



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): Chief Executive

Organisation (if applicable): Psoriasis and Psoriatic Arthritis Alliance (PAPAA)

Email:

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:

As an organisation, we believe that this is a difficult issue, at first glance making a product, which has been around for sometime, with a reasonable safety record, should be welcomed. Although the circumstances in which it is available needs to be monitored closely. In a situation as per the proposal where a previously diagnosed individual has a flare and needs access to the product without the need to consult their GP, does sound reasonable. Our concern is when that is not applied appropriately and someone could get the product where a diagnosis has not been established and will then be treating their skin inappropriately, or, when there is >10% psoriasis coverage and an individual visits numerous pharmacies to buy large quantities and subsequently 'overdoses'. Although we accept that people do currently, stockpile repeat prescription and use the product differently than the indication. A wider issue is that overtime, a lack of medical intervention from a GP and the opportunity for a referral to specialist services may be lost or missed. We believe that given the co-morbidities associated with psoriasis this loss of monitoring could miss vital signs and symptoms that would have been picked up.

We also consulted our membership. Amongst them is support for this change, in order for people with diagnosed mild psoriasis, to have easy access to a treatment as an OTC product, which they have previously used. This would be useful when the condition flares or they have run low on the product, when quick access to a GP is problematic, although we believe this can be overcome by the current pharmacy arrangements for issuing POM products.

The main issue that has been raised in the likely cost of the product, particularly for those who do not pay the prescription charge. This change may lead to a situation where they will not treat their psoriasis, which given its rapid ability to spread and flare, could lead to a need for escalation to more expensive or toxic prescription therapies.

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

The product name appears a little odd to us. It is somewhat strange to add the disease name within the brand name, as the indication is clear, and it is unlikely that a patient is self-selecting the product. We can only assume that this is advertising and marketing purposes, which appears a little against how this product is going to be dispensed. We think the term for the product of "*Dovonex® Psoriasis*" in leaflet without the word "ointment" is also a little odd, and therefore should always be called 'Dovonex psoriasis

ointment' throughout in full, as per the SPC.

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

No

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.

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.