



11th January 2011

Clare Hedges
MHRA
Room 3-0,
151 Buckingham Palace Road,
London, SW1W 9SZ

Dear Ms Hedges

**CONSULTATION DOCUMENT: ARM 69 NICORETTE 15MG INHALATOR
REQUEST TO RECLASSIFY A PRODUCT FROM P TO GSL**

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

We do not feel that the proposed reclassification of Nicorette Inhalator from Pharmacy Only to General Sales List poses any safety/risk issues for the public or any concerns for Pharmacists for the following reasons:

- It is acknowledged that NRT is effective in smoking cessation and the use of nicotine replacement products in an individual who is already accustomed to nicotine products introduces few new risks.
- It is also widely accepted that there are no circumstances in which it is safer to smoke than to use NRT.
- Most of the special warnings and precautions listed in the summary of product characteristics for Nicorette Inhalator also apply to the continuation of cigarette smoking.
- The amount of nicotine from one puff of the inhalator is less than from a cigarette and so it is necessary to inhale more often than when smoking a cigarette.
- The principle has already been established that NRT products can be classified as GSL.
- The delivery per inhalation is the same as the currently available GSL form (Nicorette inhalator-10mg cartridge) and there are no additional safety/risk issues.

We also recognize that improved access to these products could help patients quit smoking, but that this

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must be balanced with the evidence that NRT without support has not been shown to be as effective. As a result there may be advantages in maintaining supply within a healthcare environment, so that there is opportunity for appropriate professional support and it also means impulse buying is reduced. Smoking cessation should be planned and supported and the appropriate product discussed with patients depending on their smoking profile. If support is not available there could be a risk of possible treatment failure and individuals could be wasting their money. However, we accept other NRT products are available as GSL and Nicorette 15mg Inhalator would provide improved choice and access to NRT products for individuals wishing to quit smoking and, as described above, we have no safety concerns.

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

Graeme Richardson
Chair of Practice
Guild of Healthcare Pharmacists