



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Alexander

Re: Arm 67 – Request to Reclassify Regaine for Men Extra Strength Scalp Solution 5% w/v Cutaneous Solution from P to GSL

We 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 is the current 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 whilst, it also promotes the profession's policies and views to a range of external stakeholders in a number of different forums. Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new Professional body in 2010.

The Royal Pharmaceutical Society does not support the reclassification of Regaine for Men Extra Strength Scalp Solution 5% from P to GSL. The patient information leaflet repeatedly advises patients to seek advice from a doctor or pharmacist. In non-pharmacy outlets where general sale list medicines are supplied there is no professional advice available. If the product remains a P medicine then pharmacy advice is available from trained staff.

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

Reclassification Summary

Indications: It was unclear if the higher strength product would be suitable for patients who have tried the 2% formulation for a year with no improvement. The Society would like further clarification as to whether stepping up of treatment would be an option for this group of patients and if there is any evidence to support this. We would also like the time period of use with regards to assessing improvement to be clarified in patients who have already tried regular strength regaine. If the product is unsuitable for patients who have already tried the lower strength with no improvement the Society felt that this information should be included in the patient information leaflet.

Patient Information Leaflet

Section 1. Introduction: As this product is exclusively for “men only” the Society felt that the leaflet should lead with this fact as the first point on the patient information leaflet.

Section 2. Special warnings relating to Regaine for Men Extra Strength Scalp Solution 5% w/v: The Society felt the statement on page 5 –“No smoking “required further explanation for patients to indicate that smoking was to be avoided when the product was being used


Section 3 .Daily Dose for Adult Men: The Society felt that the statement “This product should not be used by women “should be located at the start of this entry instead of after providing dosing guidelines to emphasise the product was unsuitable for women.

Section 3. If anyone uses too much: The statement “including a child” was deemed to be confusing as it suggested a child could use the product despite the product being indicated for men aged 18-65 years.

We hope these comments are useful.

Thank you for contacting the Society.

Yours sincerely,



Dr. Catherine Duggan.

Director of Professional Development & Support.

