<u>Press release: Dovonex Psoriasis</u> <u>Ointment to be available to buy from</u> <u>pharmacies</u>

Today the Medicines and Healthcare products Regulatory Agency (MHRA) announced the approval of Dovonex Psoriasis 50microgram/g Ointment which will be available through pharmacies without prescription.

Over a million people are estimated to be affected by psoriasis in the UK. The availability of this medicine from pharmacies will increase the choice patients have of where to obtain treatment when their condition recurs.

'Dovonex Psoriasis Ointment' contains calcipotriol, a vitamin D analogue and the medication will be supplied as ointment in a 60gtube.

It will be sold after a consultation with a pharmacist and is suitable for adults aged over 18, with mild to moderate plaque psoriasis which has been previously diagnosed by a doctor.

This treatment can be used for up to 12 weeks after which people will be advised to see their doctor about ongoing treatment.

Pharmacists and their staff will be able to provide suitable advice to the patient to ensure that the product is suitable for them. The outer packaging and the patient information leaflet also include an image of plaque psoriasis which will help both pharmacists and patients in this respect.

MHRA is committed to widening access to medicines for the benefit of public health when it is safe to do so. The product was reclassified following a public consultation held earlier this year.

Dr Sarah Branch MHRA's Deputy Director of VRMM said:

Psoriasis is a chronic disease which can have a major impact on people's quality of life. By making this medicine more widely available, patients will be able to treat flare ups quickly without the need for a prescription.

Ash Soni, the RPS President said:

Widening access to medicine is great news for patients. Pharmacists are experts in medicines and are well trained to ensure safe supply of medicines to the public. Pharmacists are already able to sell products for the treatment of psoriasis with appropriate advice on management, application and side effects. We welcome the addition of Dovonex Psoriasis Ointment to the range of products available. Pharmacists are more easily accessible than doctors and trained to give advice on medicine use, make sure the chosen medicine is appropriate and check if a person needs to see another health professional. This is an important patient benefit and we would like to see more medicine available through pharmacy in future.

Background

- 1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
- 2. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health.
- 3. Dovonex Psoriasis 50 microgram/g Ointment is a medicine to be applied to the skin to treat mild to moderate plaque psoriasis which has been previously diagnosed by a doctor, for adults aged 18 years and over, for use for a period of not more than 12 weeks. The active ingredient in Dovonex Psoriasis (calcipotriol) is one of a group of medicines called vitamin D analogues. When calcipotriol is applied to skin affected by plaque psoriasis, it can help to reduce the number of cells made by the skin, thereby reducing the silver scaly patches and redness associated with psoriasis.
- 4. According to the <u>British Skin Foundation</u> and the <u>Psoriasis Association</u>, 2% of the UK population are affected by psoriasis.
- 5. Following assessment of the available evidence on the benefits and harms of the proposed product The Commission on Human Medicines (CHM) advised in favour of Pharmacy availability for this product. A public consultation on the proposal followed. The CHM is an advisory nondepartmental public body, sponsored by the Department of Health that advises ministers on the safety, efficacy and quality of medicinal products.
- 6. Dovonex Psoriasis 50 microgram/g Ointment has been reclassified from a prescription only medicine to one available in pharmacies. Pharmacists are experts in medicine, and have the necessary skills and training to ensure the safe and efficient supply of pharmacy medicines. The link to the public consultation is <u>here</u>.
- 7. MHRA involved the public and healthcare professionals throughout the decision-making process. We carefully analysed their contribution in the public consultation phases before deciding how to proceed. The responses to the consultation were predominantly positive. Full set of consultation responses can be seen <u>here</u>.