



Australian Government
Department of Health

Thank you for your letter of 29 May 2015 to the Minister for Health and Minister for Sport, the Hon Sussan Ley MP, regarding access to Vagifem® vaginal pessary (containing oestradiol 25 microgram), a hormone replacement therapy (HRT) product, through the Pharmaceutical Benefits Scheme (PBS). The Minister for Health has asked me to reply.

Oestradiol is similar to the hormone oestrogen, which is produced in the human body.

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body comprising doctors, other health professionals and a consumer representative, makes recommendations to the Australian Government about PBS listings. It is usually an industry sponsor of a product which holds the clinical and other data required for a PBS listing submission.

Vagifem 25 mcg was delisted from the PBS on 1 May 2015 at the request of the product's sponsor, Novo Nordisk Pharmaceuticals Pty Limited.

At its March 2014 meeting, the PBAC considered a submission from Novo Nordisk for the listing of Vagifem® Low (oestradiol 10 mcg pessary). As part of this submission, the company provided advance notification that Vagifem Low would replace Vagifem, which was being discontinued globally.

The PBAC recommended the PBS listing of Vagifem Low for the treatment of atrophic vaginitis due to oestrogen deficiency and this listing occurred on 1 January 2015. Vagifem Low remains listed on the PBS, along with a range of other oestrogen replacement tablets, gels and transdermal patches.

At that time of its Vagifem Low submission, Novo Nordisk expected discontinuation of Vagifem in Australia to occur no later than January 2016. However, during 2014, circumstances connected with another company's oestradiol product, Ovestin® cream, affected Novo Nordisk's plans.

During 2014 Ovestin cream, sponsored by Aspen Pharmacare Australia Pty Ltd, was out of stock during several periods. This Ovestin supply problem affected the market in such a way as to result in an increased demand for Vagifem. Novo Nordisk employees conscientiously noted this trend and recalculated that stocks of Vagifem could be exhausted by 1 May 2015, faster than the company had originally anticipated.

Responding to the altered market reality, Novo Nordisk requested that the delisting of Vagifem from the PBS be brought forward to 1 May 2015. This was a responsible choice in the light of evolving market demands, some of which were outside the control of Novo Nordisk and the Australian Government.

Novo Nordisk anticipated that patients using Vagifem would be transitioned to Vagifem Low. The company advised that healthcare professionals would be informed of this change to the availability of Vagifem and the clinical data available for Vagifem Low.

Women and their healthcare providers should talk regularly about whether they continue to need treatment with a hormone replacement product. Women prescribed Vagifem may wish to confirm with their doctors that continued hormone replacement therapy is appropriate in their circumstances and ask whether Vagifem Low could be prescribed in place of Vagifem.

I trust that this information is of assistance in clarifying this matter.

Yours sincerely



Roger Busch
Director
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Pharmaceutical Benefits Division

4 June 2015.