2

Issues and conclusions

2.1 Some of the current practices employed to sell or prescribe impotence medications in Australia have raised concerns amongst healthcare professionals, consumer advocates and the general public. Much of the criticism is directed at the practices of commercial erectile dysfunction (ED) clinics, although many of the concerns also apply to the selling of impotence medication online.

2.2 This chapter examines four of the major issues related to the health impacts of the sale of impotence medications in Australia that were discussed at the committee's roundtable. They are:

- the extent of men's interaction with the health system;
- 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.

Men's interaction with the health system

2.3 The Federal Government is currently seeking to reorient the health system towards a greater focus on the prevention of serious chronic disease. This focus is evidenced by the commissioning and subsequent report of the National Preventative Health Taskforce strategy *Australia the healthiest*

country by 2020.[1] The strategy proposes ways to prevent diseases associated with alcohol, tobacco and obesity. This committee also has an interest in preventative health, having previously convened an inquiry into obesity in Australia and investigated the benefits of prevention as a means to cut costs to the health system and to improve the lives and health of Australians in general.

2.4 There is now emerging evidence that ED is a marker of chronic health problems, including cardiovascular disease and diabetes.[2] There will, therefore, be long-term benefits for men's health and the health system generally if ED diagnosis can be treated in a preventative health context.

Do men visit their General Practitioner?

2.5 Anecdotal evidence suggests that men are not proactive about maintaining their good health and therefore do not regularly visit a general practitioner (GP) to discuss their health, including their sexual health.[3] However, evidence given at the roundtable suggests that this anecdotal advice is somewhat misleading, and that men - particularly those over 40 years of age – are more likely to visit a GP than is imagined.

2.6 The committee heard from Professor Handlesman, who represented Andrology Australia at the roundtable, that the Men in Australia Telephone Survey (MATeS) found that the men surveyed did indeed visit a GP.[4] That survey asked men questions focusing mainly on their reproductive health but also on a broad range of questions about lifestyle, sexual behaviour and general health. The MATeS study suggests that almost 90 percent of men aged 40 and over visit a GP at least once a year. The study was conducted in 2003 and was the:

> … first whole-of-nation, population-based study focusing on the reproductive health and other problems of middle-aged and older Australian men.[5]

2.7 The MATeS study found that:

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1 The National Preventative Health Taskforce viewed on 19 October 2009 at <http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/national-preventative-health-strategy-1lp>.

2 Marshall, V., Freemason's Foundation Centre for Men's Health, Transcript, p 13.

3 Vartto, K., SHine SA, Transcript, p 16.

4 Handlesman, D., Andrology Australia, Transcript, p 21.

5 de Krester, D., et al, *The Men in Australia Telephone Survey (MATeS) – lessons for all* viewed on 19 October 2009 at <http://www.mja.com.au/public/issues/185_08_161006/dek10080_fm.html>.

> … men expressed high levels of concern about developing reproductive health problems as they age: 80 percent were concerned about developing erectile dysfunction, and 57 percent about developing prostate cancer.[6]

2.8 However, the MATeS study also identified that men are selective about the topics which they choose to raise with their doctor. Mr Doyle, a representative of the Advanced Medical Institute (AMI), informed the committee that evidence from the MATeS study indicated that only one third of patients raise their ED with a GP. He added that:

> There are a number of reasons why people do not want to speak to their GP about this issue. Firstly … that many doctors were uncomfortable taking a sexual history. Secondly … that men are very embarrassed about their condition … men do not believe that their family GPs understand what the impact is of ED on their lives.[7]

2.9 Other witnesses argued that embarrassment alone does not deter men from seeking appropriate medical assistance. The committee heard that men do present to clinics that treat sexually transmitted infections (STIs), which are also embarrassing conditions. Mr McCann from Impotence Australia explained that men present to STI clinics because men accept that STIs are a medical problem and because the clinics are specialised and only treat STIs.[8]

2.10 GPs are the health system's "gatekeepers" - intended to assess the totality of their patients' health, to refer them to specialists if necessary and to encourage patients to adopt preventative health strategies. The committee accepts that patients do visit GPs. However, the fact remains that there is a demonstrable consumer demand for commercial ED clinics and the services they provide. Men approaching these clinics instead of a GP may therefore be missing out on the holistic health care advice they require. The challenge is to identify and reduce the barriers that make men reluctant to discuss sensitive health problems face to face with a GP.

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6 de Krester, D., et al, *The Men in Australia Telephone Survey (MATeS) – lessons for all* viewed on 19 October 2009 at <http://www.mja.com.au/public/issues/185_08_161006/dek10080_fm.html>.

7 Doyle, R., Advanced Medical Institute (AMI), Transcript, p 26.

8 McCann, B., Impotence Australia, Transcript, p 31.

What are men's experiences of the health system?

2.11 Treating ED when men do present to a GP is made more difficult by the fact that there is a general lack of health literacy in the Australian population. Health literacy is a basic level of knowledge which enables a person to "obtain, process and understand" health information to enable them to make good quality health decisions.[9] Dr Pinskier from the Royal Australian College of General Practitioners (RACGP) informed the committee that Australian Bureau of Statistics (ABS) data suggests that 60 percent of Australian men have insufficient health literacy to properly understand a medical consultation when they do go for one.[10]

2.12 The committee also heard from Professor Marshall from the Freemasons Foundation Centre for Men's Health that evidence from a study they are conducting is showing that when men do visit a GP they are dissatisfied and do not feel like they have had an adequate opportunity to properly discuss their health concerns. He conceded that there is also a limited understanding in the medical profession about the best ways to achieve a satisfactory interaction between patients and the health profession more broadly.[11]

2.13 Finally, the MATeS study stressed the need to understand the "social, cultural and environmental influences" that drive men's health seeking behaviour and reluctance to raise some issues with their GP.[12]

What improvements are needed?

2.14 Discussions among health professionals arising out of the MATeS study have canvassed ways to reduce the barriers that make it difficult for GPs and patients alike to discuss ED:

> In a clinical setting, these barriers need to be overcome by allowing men, particularly older men, opportunities to disclose reproductive health concerns that may otherwise remain unspoken. Health promotion strategies that address men's health concerns may assist in overcoming barriers to help-seeking behaviour. Examples include targeted health education sessions

9 National Network of Libraries of Medicine viewed on 19 October 2009 at <http://nnlm.gov/outreach/consumer/hlthlit.html>.

10 Pinskier, N., The Royal Australian College of General Practitioners (RACGP), Transcript, p 46.

11 Marshall, V., The Freemasons Foundation Centre for Men's Health, Transcript, p 29.

12 de Krester, D., et al, *The Men in Australia Telephone Survey (MATeS) – lessons for all* viewed on 19 October 2009 at <http://www.mja.com.au/public/issues/185_08_161006/dek10080_fm.html>.

> and promotional displays as part of other social events, such as community men's health nights, and workplace or local community events.[13]

2.15 The committee was also interested to learn the opinions of roundtable participants about ways to better equip GPs to discuss ED, in particular with men.

2.16 Dr Patricia Weerakoon coordinates the Graduate Program in Sexual Health at the University of Sydney which is designed to train health professionals and develop their expertise in the specialised area of sexual health.[14] She stated that, historically, training in sexual health has not been a priority, even in the best medical training programs, and that:

> … the fact that [ED] is an early marker for lifestyle and for many diseases is fairly new research and it has been picked up fairly recently.[15]

2.17 Dr Pinskier from the RACGP explained that doctors could be trained to better deal with men's health conditions, including ED, through already established training processes:

> There is a well-established process for postgraduate GP education. If there is an issue around the education and capacity of general practitioners to deal with that then we need to sort that out. We have well-developed educational training processes and a well-distributed network through the divisions of general practice, which is funded by and large by the Commonwealth.[16]

2.18 Several other ways of improving ED treatment were also canvassed at the roundtable, including better training of all health professionals (not just GPs), educating men about the underlying causes of ED and improving the amenity of GP surgeries so that they are more welcoming to male patients.[17]

2.19 AMI informed the committee that half of its business was done through its clinics, and these have been specially designed to cater for the unique needs of its patients. For example, Mr Doyle stated that AMI clinics have

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13 de Krester, D., et al, *The Men in Australia Telephone Survey (MATeS) – lessons for all* viewed on 19 October 2009 at <http://www.mja.com.au/public/issues/185_08_161006/dek10080_fm.html>.

14 Graduate Program in Sexual Health viewed on 19 October 2009 at <http://www.fhs.usyd.edu.au/sexual_health/about/index.shtml>.

15 Weerakoon, P., University of Sydney, Transcript, p 16.

16 Pinskier, N., RACGP, Transcript, p 37.

17 Marshall, V., The Freemasons Foundation Centre for Men's Health, Transcript, p 29.

individual waiting rooms so that men are not forced to sit in a public area while waiting for their consultation:

> That is a very important issue to these men. They do not want to run into friends, acquaintances or anyone else.[18]

2.20 The Federal Government has recognised that the maintenance of men's health requires a specific approach and is developing a National Men's Health Policy that:

> … will focus on reducing the barriers men experience in accessing health services, tackling widespread reticence amongst men to seek treatment, improving male-friendly health services, and raising awareness of preventable health problems that affect men.[19]

Committee comment

2.21 There is emerging evidence about the link between ED and serious underlying conditions such as cardiovascular disease and diabetes. These conditions represent a significant cost to the health care budget and are targeted as part of the Federal Government's focus of preventative health.

2.22 Accordingly, the committee believes that the health system collectively needs to better identify ED as an early warning for more serious conditions. That however, requires health professionals to create the conditions that make men more comfortable seeking help for ED and then for any underlying conditions.

2.23 The committee thinks that there is value in implementing a targeted public health campaign to better inform men about underlying conditions for which ED may be an early marker. This campaign should educate men about the need for those who experience ED to seek advice from a medical practitioner in order to ensure that any serious health issues are identified early.

2.24 Commercial ED clinics exist because there is a demand for the services they provide. These clinics are effective because they make it as easy as possible for men to seek treatment for ED. The downside, discussed in greater detail below, is that the clinics treat ED in isolation and are not as effective in identifying other, underlying conditions that should be targeted in a preventative health strategy.

18 Doyle, R., AMI, Transcript, p 30.

19 National Men's Health Policy, viewed on 19 October 2009 at <http://www.health.gov.au/menshealthpolicy>.

2.25 General practitioners are ideally placed to identify any underlying health issues that may be manifesting at an early stage. However, by definition, general practitioners, do not have the luxury of being able to specialise, as ED clinics do, in talking to men about their sexual health. As part of an effective preventative health strategy though, the capacity of health care professionals to treat and manage ED should be strengthened and the barriers that men face when discussing sensitive health conditions should be addressed and reduced as much as possible. The will enable men to feel comfortable seeking treatment for ED through their GP.

Is telemedicine appropriate?

2.26 One of the significant criticisms levelled at commercial ED clinics such as AMI is their use of telemedicine as a vehicle to prescribe pharmaceuticals to patients. Telemedicine is the use of technology, such as telephone and video conferencing, to connect doctors with patients.[20]

2.27 The committee recognises that there is a legitimate role for telemedicine to play in providing health services in Australia, particularly rural and remote Australia. Nevertheless, the committee is worried about the use of telemedicine as a routine prescribing service. Dr Pinskier from the RACGP stated that the practice of telemedicine is to provide advice and not prescribe medication:

> There is some telemedicine that occurs around the country that is well accepted, particularly around nurse call centres … What they are not doing at the end of the day is selling medication. They are prescribing advice. They are advice lines only.[21]

2.28 A risk of telemedicine is that it makes it difficult for doctors to detect and manage lifestyle factors associated with ED through a telephone consultation.[22] Roundtable participants stressed the importance of face-to-face consultations and stated that these should serve as the minimum standard for ED treatment.[23] Dr Weerakoon from the University of Sydney argued that:

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20 NSW Health viewed on 19 October 2009 at <http://www.chw.edu.au/parents/telehealth/nsw_health_consumer_telehealth_brochure.pdf>.

21 Pinskier, N., RACGP, Transcript, p 46.

22 Malouf, D., USANZ, Transcript, p 19; Fitzsimons, M., Medicines Australia, Transcript, p 23.

23 See Handlesman, D., Andrology Australia, Transcript, p 34.

> If GP's with all their medical training and other health professionals, nurses, rehab counsellors, none of them are indicating that they feel comfortable or have the knowledge to talk about it, I seriously doubt that somebody at the end of a telephone line can really have the training to be able to detect and manage lifestyle factors and early markers for diseases.[24]

2.29 AMI responded that there were a number of reasons why telemedicine suited its patients, including the anonymity of the service and the fact that men do not need to present to a pharmacy to collect their medication.[25] AMI further added that while 50 percent of its current patient load was treated using telemedicine,[26] some of the telemedicine involves a video consultation.[27] In fact, AMI submitted that using technology based consultations may actually improve the number of men seeking treatment for their condition.[28]

2.30 In response to criticism at the roundtable that medicine was prescribed over the telephone by individuals who are not doctors, AMI was emphatic that:

> No-one can obtain a treatment without speaking to a properly qualified doctor.[29]

2.31 The committee also acknowledges that AMI encourages all patients to visit a GP for a general health check to deal with any health issues other than ED which may be present.[30] Nevertheless, this does not mean that the patients do so.

2.32 The committee sought advice about the regulations surrounding the use of telemedicine in Australia. Professor Marshall from the Freemasons Foundation Centre for Men's Health indicated that establishing guidelines for telemedicine is very complex and difficult to achieve, particularly when the provision of care crosses jurisdictional boundaries.[31]

2.33 Mr Doyle from AMI stated that:

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24 Weerakoon, P., University of Sydney, Transcript, p 15.

25 Doyle, R., AMI, Transcript, p 26. The AMI submission further details the benefits of technology based consultations. See Submission No. 13, p 4.

26 Doyle, R., AMI, Transcript, p 34.

27 Doyle, R., AMI, Transcript, p 34.

28 AMI, Submission No. 13, p 5.

29 Doyle, R., AMI, Transcript, p 27.

30 Doyle, R., AMI, Transcript, p 28.

31 Marshall, V., The Freemasons Foundation Centre for Men's Health, Transcript, p 42.

> For telephone consultations there is a national standard that applies to all telemedicine, which all medical practitioners are required to comply with.[32]

2.34 Others felt that the National Policy for Technology Based Consultations to which Mr Doyle referred does not specifically mention prescribing.[33] The National Policy for Technology Based Consultations, which has been adopted by the medial boards in all the states and territories, outlines principles to which medical practitioners who utilise technology consultations should adhere. To comply with the principles a doctor should:

- Include an adequate assessment of the patient's condition, based on the history and clinical signs and appropriate examination.
- Keep colleagues well informed when sharing the care of patients.
- Make their identity known to the patient.
- Ensure they communicate with the patient to establish the patient's current medical condition and history, and concurrent or recent use of medications, including non-prescription medications; identify the likely cause of the patient's condition; ensure that there is sufficient clinical justification for the proposed treatment; ensure that the proposed treatment is not contra-indicated. This particularly applies to technology-based consultations where the practitioner has no prior knowledge and understanding of the patient's condition(s) and medical history or access to their medical records.
- Be ultimately responsible for the evaluation of information used in treatment, irrespective of its source. This applies to information gathered by a third party who may have taken a history from, or examined, the patient.
- Be confident that a direct physical examination would not add important information to inform their treatment decisions or advice to the patient. This particularly applies to consultations where the practitioner has no prior knowledge or understanding of the patient's condition(s) and medical history or to access to their medical records.
- Make appropriate arrangements to follow the progress of the patient by monitoring the effectiveness and appropriateness of the recommended

32 Doyle, R., AMI, Transcript, p 49.

33 McMahon, C., The Royal Australasian College of Physicians, Transcript, p 45.

treatment and by informing the patient's general practitioner or other relevant practitioners.[34]

2.35 AMI rejects the need for face-to-face consultations to diagnose and treat either premature ejaculation or ED. Their submission refers to the American Urological Association guidelines on the treatment of premature ejaculation which states that it is a diagnosis based on sexual history alone. Further, in relation to ED, AMI claims that there is a divergence of opinion as to whether or not a physical examination is necessary to diagnose ED. They submit that the Boots pharmacy in the UK dispenses Viagra without a prescription and therefore no consultations with a medical practitioner.[35]

2.36 Another issue with the use of telemedicine to treat ED is that patients may not be aware of who their doctor actually is. The committee thinks that AMI should do more to ensure that patients have continuity of care. This means that AMI should endeavour to ensure that a patient knows the name of the treating doctor, and that, where possible, any follow-up is undertaken by the same treating doctor. The committee recognises that this may be difficult to achieve, but there would be significant benefits in ensuring, as much as possible, that a patient speaks to the same doctor each time they call. It is easy to understand how people can be confused about whether or not they are speaking with a doctor when they deal with more than one AMI employee in the course of a single telephone consultation.[36]

2.37 A number of witnesses at the roundtable criticised AMI for not prescribing globally recognised first-line treatments for ED,[37] or presenting patients with the option of undertaking psychological counselling.[38] The committee argues that it is incumbent on AMI doctors to present patients with the full range of treatment options for ED, given that AMI is often the first point of call for men who are experiencing ED. It is not sufficient for AMI to simply assess whether or not a patient is a suitable candidate for AMI treatment options. There is a risk that if the AMI treatment fails to correct a patient's ED then the mental health of that patient will be adversely affected because they are not aware of the many other treatment options open to them and therefore think that they will have ED for the rest of their lives.

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34 New South Wales Medical Board, Exhibit No. 5.

35 AMI, Submission No. 13, p 5.

36 Doyle, R., AMI, Transcript, p 27.

37 Malouf, D., USANZ, Transcript, p 18.

38 Spierings, D., Impotence Australia, Transcript, p 14.

Committee comment

2.38 The committee questions whether commercial ED clinics which prescribe medication over the telephone can be complying with all the principles of the National Policy for Technology Based Consultations. In particular, given emerging evidence about the links between ED and chronic disease, commercial ED clinics cannot "be confident that a direct physical exam would not add important information to inform their treatment decisions of advice to the patient" as is required under the guidelines. Without such a direct physical exam, detection of chronic conditions such as heart disease and diabetes will be next to impossible.

2.39 Notwithstanding AMI's concerns that limiting the use of telemedicine based treatment would limit the options of men seeking treatment for ED,[39] the committee believes that it is inappropriate to use telemedicine to prescribe any new treatment to patients unless absolutely necessary. There are a number of benefits of telemedicine in Australia, including its use as a tool to provide advice to patients and perhaps to provide repeat prescriptions. However, the practice of prescribing medication to a previously unknown patient based on a relatively short telemedicine consultation as a first and routine option should, in the committee's opinion, cease.

2.40 Accordingly, the committee believes that the Minister for Health and Ageing should, as a first step, ask state and territory medical boards to review the adequacy of the National Policy for Technology Based Consultations with a view to curtailing the use of telemedicine as a first and routine method of prescribing.

The adequacy of the regulations

2.41 The sale of therapeutic goods in Australia is regulated, at the Commonwealth level, by the *Therapeutic Goods Act 1989* (TG Act) which provides a national framework for the regulation of therapeutic goods in Australia.[40] The TG Act makes it an offence to import, export, manufacture or supply a therapeutic good, which includes medicines and therapeutic

39 AMI, Submission No. 13, p 8.

40 Therapeutic Goods Administration (TGA) viewed on 19 October 2009 at <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm>.

devices, unless it is included in the Australian Register of Therapeutic Goods.[41] A therapeutic good is defined as:

> … a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use.[42]

2.42 Certain therapeutic goods can be exempted from the requirements of the TG Act and can thus be manufactured and dispensed outside the requirements of the act. In this instance the relevant exemptions allow medical practitioners to prescribe "compounded" medicines for their own patients and for pharmacists to produce the compounded medicines.[43]

2.43 Compounded medicines are one off products made for an individual patient from raw ingredients which may or may not have been assessed by the Therapeutic Goods Administration (TGA) for safety and efficacy.[44] Doctors can prescribe compounded medications for patients when there is no suitable existing medicine. However, the vast majority of patients are treated with various doses of existing registered medicines.[45]

2.44 The committee questioned the Pharmaceutical Society of Australia (PSA) about the need for and practice of compounding within pharmacies. The PSA indicated that the original purpose of compounding was to allow doctor to prescribe and pharmacists to provide treatment to a patient when no suitable alternative existed. According to the PSA, compounding:

> … it is very much focused on the needs of an individual patient where there is not a commercially available product that is suitable for their needs. So it would be the exception rather than the rule. And it would not be first-line therapy; it would be second-line. If there is nothing available in the commercial sphere for the needs of that particular patient, the doctor may consider prescribing a compounded product, which the pharmacist would make up according to those instructions.[46]

2.45 AMI prescribes compounded medications for its patients which are individually tailored to the unique needs of each patient.[47] While AMI strongly defends the efficacy of the individual ingredients of their

41 Maskell-Knight, C., TGA, Transcript, p 3.

42 TGA viewed on 19 October 2009 at <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm>.

43 Maskell-Knight, C., TGA, Transcript, p 4 and 8. See also Pinskier, N., RACGP, Transcript, p 8.

44 Maskell-Knight, C., TGA, Transcript, p 8.

45 Mackey, P., Pharmaceutical Society of Australia (PSA), Transcript, p 25.

46 Mackey, P., PSA, Transcript, p 27.

47 Doyle, R., AMI, Transcript, p 27. See also a number of supporting documents provided by AMI and accepted as Exhibits to the inquiry which are listed at Appendix C.

treatments,[48] a number of witnesses at the roundtable questioned whether or not AMI products were, in fact, effective at treating ED.[49]

2.46 The committee is not in a position to make a judgement of the efficacy of AMI's compounded prescriptions - in fact no one is. The exemption from the TG Act for compounded products also exempts AMI from having to run clinical trials on the products in their compounded form.[50] Each treatment is individually formulated, and therefore there is no clinical evidence to support whether the unique combination is or is not effective.

2.47 The committee is concerned that consumers are not aware of the fact that the products, in their compounded form, have not been subject to clinical trials. The committee thinks that this is important information that consumers should be aware of, and urges the Federal Government to ensure that compounded medications are clearly identified as such so that consumers can make an informed choice about their treatment.

2.48 Irrespective of claims about the efficacy of the drugs, the fact remains that AMI is prescribing a significant number of patients with individual compounded treatments. Australian Custom Pharmaceuticals (ACP), which is the largest compounding pharmacy in Australia and the supplier of AMI medications, submitted that it has created over 15 million individually compounded treatments for AMI patients alone, and another 2,500 for other medical practitioners.[51] This is despite the fact that there are clinically proven and registered drugs that are recognised as first-line drug therapies for ED.[52]

2.49 The committee believes that the number of individual treatments being prescribed by AMI and manufactured by ACP verges on mass production and is not in keeping with the justification for exempting compounding from the standards required by the TG Act.

Compounding subject to review by Therapeutic Goods Administration

2.50 The significant growth in the practice of compounding resulted in the TGA commissioning a review of the industry which was undertaken in 2005. This review has led to the production of a discussion paper by the

48 Doyle, R., AMI, Transcript, p 54.

49 See for example: Malouf, D., USANZ, Transcript, p 18 and Lording, D., Andrology Australia, Transcript, p 20.

50 Maskell-Knight, C., TGA, Transcript, p 7.

51 Australian Custom Pharmaceuticals, Submission No. 14, p 1.

52 Malouf, D., USANZ, Transcript, p 40.

National Co-ordinating Committee on Therapeutic Goods (NCCTG) which proposed the following amendments:

> … traditional low-risk extemporaneous dispensing for individual patients would continue to be self-regulated against professional standards; moderate levels of compounding would be regulated by credentialling of pharmacists and accreditation of pharmacies by a professional pharmacy body against new professional standards; and higher volume compounding and the compounding of high-risk medicines would be brought under the scope of the TGA, and people carrying out those activities would be required to hold a manufacturing licence.[53]

2.51 The committee questioned AMI about its response to the recommendations of the NCCTG. AMI responded that it accepted the issue around high risk medication but rejected concerns about high volume compounding:

> The real question here is whether the medications [you're] using are high-risk medications or low-risk medications. High-risk medications should be subject to a higher degree of regulation than low-risk medications. Volume I think should actually be irrelevant. You are more likely to have an error with someone who does not know what they are doing than with someone who does.[54]

2.52 In its supplementary submission to the inquiry, AMI states that it does not support proposals to limit the number of prescriptions which a compounding pharmacy may dispense. AMI adds that changes to the regime allowing the provision of compounding and off-label treatments to patients will impede the ability of practitioners to treat them.[55]

2.53 However, at the hearing AMI indicated that it will comply with relevant laws and regulations and it would change its business practices to comply with any possible changes to regulations.[56]

2.54 The NCCTG discussion was open for consultation until 23 May 2008, and the NCCTG is still considering the proposal.[57]

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53 Maskell-Knight, C., TGA, Transcript, p 5.

54 Doyle, R., AMI, Transcript, p 28.

55 AMI, Supplementary Submission No. 13.1, p 5.

56 Doyle, R., AMI, Transcript, p 53.

57 Further information about the review can be accessed from the TGA website at <http://www.tga.gov.au/meds/extempcomp2.htm>.

Committee comment

2.55 The committee supports the need for an exemption for compounding from the TG Act for truly unique preparations when no other suitable products are on the market. However, it appears to the committee that the volume of compounded drugs prescribed by AMI goes beyond the justification for exemption. The committee believes that the NCCTG proposed recommendations are a sensible approach to strengthening the regulations around compounding, and therefore supports their development and speedy implementation.

Integration with the proposed e-health record

2.56 A key health reform is to reduce the fragmentation of services to patients. GPs are the primary "gatekeepers" to the health system and play a role in coordinating patient treatment. However, while a patient can receive prescriptions from more than one doctor, specialist or outpatient clinic the risk remains that no one health professional may be even aware of all the patient's treatments or total drug intake. The result may be prescriptions of contra indicated drugs as patients are placed on multiple medications by different health professionals.

2.57 In response, the National Health and Hospital Reform Commission is considering an electronic record system into which medical professionals enter patient records. This would allow different health professionals to access an individual's complete health record. As Dr Pinskier explained:

> The National Health and Hospitals Reform Commission is now focusing on the concept of a patient centred record, which will contain information from all providers. We are not sure how this particular process will be incorporated into that process.[58]

2.58 The committee is concerned that patients treated by commercial ED clinics and the doctors working in them are particularly isolated from the wider health system. The exchange of patient information to and from a patient centred record would help reduce the risks that patients are prescribed or treated inappropriately.

2.59 At the roundtable, Dr Malouf from the Urological society outlined the difficulty one of his peers had experienced in trying to access patient

58 Pinskier, N., RACGP, Transcript, p 23.

treatment information from AMI in order to provide care to a shared patient. Upon questioning, Mr Doyle from AMI responded that:

> If someone wants to contact the CEO of the organisation rather than trying to call a call centre operator who is obviously not qualified to deal with third parties, who might be competitors and so on, it is just a matter of someone making appropriate contact and, unfortunately, people do not do that.[59]

2.60 The committee is aware that it is a relatively simple procedure to obtain patient records from other medical practitioners in the mainstream system. The committee does not think that it is sufficient to state that medical professionals should contact the CEO when requesting patient records. These records should be more easily available to practitioners who have requested them on behalf of a patient, with informed consent. This existing difficulty of professional communication further isolates AMI from the wider health system.

2.61 Given the current difficulties that doctors face in obtaining information from AMI, the committee questioned AMI about the proposed e-record system and whether or not they would freely participate. AMI indicated that it would be relatively easy to integrate their records with any proposed e-record system:

> We would have absolutely no issue with that. AMI actually has a fully computerised database, which is web based. For every single person who interacts with our clinics every interaction is recorded on our patient database. For us to interact already computerised records into another computerised system is not difficult at all.[60]

Committee comment

2.62 The committee encourages the Federal Government to ensure that it consults with commercial ED clinics when developing and implementing the proposed e-record system, given AMI's stated willingness to participate in the proposed reform agenda. It will be important to ensure that they and their doctors, like other medical practitioners, are included in the program.

59 Doyle, R., AMI, Transcript, p 27.

60 Doyle, R., AMI, Transcript, p 27.

Conclusion

2.63 The roundtable has raised issues about the way that men suffering ED are diagnosed and treated in the health system. The evidence highlighted the need to better equip GPs to manage and treat ED. Moreover, the committee was alerted to the need for the regulations covering the prescription and supply of compounded medications to be tightened and for the use of telemedicine as a routine method of prescribing to be restricted.

2.64 As the committee has learned, ED is often an indicator of underlying health problems. We need to make it easier for men suffering ED to turn to GPs rather than to commercial ED clinics. GPs are far better placed to identify underlying conditions while treating ED than are commercial ED clinics as they currently practice. Bringing men suffering ED into the wider health system will hopefully lead to earlier detection of any more serious conditions they have and also reduce the longer term burden to the health system.

Steve Georganas MP
Chair