. While the evidence-base regarding gateway effect remains limited, there is not sufficient evidence to rule out e-cigarettes acting as a gateway into smoking tobacco.”</i></p>		

What are the policy objectives and the intended effects?

“The policy objective of the regulations is to limit the sale of nicotine inhaling products, such as electronic cigarettes (and related products including refill cartridges and nicotine liquids) to adults only, with certain limited exceptions for medicinal products. The intended effect is to limit the availability of nicotine inhaling products to young people and therefore restrict the scope for young people to become addicted to nicotine and any potential gateway effect into smoking tobacco.”

Comments on the robustness of the OITO assessment

The IA says that this is a regulatory proposal that would impose a net cost on business (an ‘IN’) with an estimated equivalent annual net cost to business of £0.20 million. This is consistent with the current Better Regulation Framework Manual (paragraph 1.9.10) and, based on the evidence presented, appears to provide a reasonable assessment of the likely impacts.

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

The proposals increase the scope of regulation on business. A SaMBA is, therefore, required.

The SaMBA is sufficient and has been strengthened for final stage. The IA explains that, with over 50,000 convenience stores, newsagents and petrol station forecourts potentially able to sell e-cigarettes, these proposals will have an impact on a significant number of small and micro businesses. However, the Department explains that any exemption from regulation for such businesses would not “enable any of the identified benefits to be realised” (paragraph 203) and estimates an annual cost of £170,000 to small and micro businesses. In regard to manufacturers, the Department explains that the majority of independent nicotine inhaling products manufacturers have been acquired by the established tobacco manufacturers. The impact on the remaining small or micro businesses is, therefore, expected to be small (paragraph 211). This appears to be a reasonable assessment.

Quality of the analysis and evidence presented in the IA

The Department proposes to prohibit the sale of nicotine inhaling products to those under 18 years and make it an offence for adults to make proxy purchases of such products on behalf of children. The main impact will be loss of profit for retailers, distributors and manufacturers due to reduced sales of these products.

The Department has provided an explanation of the percentage of manufacturing profits attributable to businesses located in the UK (paragraphs 158 to 165). The IA states that the vast majority of the manufacturing of both e-cigarettes and e-liquid is undertaken overseas. It, therefore, makes the assumption, based on ECigIntelligence reports, that 8% of costs to the e-cigarette manufacturers fall on UK-based business activity. While the Department could have provided further

evidence on the proportion of value-added activity that occurs in the UK, this assumption appears reasonable.

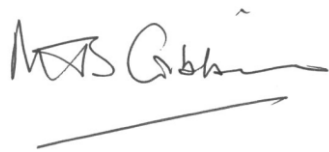
The Department explains that the consultation did not yield many responses to support some of the underlying assumptions. While, on the whole, the assumptions made appear reasonable, the IA would have benefitted from further evidence in areas such as:

- the IA , in projecting impacts on retailer profit margins over a ten year horizon (paragraph 127), assumes this will reduce from 40% in year 1 to 20% in year 2 and then 10% from year 3 onwards. In addition, IA could have provided more evidence to support the assumption that manufacturers' profit margins will fall from 18% to 11% by year 3 (paragraph 134). These assumptions could have been supported by greater evidence; and
- staff training awareness. The Department has used evidence from the Trading Standards Institute on costs to retailers of advisory visits by trading standards (paragraph 56). However, the Department has taken the estimate provided (£3,000) and assumed the cost to retailers of these visits to be half this figure. The assumption to halve the figure provided could have been supported by greater evidence.

The RPC notes that while evidence supporting such areas could have been stronger, such changes to these assumptions would not have a significant impact on the EANCB.

The RPC notes that the Department has, not for the first time, requested an opinion from us to meet its very tight timetable to enable the legislation to be made during this Parliament. Under no circumstances should such requests be considered as forming a precedent. Whilst the RPC has given a high priority to this IA in order to provide a full and proper scrutiny of the issues raised, the Department should plan for and enable the RPC to commit the time needed for the attention measures such as this require . The RPC further understands that the Department has proceeded with laying the regulations and will now publish a fit for purpose Opinion alongside the IA.

Signed



Michael Gibbons, Chairman