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

Your details
Name: [redacted]

Position (if applicable): Chief Executive

Organisation (if applicable): PAGB (Proprietary Association of Great Britain)
www.pagb.co.uk

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:

Empowering people to self care appropriately brings many benefits, not only for the individual, but for clinicians, the NHS, government and society as a whole.

PAGB supports the proposal to reclassify Dovonex Psoriasis Ointment to a P medicine. Expanding the range of medicines available to buy over-the-counter (OTC), where appropriate, helps to empower more people to self care, giving them faster, easier access to medicines. It also allows for more appropriate use of NHS resources by reducing the number of GP consultations, freeing up time and resources to be reinvested in other areas.

Dovonex Psoriasis Ointment contains calcipotriol. It is indicated for topical treatment of adults with mild to moderate plaque psoriasis which has previously been diagnosed by a doctor.

Psoriasis is a common condition, affecting around 2% of people in the UK (NHS Choices). It is a chronic condition which usually involves symptom free periods interspersed with flare-ups which are characterised by red, flaky patches on the skin typically on the elbows, knees and lower back which can be itchy or sore.

There is currently no cure for psoriasis but treatments are available which can improve symptoms. First line treatments are usually topical and include vitamin D analogues such as calcipotriol.

PAGB believes that the switch proposal for Dovonex Psoriasis Ointment fulfils the criteria for a POM to P reclassification and will be a useful addition to OTC treatments for people with psoriasis.

Reclassifying Dovonex Ointment to a P medicine is appropriate because:

- It will be indicated for topical treatment of adults with mild to moderate plaque psoriasis. Calcipotriol is well recognised as first line treatment for this condition.

- Pharmacists are expert healthcare professionals with the skills and expertise to and assess whether Dovonex Ointment is an appropriate treatment for the particular individual. Furthermore, there is a requirement for a previous diagnosis by a doctor in order for the product to be supplied. People will be able to recognise the signs of their psoriasis, as previously diagnosed, which will significantly reduce the chance of inappropriate use.

- People with psoriasis are able to identify flare ups in their condition and self-manage their symptoms. Making Dovonex Ointment available over-the-counter as a P medicine will enable them to access this treatment quickly and easily, without the need to wait for a GP appointment or repeat prescription.

- PAGB supports restricting the pharmacy supply of Dovonex Ointment to use on mild to moderate plaque psoriasis. People with more severe symptoms, unusual features such as nail involvement or arthropathy, or symptoms that are not responding to treatment, will be advised to seek medical advice. This provides safeguards for use and is in line with many OTC products, including other topical medicines for skin conditions.

- PAGB notes that Calcipotriol can cause hypercalcaemia however, we consider that the risk is significantly reduced by limiting the amount of product which can be applied, by instructions on the SPC and leaflet (PIL) and by the pack size of 60g.

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

The leaflet and label provided in the reclassification report give clear instructions in relation to when the product can be used, how to use it and when medical advice should be sought.

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

No.

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

Yes ☐ No ✓ Not sure ☐

*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.