

Clare Hedges,

Room 3-0

151 Buckingham Palace Road

Victoria,

London,

SW1W 9SZ

10 December 2010

Dear Clare,

Re: ARM 69 Nicorette 15mg Inhalator

We write on behalf of the Royal Pharmaceutical Society (RPS) to respond to the above consultation document.

The RPS is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain and currently have 49,000 members. There are approximately 75 pharmacists per parliamentary constituency, working in hospitals, industry, academia, GP practices, primary care trusts and community pharmacies.

The RPS leads and supports in the development of the pharmacy 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 Royal Pharmaceutical Society does not support the reclassification of Nicorette 15mg Inhalator from P to GSL .

The patient information leaflet repeatedly advises patients to seek advice from a doctor or pharmacist. In non-pharmacies where general sales list medications are supplied, professional advice is not available to customers. Sales through pharmacies have been shown to be safe because trained

staff are available to counsel customers appropriately about medicines and /or deal with any questions that may arise.

In addition, we request that the following points be taken into consideration:

Patient Information Leaflet

Section 2. Before using this medicines

This section advises patients not to use Nicorette Inhalator “if you have an allergy to nicotine or any of the other ingredients”. Non health professionals are unlikely to be able to advise against the use of this product to certain individuals or highlight potential allergy risks.

Similarly, much of this section describes circumstances where contacting a doctor, nurse or pharmacist is advised if the Nicorette Inhalator is to be used. Again, sale of this product from non-pharmacy outlets would rule out any of these checks being made at the time of purchase.

Although the Nicorette Inhalator 15mg is indicated in pregnant and lactating women who are attempting to give up smoking, this section recommends that pregnant women should try to quit smoking before resorting to using the inhalator. If this product is reclassified to a General Sales List medication, this check may be overlooked by non-pharmacy staff. Conversely, pharmacies will have trained staff ready to advise and counsel all patients types who are interested in using this product.

Section 3 and Section 5 How and when to use this medicine and Cleaning, storing and disposal.

Sections 3 and 5 describes a multi-stepped composition of how to use and maintain this product. Again, with lack of emphasis on patient care, sale of this product from non-pharmacies could lead to patient confusion resulting in inappropriate use of the inhalator and misguided care of the product .

Section 4 Possible side-effects

This section advises patients to tell a doctor, nurse or pharmacist if any of these side effects are experienced. If the 15mg Nicorette Inhalator is made available, given that it purports to be bioequivalent with the existing 10mg inhalator but lasting up to twice the duration, the patient may delay in contacting a health professional regarding a noted side effect.

We hope these comments are useful.

Thank you for contacting the Royal Pharmaceutical Society.

Yours Sincerely,

Julie Douglas.

