

Introduction

- 1.1 Several members of the committee have recently become concerned at practices that have developed to treat and manage erectile dysfunction (ED) in Australia. Their concern has arisen as a result of being approached in their electorates by men with complaints about their treatment. The main complaint of these men was the contractual practices of commercial ED clinics, which require men sign to contracts for treatment regimens that are only able to be cancelled under specific conditions.¹
- 1.2 However, what prompted the committee to hold a public hearing was concern about the potential affect that the practices of commercial ED clinics may have on men's health more broadly. The risk is that men treated for ED are not being screened for some of the common causes of ED including diabetes and cardiovascular disease.²
- 1.3 The committee determined that a single roundtable forum would be the best manner in which to conduct an inquiry of this nature, as it would afford an opportunity to gather interested individuals around the table to discuss the issues and recommend potential solutions.

What is erectile dysfunction?

- 1.4 ED, which is sometimes called impotence, refers to the inability of men to achieve or maintain an erection that allows sexual penetration.³ It affects a large number of men, with studies showing that 40 percent of men aged

1 AMI rejects this allegation, details of their response can be found in Submission No. 13, p 15.

2 Andrology Australia viewed on 19 October 2009 at <http://www.andrologyaustralia.org/pageContent.asp?pageCode=ERECCAUSES>.

3 Andrology Australia viewed on 19 October 2009 at <http://www.andrologyaustralia.org/pageContent.asp?pageCode=ERECFACTS>.

over 40 experience some level of ED and that the figure is as high as 70 percent of men aged over 70.⁴ However, there is in fact a lack of definite data on the number of men affected as Professor Marshall informed the committee:

The Florey Adelaide Male Ageing Study has been following 1,000 men for nearly five years now, and they have all had questions about erectile function. These men are aged from 35 to 80 and 57 percent of those men have already reported that they have some issues with erectile dysfunction. This obviously indicates that there is likely to be an even greater incidence than the figure that we heard earlier this morning, of one in five, from Andrology Australia.⁵

- 1.5 The most common cause of ED is ageing,⁶ but at the roundtable the committee heard evidence that ED can be an early marker for chronic, lifestyle and other diseases such as cardiovascular disease, diabetes, depression excessive use of alcohol, smoking, prostate problems, neurological disorders, hormone imbalances and the side effects of other medications and stress.⁷
- 1.6 This report focuses on the treatment of ED. A related condition is that of premature ejaculation which refers to the inability to control the timing of ejaculation and therefore ejaculating before one is ready:⁸
- Premature ejaculation is the most common male sexual problem and affects men of all ages. Premature ejaculation is more common in younger men, as they are often less sexually experienced or secure with the situation in which they are having sex.⁹
- 1.7 ED and premature ejaculation are separate conditions which require different treatments. However, while the roundtable has focussed on the treatment of ED, many of the concerns about ED treatments also apply to

4 Eli Lilly Australia, Submission No. 1, p 1.

5 Marshall, V., Freemasons Foundation Centre for Men's Health, Transcript, p 13.

6 Eli Lilly Australia, Submission No. 1, p 1.

7 Fitzsimons, M., Medicines Australia, Transcript, p 23; Marshall, V., Freemasons Foundation Centre for Men's Health, Transcript, p 13; Doyle, R., Advanced Medical Institute, Transcript, p 28; The Royal Australasian College of Physicians, Submission No. 7, p 1; Pfizer Australia, Submission No. 11, p 2.

8 Andrology Australia viewed on 19 October 2009 at <<http://www.andrologyaustralia.org/pageContent.asp?pageCode=PREFACTS>>.

9 Andrology Australia viewed on 19 October 2009 at <<http://www.andrologyaustralia.org/pageContent.asp?pageCode=PREFACTS>>.

the treatment of premature ejaculation as they are often treated by ED clinics using the same, or similar, methods.

Treatment options

- 1.8 There are many options available for men who are experiencing ED including pharmaceuticals, counselling, the use of external devices and surgery.¹⁰ Andrology Australia's website outlines the main types of treatments and these include:
- **Non-invasive** treatments such as:
 - ⇒ oral medications for example Viagra®, Cialis® and Levitra®; and
 - ⇒ external devices such as rubber rings and vacuum devices.
 - **Injectable** treatments such as:
 - ⇒ penile injections for example Caverject®.
 - **Surgical** treatments such as:
 - ⇒ penile prosthesis; and
 - ⇒ vascular surgery.¹¹
- 1.9 The treatments provided by many commercial ED clinics, such as the one of the largest providers in Australia the Advanced Medical Institute (AMI),¹² are different from those outlined above. AMI treats ED using one or more of the following; nose sprays, gel applications, lozenges or penile injections.¹³ Their products are specifically formulated for each patient using different mixtures of ingredients that have already been approved by the Therapeutic Goods Administration (TGA).¹⁴ Making specific medication for an individual patient is known as extemporaneous compounding and is discussed in greater detail in chapter 2.
- 1.10 The committee does not have the expertise to make judgements about competing claims of the efficacy of different ED treatments. AMI has presented evidence to the committee demonstrating the efficacy of the

10 Eli Lilly Australia, Submission No. 3, p 1.

11 Andrology Australia viewed on 19 October 2009 at <<http://www.andrologyaustralia.org/pageContent.asp?pageCode=ERECTREAT>>.

12 Doyle, R., Advanced Medical Institute (AMI), Transcript, p 3.

13 AMI viewed on 19 October 2009 at <<http://amiaustralia8-px.rtrk.com.au/page/17/Treatment-Information>>.

14 AMI viewed on 19 October 2009 at <<http://amiaustralia8-px.rtrk.com.au/page/4/Why-AMI>>.

ingredients in its compound formulations, which others question.¹⁵ The concerns of the committee in this report are how the treatments are prepared and how they are prescribed. Finally, the committee is not endorsing any particular method of treatment over another. Specific advice about treatment for ED should be sought from a qualified medical practitioner.

The roundtable

Parameters of report

- 1.11 This is a report of a roundtable forum and draws together the evidence received at the roundtable, and in subsequent submissions, to reach conclusions about the practice of prescribing ED treatment in Australia today.
- 1.12 The committee is aware of complaints to consumer and regulatory bodies about the contractual and advertising practices of commercial ED clinics. The report will not focus on these practices. Nevertheless, issues around contracts are a significant problem, one which AMI itself acknowledges. At the roundtable, AMI stated that 75 percent of the complaints it received were contractual complaints.¹⁶ The committee received a submission from Legal Aid Queensland detailing significant contractual issues that they had sought to resolve on behalf of their clients. The committee is concerned that by expecting patients to sign a treatment contract they are prevented from getting their money back should the treatment not work. Of particular concern are examples of financial hardship endured by consumers who were unable to cancel their contract with AMI, or who were told that they faced significant health risks, including death, if they failed to undertake treatment for ED.¹⁷ The committee urges AMI to reconsider its contracting procedures, to make it easier for patients to cease treatment should they so wish.
- 1.13 Chapter 2 contains the committee's discussion and is structured around 4 themes which are:
 - the extent of men's interaction with the health system;

15 See for example: Exhibit No. 15; Exhibit No. 39; Exhibit No. 44; Exhibit No. 45; Exhibit No. 46; Malouf, D., Urological Society of Australia and New Zealand (USANZ), Transcript, p 9.

16 Doyle, R., AMI, Transcript, p 51.

17 See Legal Aid Queensland, Submission No. 10.

- the appropriateness of using telemedicine as a first option for prescribing;
 - the adequacy of the regulations governing the sale of ED medications; and
 - the integration of commercial ED clinics with the proposed e-record system.
- 1.14 The committee has not made recommendations in the report. However, the committee has made its comments and opinions clear throughout the report, and will be presenting the issues raised in this report to Parliament and the Minister for Health for consideration.
- 1.15 The report makes significant reference to AMI which, as mentioned, is the largest and most prominent commercial ED clinic. In fact, AMI was the only commercial ED clinic to attend the roundtable forum and make a submission. The committee accordingly thanks AMI for participating in the proceedings and responding to its critics.

Conduct of roundtable

- 1.16 The roundtable was conducted around two discussion topics; diagnosis and medication, and regulation of the provision and sale of impotence medication. The discussions sought to consider the size and extent of the market for ED treatment, the different types of ED treatment, the health issues that are related to ED and the regulation of the treatment of ED in its various forms.
- 1.17 The committee selected a number of organisations which would be able to give a broad range of views and represent diverse interest groups including those representing pharmacists, medical practitioners, commercial ED clinic providers and consumers. The participants in the roundtable discussion, which was held in Canberra on Friday, 21 August 2009, were as follows:
- Advanced Medical Institute;
 - Andrology Australia;
 - The Freemasons Foundation Centre for Men's Health;
 - Impotence Australia;
 - Medicines Australia;
 - Pharmaceutical Society of Australia;

- The Royal Australasian College of Physicians, Chapter of Sexual Health Medicine;
- The Royal Australian College of General Practitioners;
- SHine SA;
- Therapeutic Goods Administration;
- Dr Patricia Weerakoon, Coordinator of the Graduate Program in Sexual Health, University of Sydney; and
- The Urological Society of Australia.

1.18 In addition to the roundtable, the committee accepted as evidence 15 submissions from interested persons or organisations, and a further 57 exhibits. These are listed in appendices B and C.

1.19 The committee would like to extend its thanks to all of the individuals and organisations that travelled to Canberra to participate in the roundtable discussion, or made submissions to the inquiry.

1.20 The committee took in-camera evidence from a person who had been a customer of various commercial ED providers. The person gave a personal and client perspective to the evidence taken at the roundtable. The committee thanks the person for having the courage to talk with the committee.