

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Popo,

Re: ARM 50 - Request to reclassify Nicorette Inhalator from P to GSL

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society requests that the following points be taken into consideration:

- **Section 2. Dosage**

Adults (over 18 years): States ‘No more than 12 cartridges per day. Use when there is an urge to smoke. *Smoking cessation:* 6-12 cartridges per day for 8 weeks. Halve the number of cartridges in weeks 9 and 10. Reduce to zero by end of week 12. Those who use Nicotine Replacement Therapy beyond 9 months should consult a healthcare professional. *Smoking reduction:* Use between smoking episodes to reduce smoking. A quit attempt should be made as soon as the smoker feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months.

Adolescents (12 to 18 years): *Smoking cessation:* As adult dosage, but duration of treatment should not exceed 12 weeks without consulting a healthcare professional. *Smoking reduction:* Only after consulting a healthcare professional.’

There is no guarantee that individuals will seek the advice of a healthcare professional if this product is reclassified from P to GSL.

- **Section 5. Specific GSL Requirements**
‘If you are pregnant, talk to your doctor, pharmacist or nurse for advice before using Nicorette Inhalator’. If a customer has already purchased the product they may not necessarily heed this advice.
- **Guide for Users (Page 3)** contains a typographical error and should read ‘Special information about using the Inhalator’ and not ‘the using the Inhalator’.
- **Guide for Users (Page 18)** states ‘Children should talk to their doctor, nurse or pharmacist before attempting to stop gradually’. This may be too late if the customer has already bought the product.
- **Guide for Users (Page 19)** states ‘Nicotine inhalation or ingestion by a child may result in severe poisoning.’ The Society has concerns regarding the patient safety implications if the product is purchased and accidentally ingested by a small child in the household.
- The length of the leaflet (35 pages) may deter customers from reading it before using the product. Particular consideration should be given to children as they may experience difficulty in interpreting the advice. Consideration should be given to increasing the age limit to ensure that younger customers are unable to purchase the product as a GSL and seek advice from a healthcare professional prior to use.

The proposal to reclassify Nicorette Inhalator cannot be supported by the Society. Sale through pharmacies has been shown to be safe because there is a pharmacist available to counsel the purchaser and /or deal with questions that arise. In non-pharmacies where GSL medicines are supplied, there is no professional advice available to customers.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care