



Response document for MHRA public consultation on the
proposal to make Dovonex Psoriasis Ointment available in Pharmacies
Ref: ARM95

ANNEX 1

Your details

Name: [REDACTED]

Position (if applicable): Policy Manager

Organisation (if applicable): National Pharmacy Association

Email: [REDACTED]

1. Do you consider that Dovonex Psoriasis Ointment should be available as a Pharmacy medicine?

Yes

No

Not sure

Please provide any comments or evidence to support your response:

Community Pharmacists are the most accessible clinicians on the high street, and they are increasingly available over extended opening hours to provide advice on medications as well as prevention to ill-health, without the need of an appointment.

The provision of Dovonex Psoriasis Ointment through the pharmacy as a P medicine would aid in the accessibility of this medication. In addition, community pharmacists are well positioned to provide the advice and support to the customer, including side-effects, potential interactions and usage advice.

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Dovonex Psoriasis Ointment?

Patient information leaflet (Annex 2)

The Patient information leaflet appears to be comprehensive as to the use, contraindications and side-effects of Dovonex Psoriasis ointment.

Throughout the leaflet, there are a number of references to percentages as an indication of usage or when to seek medical advice: for example, under point 2, "You must see your doctor if you feel that your psoriasis has not cleared by up to 50% after using this medicine for 12 weeks", and later on "You should only use the ointment to treat total area of skin no bigger than the skin surface on one of your arms (around 10% of your body surface area)". The references to these percentages may lead to some confusion in those seeking to use this product, and hence, the NPA suggests a simpler description and alternative such as "You must see your doctor if you feel that your psoriasis has not cleared up **significantly** after using this medicine for 12 weeks".

Under point 3. How to use Dovonex Psoriasis, suggest the insertion
Directions for use prior to "Remove the cap. Check the seal is not broken....."

Label (Annex 3)

The label on the box appears to be clear and well written. However, just as in the leaflet there is a reference to percentages "Have psoriasis affecting more than 10% of your body surface (about the area of skin on one arm)", suggest a simpler explanation of this.

Given that this product requires confirmation of diagnosis and specific instructions as to its usage, the NPA suggests that the supply of Dovonex Psoriasis will always require the intervention of a pharmacist and not be delegated to members of the pharmacy team.

3. Do you have any other comments on the reclassification?

The NPA as a national body for independent community pharmacy will support its members with various education and training tools (practical and theoretical), should this change be approved.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes

Partially*

No

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

As a representative body we have to consult with our members as part of the consultation process, and found the tight deadline rather a challenge, particularly over the holiday period. We would encourage MHRA to allow a longer period for these consultations.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **20 April 2017**. Contributions received after that date cannot be included in the exercise.