



8 October 2014

Submission to PBAC Secretariat

Introduction - LEO Pharma supports patients with dermatoses

LEO Pharma is an independent global research based pharmaceutical company committed to improving the treatment and quality of life of patients with dermatological conditions. In Australia it markets Daivonex® (calcipotriol) and Daivobet® (calcipotriol plus betamethasone gel and ointment) for psoriasis and Picato® (ingenol mebutate) for solar keratosis (available on the RPBS). It has research and development activities in collaboration with Universities and Health Care Professionals throughout Australia as well as a production site based in Queensland supplying active pharmaceutical ingredient to the rest of the world. LEO Pharma has plans to launch new and innovative dermatological products in the near future.

LEO Pharma is committed to achieving better health outcomes for Australian patients. We aim to do this through our activities such as the *Know Your Own Skin* campaign, provision of our Quality Care™ tailored patient support service (provided specifically for our patients by a LEO employed nurse) and educational activities for dermatologists, GPs, practice nurses and pharmacists.

LEO welcomes the public consultation on authority required medicines for the post-market review of authority required PBS Listings. It is clear from the review conducted in 2006, which led to the introduction of streamlined authorities; there were no significant changes in prescribing patterns following the shift to the less onerous streamlined authority. LEO anticipates the same would be expected should the five current authority required topical agents be shifted to streamlined authority.

The PBS Authority Hotline

The AMA has estimated that 440,000 calls are made each month by prescribers to the 'administrative' PBS authority hotline to enable doctors to provide clinically appropriate medications to their patientsⁱ. In 2009, a Productivity Commission Review again identified the need for improving the PBS authority approval process to reduce the administrative burden for medical practitionersⁱⁱ. The PBS Authority hotline has long been criticised by peak industry bodies (e.g. AMA and RACGP). Data from their surveys of prescribers in recent years have estimated that the hotline is wasting the equivalent of 25,000 patient consultants each year and rarely results in a negative outcome (only 2.8% declined)ⁱⁱⁱ. Prescribers do not believe that the hotline improves clinical decision making and the RACGP survey in 2013 indicated that 69% of respondents believed that the authority prescribing system is inefficient^{iv}. LEO Pharma welcomes the current review of the authority hotline and would like to specifically comment on Daivobet® gel but also request a review of the available pack sizes for all topical agents on the PBS.

Impact of PBS Authority Hotline on patients with dermatoses

While there are only 5 topical agents requiring authority prescription, the Authority hotline has a significant impact for prescribers and patients with dermatological conditions. Unlike most chronic conditions, such as diabetes or hypertension, there is generally only one pack size available on the PBS for topical agents. The limited pack sizes available on the PBS does not reflect the variability of extent of skin disease. With diabetes or hypertension doctors are able to increase the dosage of the anti-glycaemic or anti-hypertensive agent to reach an appropriate clinical outcome without having to ring for administrative approval. However, for patients with more extensive psoriasis (or eczema or dermatitis) the prescribers are not afforded the choice of different pack sizes on the PBS. Instead prescribers face the choice of forcing their patients to pay for multiple prescriptions for the small pack sizes listed on the PBS or to struggle through the administrative burden that is the PBS authority hotline. LEO believes that this current situation is discriminating against patients with dermatoses and request that a review is conducted to enable more equitable prescribing of topical agents for patients with dermatoses.

We help people achieve healthy skin

Impact of PBS Authority Hotline on patients with psoriasis

Psoriasis is a chronic life-long disease affecting approximately 2-2.5% of the Australian population^v. By the exact nature of the disease, psoriasis and other dermatoses are often visible on exposed skin and have been shown to have significant impact on patient's quality of life (QOL) and self esteem^{vi}. Patients with psoriasis experience a level of disability that is comparable to that of patients with other chronic illnesses such as heart disease, diabetes, cancer and depression^{vii}. While the condition may start at any age, many patients are diagnosed in their formative teenage years (peaks of diagnosis in 2nd -3rd decade and 6th decade)^{viii} so the impact on self esteem is particularly important in the early years when patients are establishing careers and partnerships, self image is important.

The extent of skin affected by psoriatic plaques varies greatly. LEO recognises that for all patients early, self initiated treatment of recurrent disease flares with topical agents is the key to management of this chronic disease. To this end LEO has listed a larger size of Daivobet[®] gel to assist patients who suffer from scalp psoriasis which is one of the most visible and distressing forms of psoriasis. Prescribers need to encourage patients to regularly use adequate amounts of product and ensure they have access to the same to prevent treatment failure and loss of patient's faith in topical agents. Guidelines from the UK NICE^{ix} highlights the use of topical agents to prevent the requirement for referral to specialists and the requirements for more expensive systemic treatments, such as methotrexate, cyclosporine or the biologicals. This underpins the importance of patient's involvement with their topical treatments, it is important that the prescriber works with the patients to ensure adequate volumes are used to match the extent of skin involvement in the disease.

When listed in 2013 the PBAC placed an Authority requirement on the Daivobet[®] gel 60g product whilst the 30g product is available as a restricted benefit. This authority requirement has limited the use of this product. Based on epidemiology and clinical trial evidence the minor submission in 2013 estimated that approx 6,500 packs of Daivobet[®] gel 60g would be dispensed through the PBS in the first year of listing. A check of PBS statistics demonstrates that only 551 units have been dispensed in the 4 months since listing in May 2014. This suggests that the authority system (hotline or paper requests) maybe preventing patients with extensive scalp psoriasis from receiving adequate amounts of suitable product. This is expected to impact on successful topical treatment of patients with more extensive scalp psoriasis.

Dermatologists recognise the need to provide adequate volumes of products and failure to do so is often cited as the reason for failure of topical treatment. Recognising this, in a survey of dermatologists in the UK in 2008, retreatment with adequate volumes of topical agents, often applied by nurses was the most common initial treatment following referral of patients for specialist care^x. In Australia recent analysis of PBS prescription data demonstrates that at least 21% of prescriptions written by specialists included 5 repeats^{xi}. Unfortunately the same is not seen for prescriptions written by GPs where only 6% of scripts included 5 repeats. Given the time constraints on GPs is the authority hotline red tape preventing them from providing adequate volumes of products for their patients with psoriasis.

With a small and easily defined restricted patient population the expected PBS spend on Daivobet[®] gel 60g is estimated to be less than \$35k pa (Daivobet[®] gel 60g Submission, Aug 2013). The authority requirement is expected to continue to prevent GPs providing adequate volumes of products for their patients with extensive scalp psoriasis, resulting in poor clinical outcomes. LEO Pharma would request that the authority requirement is altered to a restricted benefit in line with the Daivobet[®] gel 30g product in a similar way to products used to treat other chronic illnesses (e.g. diabetes), or at least simplified to a 'streamlined' authority.

Kind Regards



Jacob Anker Rasmussen – General Manager

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- ⁱ <https://ama.com.au/gpnn/do-you-really-need-call-pbs-authority-phone-line>
- ⁱⁱ http://www.pc.gov.au/__data/assets/pdf_file/0003/91344/social-economic-infrastructure.pdf
- ⁱⁱⁱ <https://ama.com.au/pbs-authority-prescriptions-0>
- ^{iv} <http://www.pbs.gov.au/reviews/authority-required-files/submission26.pdf>
- ^v Augustin M, Holland B, Dartsch D, et al. (2011) *Dermatol.*222(4):363-74.
- ^{vi} Choi, J and Koo J .Y.M. (2003) *J AmAcad. Dermatol.* 49,S57 – S61
- ^{vii} Choi, J and Koo J .Y.M. (2003) *J AmAcad. Dermatol.* 49,S57 – S61
- ^{viii} GawkrödgerD. (2002). *Dermatology*, Third Edition Published by Churchill Livingstone, p. 26 -27
- ^{ix} (<http://www.nice.org.uk/guidance/cg153/resources/guidance-psoriasis-pdf>)
- ^x Smith DR, Bottomley JM, Auland M, Jackson P and Sharp J. (2011). *Curr Med Res Opin.* 27(1);239-49.
- ^{xi} (Prospection; Jan 2011-Dec 2013)