



Public Affairs & Policy  
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## Pfizer Australia

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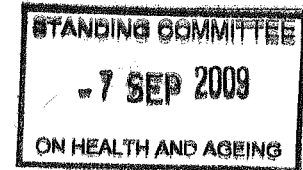
**Submission No. 11**  
(Impotence)

19 August 2009

PW 719109

Committee Secretary  
Standing Committee on Health and Ageing  
House of Representatives  
PO Box 6021  
Parliament House  
Canberra ACT 2600

via email: [haa.reps@aph.gov.au](mailto:haa.reps@aph.gov.au)



Dear Secretary,

**RE: Roundtable Forum on Impotence Medicines**

On behalf of Pfizer, I would like to provide the Standing Committee on Health and Ageing with a statement from Pfizer to assist Committee Members in their deliberations on this important topic.

We do not seek to attend the Roundtable, as our industry association, Medicines Australia, will appear on our behalf.

We are happy for this statement to be considered a submission for the purposes of the Roundtable, and to be made publicly available on the Committee website.

Committee Members and the Secretariat should feel free to contact me should they require any further information.

Yours sincerely,

**David Miles**

# House of Representative Public Roundtable into Impotence Medications

## Statement by Pfizer Australia

1. Pfizer is the Australian supplier of Viagra® (sildenafil citrate)
2. Pfizer supports the responsible use of Viagra for the treatment of erectile dysfunction (ED) in adult men, in line with the principles of Quality Use of Medicines – in particular:
  - a. *Selecting options for treating ED wisely by:*
    - considering the place of medicines in treating ED and maintaining overall health
    - recognising that there may be better ways than medicine to treat ED and the underlying causes
  - b. *If a medicine is considered necessary to treat ED, choose the most suitable by taking into account:*
    - the individual
    - the underlying causes of ED, and overall health
    - risks and benefits of ED medicines
    - dosage and length of treatment
    - any co-existing conditions
    - other therapies the individual is taking which might contraindicate an ED medicine or require a different dose
    - costs for the individual.
  - c. *Using ED medicines safely and effectively to get the best possible results by:*
    - monitoring outcomes
    - minimising misuse, over-use and under-use
    - improving the patient's ability to resolve problems related to ED medication, such as side effects or managing multiple medications for other conditions.
3. Men with erection problems should begin by seeing a qualified medical practitioner for a complete medical examination and they should give a full medical history. Only once this is done, should doctors discuss treatment options that are appropriate for them.

*We are concerned that Advanced Medical Institute's (AMI) practices appear to be more about assessing men's ability to take AMI medicines, than assessing their overall health. Our understanding is that patients are administered a questionnaire by a nurse, and that a doctor is usually consulted only by telephone, and only for a few minutes. We feel this is would not be considered adequate medical examination for other chronic diseases, and feel that ED should be treated no differently.*



**4. It is important that doctors not only treat ED but also identify and address any underlying causes of ED and the patient's overall health.**

ED may be the result of, or found in combination with important underlying conditions or factors. If present, the doctor should also discuss treating these with the patient. These conditions and factors include<sup>1</sup>:

- cardiovascular disease
- high cholesterol and high blood pressure
- diabetes
- neurological disorders
- smoking and excessive alcohol
- low testosterone levels or hormone imbalances
- prostate problems after treatment for prostate cancer with radiation treatment or surgery
- other medicines causing or contributing to ED
- relationship and stress related issues
- depression

Doctors have a responsibility to treat their patient's overall health, not just treat ED – even if that is the patient's expectation and their immediate reason for visiting their doctor.

*We are concerned that AMI's practices (particularly telephone consultations) appear insufficient to assess patients' overall health – and that AMI appears to focus narrowly on providing medicines to treat ED, rather than treating the whole patient and the underlying causes of their erectile dysfunction.*

*Also, we are concerned that AMI practices appear to encourage men to separate ED from their other health problems, and discourage men from fully disclosing their complete medical history to their main treating doctor. If so, this would not be good medical practice, and may be to the detriment of their patient's overall health.*

**5. There should be a clear separation of the doctor who prescribes a medicine, and the pharmacist who dispenses the medicine.**

Whatever treatment the doctor offers should be uninfluenced by financial reward from prescribing any particular treatment. If the doctor does stand to make a return for prescribing a medicine, this should be clearly disclosed and the relationship should be transparent.

*While we do not have certain knowledge of the relationship between AMI's prescribing doctors and AMI's products – particularly any financial connection – we are concerned that there is no clear separation between them. The relationship is not transparent in the case of AMI.*



**6. If the doctor prescribes a medicine for ED, it should be safe, effective and registered with the Therapeutic Goods Administration (TGA).**

The only medications that Pfizer is aware of that are registered and available in Australia for the treatment of ED are:

- sildenafil (Viagra® tablet)
- tadalafil (Cialis®, tablet)
- vardenafil (Levitra®, tablet)
- alprostadil (Caverject Impulse®)
- DBL papaverine hydrochloride injection (Hospira®)

Other products may be used in Australia, but Pfizer is not aware of clinical evidence to support either their effectiveness or safety in the treatment of ED.

*We are not aware of any TGA approved ED product delivered nasally or as lozenges.*

*We have heard anecdotally that AMI advises patients that only its doctors can supply AMI products – they are not available to other GPs.*

*AMI does not advertise the active ingredients in the products it supplies, and we understand that AMI does not write the names of any ingredients on their medicine labels. Their products do not appear to be registered with the TGA, as pharmaceutical manufacturers are required to do for all of their prescription products.*

*We do not believe that Viagra® (sildenafil) is used in any of AMI's compounded products.*

*Pfizer supports the supply and promotion of medicines for the treatment of ED in Australia. However, all such products must at least be (a) supported by clinical evidence to show they are safe and effective; (b) registered with the TGA for the treatment of ED; and (c) promoted strictly within the law. Finally, the sponsors of all ED products need to be regulated equally. We feel that AMI is being treated differently from other sponsors of pharmaceutical medicines in Australia.*

**7. The manufacture of ED medicines – indeed all medicines – should be done in compliance with Good Manufacturing Practice (GMP). In Australia, GMP is overseen in Australia by the TGA, and include regular inspections of manufacturing facilities. This is essential to ensure that Australians are supplied with medicines that are safe and meet high manufacturing standards.**

*Our understanding is that AMI's products are prepared by a 'compounding pharmacy' – that is, a pharmacy that mixes pre-registered medicines, often into new formulations. Legally, all pharmacists are allowed to do this, but the intention of the law is to allow pharmacists to*



*address the specific needs of individual patients; it is not intended for mass-manufacturing of products.*

**8. Patients should be given written information and counselling about the safe and effective use of ED medicines, before they commence treatment.**

Pfizer provides information on Viagra (and all its other prescription medicines) which includes the benefits and potential risks including contraindications and possible side effects, as well as, how to prescribe and use the medicine effectively:

- Product Information (PI) for doctors
- Consumer Medicine Information (CMI) for patients.

Like all prescription medicines, these documents are registered with the TGA. The CMI should be made available to all patients in all pharmacies. Pharmacists are recommended to provide a CMI to patients the first time any medicine is dispensed, and again after extended use. The Viagra PI and CMI are also available from the Pfizer website ([www.pfizer.com.au](http://www.pfizer.com.au)).

*Pfizer has not seen PI or CMI for any AMI products, or any other written information for patients about to use their products.*

**Reference**

- 1: Pfizer Australia website ([www.thingswedoforlove.com.au](http://www.thingswedoforlove.com.au))

**For further information**

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