

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Ms Veronica Popo
Department of Health
Medicines and Healthcare products Regulatory Agency
Room 14-138 Market Towers
1 Nine Elms Lane
London
SW8 5NQ

PRACTICE AND QUALITY
IMPROVEMENT DIRECTORATE
Practice Division
Telephone: 020 77572 2537
Facsimile: 020 7572 2501
e-mail: sadia.khan@rpsgb.org

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Dear Ms Popo,

Re: ARM 53 - Request to reclassify Nicorette 25mg patch from P to GSL

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

The Royal Pharmaceutical Society of Great Britain (RPSGB) 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:

Consultation Document

Currently all the nicotine replacement patches on the market are already available as GSL medicines:

Nicopatch 7mg, 14mg, 21mg / Nicorette patch 5mg, 10mg, 15mg / Nicotinell TTS 10 (7mg/24 hrs), Nicotinell TTS 20 (14mg/24 hrs) / Nicotinell TTS 30 (21mg/24 hrs) / Niquitin patches 21mg / Niquitin CQ Patches 7mg, 14mg, 21mg

Nicorette patches are applied for a maximum of 16 hours whilst the other brands of nicotine replacement patches are applied every 24 hours. Nicorette 25mg patch delivers 25mg of nicotine over 16 hours, whereas currently the maximum delivery of a nicotine replacement patch available GSL is 21mg over 24 hours. Thus there is a greater possibility of adverse effects with Nicorette due to the higher delivery rate of nicotine, which has been suggested in Section 6 Safety Profile: nausea/vomiting reported as being higher in the 25mg group.

Section 6. Safety profile – states that the patch is ‘well tolerated in local tolerance studies’. The Society requests further details of these studies particularly as the 25mg strength patch has a higher incidence of certain side effects.

Proposed booklet / leaflet for users

Step 3. Nicorette 10mgi – should presumably read 10mg.

Section 4. Possible side-effects

‘Chest palpitations’ and ‘abnormal beating of the heart’ may be mistaken for the same side-effect yet the former has been classified as ‘uncommon’ and the latter as ‘very rare’.

‘When you stop smoking you may also develop mouth ulcers’. The Society suggests that additional information is given on why customers may develop mouth ulcers when they stop smoking.

The Society cannot support the reclassification of this product from P to GSL status and believes that the public is best protected by purchasing their medicines through a pharmacy where professional advice is available.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Practice Pharmacist - Lead for Self-care