OUTCOME OF CONSULTATION EXERCISE MLX364 ON THE REGULATION OF NICOTINE CONTAINING PRODUCTS (NCPs)

Outcome of consultation

The Medicines and Healthcare products Regulatory Agency (MHRA) has today published the outcome of public consultation exercise MLX 364 on proposals to regulate nicotine containing products (NCPs) under medicines regulation.
The MHRA has received a total of **1,217** responses, which can be broadly categorised as follows:
• Consumers of NCPs and patient groups
• Medical profession, including Royal Colleges, and pharmacy
• Public Health and NHS bodies
• Local Authorities and Trading Standards
• Manufacturers/importers of NCPs
• Pharmaceutical industry
All the responses have been placed on the MHRA's website (http://www.mhra.gov.uk).
The response to consultation suggests there is clear support for MHRA regulation, including from medical professional bodies, royal colleges, NHS bodies, public health bodies and trading standards. In addition, some of the importers of electronic cigarettes have said they are willing to work with the Agency with a view to working towards licensed products.

The majority of importers and users of unlicensed electronic cigarettes were opposed to regulation by the MHRA, the latter fearing that this would mean an immediate ban on products currently available and that this could lead them back into smoking tobacco. Public health focussed organisations too raised concerns that an immediate move to medicines regulation would lead to potentially useful products being taken off the market and/or innovation being stifled.

The MHRA also commissioned an independent research organisation to engage voluntary organisations, health professionals and consumer groups in the consultation process. The findings from that research mirror closely the picture which has emerged from the responses to the consultation. The report of the independent research is published on the MHRA's website (http://www.mhra.gov.uk).

Further research

The consultation highlighted the uncertainty around levels of nicotine that have a significant pharmacological effect and the need for further information on the impact of regulation on public health and business. A period of further scientific and market research will therefore be coordinated by the MHRA with the aim of answering these important questions. The research will be informed by the advice of an expert working group of the Commission on Human Medicines (CHM) and the draft Terms of Reference for the programme of research have been published on the MHRA's website (http://www.mhra.gov.uk).

The programme of research will include a work stream on investigation of the levels of nicotine which have a significant pharmacological effect, the actual use of existing nicotine products in the marketplace, their effect on smoking cessation and modelling of the potential impact of bringing these products into medicines regulation on public health outcomes. We envisage the programme of research will take about 18 months to complete and that a final decision on the regulation of nicotine containing products will be made in Spring 2013.

Background

Smoking is the greatest single cause of avoidable ill-health and death, accounting for 80,000 deaths each year in England alone. Reducing the impact of smoking remains a public health priority for the Department of

Health and the MHRA. It is important that new developments in NCPs and the potential impact on public health are critically assessed. Following advice from the CHM, the use of licensed Nicotine Replacement Therapy (NRT) products has been extended to include harm reduction. This means the use of these products has been extended to include those who are still smokers but who choose or are forced not to smoke for a period of time. This would include when smokers do not wish to expose others to second-hand smoke or cannot smoke because they are in a smoke-free area. It also includes those who wish to reduce the number of cigarettes smoked but with no immediate plan to quit.

The extended indication for a Nicorette Inhalator product was approved in December 2009 and other Marketing Authorisation (MA) holders have since successfully applied to extend the indication for their products. There are a number of products on the market such as nicotine containing electronic cigarettes claiming to contain nicotine that are widely and easily available but are not licensed medicines. Currently, any NCP that claims or implies that it can assist in giving up smoking is considered by the MHRA to be a medicinal product. This approach has allowed NCPs that do not make such claims to be used and sold without the safeguards built into the regulation of medicinal products.
Legal advice, sought in the context of the application to extend the indication of NRT to include harm reduction, was that NCPs which appreciably affect metabolism in normal usage could arguably fall within medicines legislation in terms of their pharmacological action. In the light of this advice, the MHRA published a consultation exercise to seek views on the regulation of NCPs.
The consultation was launched on 1 February 2010, with a deadline for comments of 4 May 2010. Following the announcement of the General Election, the deadline for response was extended to 2 June 2010.
MHRA

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