

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Ms Amanda Lawrence
Policy Advisor & Reclassification Manager
Room 14-110
Medicines and Healthcare products Regulatory Agency
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

Ref: SK07/05
25 August 2005

Dear Ms Lawrence,

Re: ARM 31 - Request to reclassify Curanail lacquer from POM to P

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

The Society welcomes the proposal to reclassify Curanail (amorolfine hydrochloride 5% w/v) lacquer from POM to P for the treatment of onychomycoses for finger and toe nails. This is a common condition that people often seek the advice of community pharmacists. Pharmacists are familiar with diagnosing and referring to other health care professional's people with this condition.

It is important that pharmacists receive the relevant information prior to launch of this product to enable them to advise people appropriately. Pharmacists are ideally placed to counsel and support people on the "relatively" long term use necessary for this product to be effective (6 months for finger nails and 9-12 months for toe nails) and reminding them not to use nail varnish or artificial nails during treatment.

We request that the following points be taken into consideration:

- There is a discrepancy between the POM dose and the proposed P dose. The Society would like further information on whether efficacy is likely to be affected by administering the product once weekly as opposed to 1-2 times weekly.
- Documentation needs to state more clearly that the diagnosis is being made by the pharmacist as opposed to self-diagnosis by the customer.

- The consultation letter refers to the 'wealth of training material that exists currently for general practitioners and specialists' but does not indicate how this information will be cascaded to community pharmacists.
- It may be appropriate for the Patient Information Leaflet to emphasise the advice regarding returning to the pharmacy at approximately three month intervals for further assessment.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sue Kilby
Head of Practice