

8 June 2010

Dear Sir/Madam

**CONSULTATION DOCUMENT: ARM 67 REGAINE FOR MEN EXTRA STRENGTH
SCALP SOLUTION 5% W/V CUTANEOUS SOLUTION**

REQUEST TO RECLASSIFY A PRODUCT FROM P TO GSL

I am writing to inform you that consultation document ARM 67 which includes the applicant's Reclassification Summary and Patient Information Leaflet, has been posted on the MHRA website today (www.mhra.gov.uk). The consultation seeks your views on the reclassification of Regaine for Men Extra Strength Scalp Solution 5% w/v Cutaneous Solution from P to GSL.

You are invited to comment on the proposal, a copy of which is attached. A form for your reply is also attached.

Comments should be sent to me either by post to room 14-138, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ or by email (reclassification@mhra.gsi.gov.uk) to arrive by **6 July 2010**. Contributions received after that date cannot be included in the exercise.

To help informed debate on the issues raised by this consultation exercise, and within the terms of the Freedom of Information Act, the Agency intends to make copies of comments received publicly available. Unless you state otherwise we will assume that you have no objections to your comments being publicly available on the Agency's website.

Yours faithfully

Veronica Alexander
Reclassification
Unit

To: Veronica Alexander From: British Association of Dermatologists
Department of Health 4 Fitzroy Square
MHRA London
Room 14-138 Market Towers N22 6LD
1 Nine Elms Lane
LONDON SW8 5NQ

ALL RESPONDENTS MUST TICK ONE OF THE FOLLOWING BOXES

- **My reply may be made freely available**
- ~~**I wish parts of my reply to remain confidential***~~
- ~~**I wish my reply to remain confidential***~~

This proposal was considered by members of the Therapy & Guidelines Sub-committee of the British Association of Dermatologists. Whilst there were no adverse comments regarding reclassification of this product, there were two minor issues:

- Despite a brief description of androgenetic alopecia in the prescribing instructions, there is possibility that individuals may misdiagnose themselves and overlook another cause for their hair loss.
- The prescribing instructions suggest that the correct dose of Regaine is always 2mls per day, regardless of the area of hair loss.

Name: Dr Michael J. Tidman



Signature Date: 05/07/2010