

17 August 2009

**Submission No. 3**  
**(Impotence)**

PN 18/08/09

The Secretary  
House of Representatives  
Standing Committee on Health & Ageing  
Parliament House  
CANBERRA ACT 2600



#### ROUNDTABLE FORUM INTO IMPOTENCE MEDICATIONS

Eli Lilly Australia Pty Ltd welcomes the House of Representatives Standing Committee on Health & Ageing roundtable forum into impotence medications. As a responsible provider of medicines, including impotence medicines, Eli Lilly Australia would like to provide the following observations to the Committee in relation to the roundtable forum.

##### Impotence / Erectile Dysfunction

Impotence or erectile dysfunction (ED) is the inability to achieve or maintain an erection of sufficient quality for sexual activity. Several studies have estimated that about 40% of males aged 40 years have some degree of ED, increasing to 70% of men aged 70 years<sup>1</sup>.

While ageing is the most common cause, ED can be associated with a number of health problems such as: diabetes high blood pressure and other cardiovascular disease. It is believed that around 80% of ED has a physical cause<sup>2</sup>. It is, therefore, vital that any responsible treatment of ED should begin with an appropriate medical check up undertaken by a qualified medical practitioner.

There are a range of available treatments for ED, from counselling to pharmaceuticals (administered via tablet or, in some cases, injection) and the use of external devices (rings and vacuums) through to surgery. It is estimated that 95% of ED can be successfully treated<sup>3</sup>.

A key barrier to treatment of ED is the stigma attached to the condition. Many sufferers find it difficult, awkward or embarrassing to seek treatment or raise symptoms with their doctors. With little specific training in ED communications doctors also often find it difficult to raise the subject. As few as 22% of doctors proactively raise the subject of ED with their patients<sup>4</sup>.

## Eli Lilly

Lilly and Company is a leading, innovation-driven corporation committed to developing a growing portfolio of best-in-class and first-in-class pharmaceutical products that help people live longer, healthier and more active lives.

Lilly products treat depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, acute coronary syndrome, osteoporosis, as well as ED. We are committed to providing answers that matter - through medicines and information - for some of the world's most urgent medical needs. Founded in 1876 in the United States, Eli Lilly Australia Pty Ltd has been developing and providing medicines in Australia for over 50 years.

Lilly is committed to the concept of Quality Use of Medicines as described in the National Medicines Policy, namely:

- selecting management options wisely;
- choosing suitable medicines if a medicine is considered necessary; and
- using medicines safely and effectively.

Lilly is an active member of Medicines Australia and is subject to the Medicines Australia Code of Conduct. This Code sets our rigorous standards governing the conduct of pharmaceutical companies in communicating about their products. It prohibits direct promotion of prescription medicines to the general public. The Code incorporates a number of aspects of the Quality Use of Medicines. Lilly takes adherence to the Code, as well as its own stringent ethical guidelines, very seriously. The Code does not cover non-prescription medicines or other medical interventions.

## Eli Lilly Australia & ED

Lilly's treatment for ED is CIALIS® (tadalafil). It is provided in a number of different strength tablets for different treatment regimes. It works by inhibiting the enzyme phosphodiesterase type 5 (PDE5). Sexual stimulation causes the release of nitric oxide and allows for increased levels of the nucleotide cGMP in the male erectile tissue. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the absence of sexual stimulation<sup>5</sup>.

Cialis has undergone an extensive, heavily scrutinised development process. This included rigorous testing of its safety and efficacy over three phases of clinical trials. Following this process, Cialis was submitted for review and approval for use in Australia by Australia's Therapeutic Goods Administration. Cialis is only available on prescription.

Treatment of ED with Cialis, therefore, requires diagnosis by a qualified doctor. Where appropriate, the doctor will prescribe one of the PDE5 inhibitors, which may be Cialis. The duration and cessation of the treatment is entirely at the discretion of the patient and his doctor.

Lilly closely monitors all adverse events associated with Cialis and communicates important information to regulators and healthcare professionals to ensure they are fully apprised of the medicine's safety and efficacy.

A key focus of Lilly's communications involving Cialis is to address the issues arising from the stigma surrounding ED. Lilly has developed a range of simple, practical tools to make it easier for sufferers and doctors to commence a conversation about ED. At its most basic, Lilly provides simple desk signs for doctors' surgeries stating: "Are you frustrated by

erection problems? Ask me about your treatment choices". Lilly also provides a range of information resources available for sufferers and their partners to help educate about ED, its prevalence and treatment. The aim is to assure sufferers that it is a common condition; it can be treated so that they understand they are not alone and that professional medical help is available from their doctor.

The aim of Lilly's material is, amongst others, to:

- demystify ED by providing balanced, accurate information;
- provide helpful resources, in appropriate language, to facilitate opening the dialogue between the doctor and the patient;
- provide easy to read brochures to help the sufferer and/or partner overcome his/her embarrassment or hesitation in proactively raising the issue with his doctor;
- highlight the potential link between ED as a risk factor for cardiovascular disease and the rationale for why treatment is important;
- describe the whole range of treatments options available;
- urge potential sufferers to talk to their doctor and ask about treatments available;
- emphasise that treating ED is not just about sex but about maintaining a healthy relationship; and
- identify third party sources of information and support (eg. Impotence Australia).

These aims are exemplified on Lilly's ED website: [www.respondagain.com.au](http://www.respondagain.com.au). Cialis is not promoted to consumers through this website.

As part of its commitment to the principles of the quality use of medicines Lilly works with a cross section of prescribers: urologists, endocrinologists, psychiatrists, general practitioners and nurse practitioners dealing with diabetes to promote awareness and understanding of ED. Lilly also works closely with key consumer health care organisations, including: Prostate Cancer Australia, Diabetes Australia and Impotence Australia.

#### Counterfeit medicines and the internet

We would also like to draw the Committees attention to the significant issue with the availability of supply of impotence medications via the internet. We understand, anecdotally, that internet offers to supply Cialis and a competitor, Viagra, are amongst the most widely spammed messages in the world.

This offer of supply is made without prescription or even a medical check-up and comes at a very high risk of fraud to the would-be purchaser. However, counterfeit medications are not just a waste of a sufferer's time and money but are also potentially harmful or deadly and, at the very least, prolong the time taken for a sufferer to actively from seek a proper consultation with their doctor to obtain a legitimate treatment.

Needless to say, Eli Lilly and Company has nothing, and never will have anything, to do with this wholly unregulated practice.

#### Lilly's key message

ED can have a serious impact on the lives of sufferers. It can indicate the presence of serious, even deadly, underlying medical conditions. Diagnosis and treatment can be complex and involve a range of approaches including but not limited to counselling, pharmacological treatment and other options. It is vital that ED is diagnosed and treated in a responsible manner with the needs of the sufferer as the first and last consideration. To this end, all Lilly's disease awareness communications include a call to action that directs the sufferer to discuss ED with their doctor.

Please don't hesitate to contact Stuart Englund (on 02 9325 4669 or [englundst@lilly.com](mailto:englundst@lilly.com)) if you require any additional information in regard to any of the issues raised in this letter.

Regards,



**Peter Vermeer**  
**Director, Corporate Affairs & Health Economics**

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1. Feldman HA, et al. '*Impotence and its medical and psychosocial correlates: Results of the Massachusetts male aging study*', *Journal of Urology* 1994, vol 151; pp. 54-61
  2. Lue TF. '*Erectile dysfunction*', *N Engl J Med* 2000, vol 342; pp.1802-13
  3. WGBH Educational Foundation 2006, *Impotence: Causes and Treatments*, viewed 26 May 2006, <http://www.jcn.co.uk/journal.asp>
  4. Lilly segmentation research, 2008 (n=400)