

Hot topics

Nicotine replacement therapy and harm reduction

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- There is a new element to the indication for nicotine replacement therapy (NRT) of “harm reduction”, since it has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT
- The extension of the indication for NRT to include harm reduction raises the question of the regulation of other unlicensed nicotine containing products on the market such as electronic cigarettes, which have not been assessed for safety, quality, and efficacy. The MHRA has launched a public consultation on whether/how to bring these products into regulation

Reducing the adverse impact of smoking on health remains a high priority for government, and over several years the MHRA has been in discussion with the Department of Health and other interested parties to determine and implement actions necessary for the effective regulation of nicotine delivery products. This evolving approach has focussed on extending access to new patient populations and supporting wider access to new formulations of nicotine replacement therapy (NRT).

An Expert Working Group set up in 2005 reviewed the usage of NRT and recommended that restrictions on use for all NRT products should be minimised for pregnant and breastfeeding women; patients with heart disease; patients with kidney or liver problems; patients with diabetes; and children aged 12–18 years. Since then the indication for NRT has been extended, such as by ‘cut down to quit’ and ‘temporary abstinence’ introduced in 2005 and 2006, supported by data from clinical trials showing NRT as an effective intervention in achieving sustained smoking abstinence for smokers who have no intention to stop completely, or who are unable to attempt an abrupt quit.

Since the advice of the Working Group in 2005, it has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT, and following advice from the Commission on Human Medicines (CHM) in October 2009, the MHRA has approved an extension to the indication to include a ‘harm reduction’ element for a particular product—the Nicorette Inhalator either as a complete or partial substitute for smoking. This now includes its use in those who choose or are forced into temporary abstinence (i.e. who do not wish to expose others to their second-hand smoke or cannot smoke because they are in a smoke-free area), and those who wish to reduce the number of cigarettes smoked without a specific intention to quit completely, without a limit to the duration of use.

The CHM also agreed the principle for all currently licensed forms of NRT and advised that there should be an indication for the harm reduction approach in pregnancy. It is important to be clear that smokers should quit without the use of NRT if they are able to, particularly in pregnancy and in patients with very severe pre-existing cardiovascular disease; however, it is also recognised that the use of NRT could increase, by several fold, the chances of a successful quit attempt and that there are consequences of failed quit attempts, including lifelong effects on the unborn child.

The products with the new indication are expected to be on the market in 2010. The 'harm reduction' approach to the use of NRT is a significant plank of the wider tobacco strategy launched on 1 February 2010 (www.dh.gov.uk).

The extension of the indication for NRT to harm reduction marks a major shift in approach in medicines regulation. NRT has to date not been licensed for harm reduction and the decision to do so raises the question of the regulation of other unlicensed nicotine containing products on the market such as electronic cigarettes, which have not been assessed for safety, quality, and efficacy. The MHRA has launched a public consultation exercise www.mhra.gov.uk on whether/how to bring these products into regulation. All comments are welcome and should be submitted to Amanda Bryan (Amanda.bryan@mhra.gsi.gov.uk) by 4 May 2010.