

9 June 2010

OPINION

Consultation on regulation of nicotine containing products

Introduction

1. The Medicines and Healthcare products Regulatory Agency (**MHRA**), an executive agency of the Department of Health (**DH**), is consulting on introducing new regulations on nicotine containing products (**NCPs**) (excluding tobacco). At present any nicotine containing product that claims or implies that it can help with the cessation of smoking is considered a medicinal product by presentation and is regulated by MHRA (“regulation by claims”). These products are widely referred to as Nicotine Replacement Therapy (**NRT**). However, there are a number of NCPs, such as electronic cigarettes, which do not currently make such claims and hence are not regulated by MHRA.
2. MHRA believes that the regulation of all NCPs will “*protect public health from products that have not been assessed for safety, quality and efficacy*”. Any requirement for NCPs to be brought within medicine licensing would apply throughout the UK¹.
3. The RPC has looked at the quality of evidence and analysis provided in the consultation letter² and accompanying impact assessment (**IA**) and, following a meeting with MHRA and DH, would like to make the following comments.

Summary Opinion

4. The RPC is of the opinion that the IA and consultation letter do not provide sufficient evidence to suggest that there is a significant risk to public health from currently unlicensed NCPs which would justify the future regulation of these products. MHRA should have made clearer what evidence is available to suggest there are safety and public health concerns about these products and considered a wider range of policy options before consulting on the introduction of a mandatory licensing requirement for all NCPs. In addition, the data and assumptions used in the IA for estimating the costs and benefits of the new regulations do not appear to be robust.

Detailed Opinion

Policy background and rationale

5. Following a recent review of its current policy on the application of the definition of a medicinal product in the context of nicotine and, after obtaining legal

1 To the extent that this RPC opinion refers to a devolved matter it relates only to England.

2 There is a consultation letter sent to all interested organisation, and not a full consultation document.

advice, MHRA has concluded that nicotine may potentially fall within medicines legislation because it affects human metabolism. MHRA is therefore proposing to regulate all NCPs (“regulation by function”), which means that all currently unlicensed products containing nicotine (excluding tobacco products) will either need to be removed from the market or licensed by a specific date. However, if MHRA considers changing its practice from regulating “based on claim” to a “regulation by function” principle, then it is not clear from the consultation letter how this will affect tobacco products (e.g. cigarettes), which also contain nicotine and hence will be within scope for these new regulations. MHRA has told the RPC that the tobacco products are excluded from this consultation as they have a separate regulatory regime and have no medicinal function.

6. It is not clear from the consultation letter or IA what specific policy problem MHRA is trying to address through the proposed new regulations. MHRA claims that the licensing of all NCPs is needed *“in order to ensure there is no risk to public health from these products”* (paragraph 18 of consultation letter). However, the evidence provided in the IA and consultation letter is not sufficient to conclude that there are serious risks to public safety and health to warrant regulatory intervention. In fact, the consultation letter itself acknowledges that the risk to the public health from NCPs is *“unknown”* (paragraph 17 of the consultation letter). MHRA has informed the RPC that there is potentially a legal obligation to licence these products. However, this issue is not clearly discussed and presented in the IA. The RPC also understands there is some limited evidence of potential harm from testing carried out by the US Food and Drug Administration.

Options

7. The IA considers two options in addition to the “do nothing” option. These two options both propose the regulation of all currently unlicensed NCPs, and the only difference between them is the proposed timeline for implementation of licensing requirements. It appears that Option 1, which provides a much shorter transition period (21 days) than Option 2 (implementation by June 2011), is preferred by MHRA on the grounds of being consistent with their current practice. In addition, the “do nothing” option is not developed because MHRA believes that *“it is neither in the public health interest nor commercial interest to leave the current regulation of NCP/NRTs untouched”* (paragraph 10 of the IA).
8. Subsequent to this the RPC believes that the range of options considered is too limited and the selection of the preferred option is not based on a robust appraisal of alternative options and their costs and benefits.

Costs and benefits

9. The data and assumptions used in the cost and benefit analysis of the IA do not seem to be robust. In the consultation letter MHRA acknowledges that the number of manufacturers of unlicensed NCPs and the number of products on the UK market are unknown. However, the IA estimates of costs and benefits are based on the assumption that there are 24 manufacturers and 50 products available on the UK market currently. However, the origin of these numbers is not provided and this raises concerns about the subsequent quality of cost

estimates. MHRA has told the RPC that these estimates were based on the number of importers contacting the agency about licensing requirements. This needs to be clearly explained and presented in the IA.

10. MHRA estimates that there will be 1,312 additional permanent quitters of tobacco product users as a result of licensing of all NCPs. However, the assumptions and analysis behind this estimate do not appear to be supported by strong evidence. For example, the assumption that the proposed new regulations will bring a further 5% reduction in the number of individuals who permanently quit smoking using licensed NCPs per year is not based on a robust evidence and analysis.
11. Also, it is assumed that 50% of producers of currently unlicensed NCPs will obtain licences. It is not clear on what basis this assumption is made, nor is it clear why the cost of the remaining manufacturers and importers (for not being able to sell their products in the UK market) is not included in the cost estimates.

Impact on competition

12. The IA does not provide an appropriate assessment of the impact of the proposed regulations on competition. For example, the IA claims that all businesses will be equally affected by the regulations, while at the same time it assumes that at least 50% of manufacturers will be required to remove their products from the market as a consequence of the regulations.
13. The regulations are likely to create additional barriers for entry for new producers and importers of NCPs, which is not fully discussed in the IA. According to MHRA the European Commission has said that nicotine could fall within the medicines licensing regime. It is however not clear how consistent the proposed new regulations are with European Internal Market rules and how effectively they would be enforced to achieve their aims in this context.
14. The RPC is pleased to note that MHRA acknowledges the deficiencies in the existing analysis and evidence base, and the way the available evidence is presented in the consultation letter and the IA. The RPC hopes that these shortcomings will be addressed in the next version of the IA.



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