Advanced Medical Institute (NZ) Ltd

A Report by the

Health and Disability Commissioner

(Case 12HDC01266)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Factual background

1. The Advanced Medical Institute (NZ) Limited (the Advanced Medical Institute) is a specialist clinic offering treatment for erectile dysfunction and premature ejaculation. The Advanced Medical Institute supplies its patients with its own medications on an "off-label" basis.

2. Mr A consulted an Advanced Medical Institute doctor in November 2010 for assistance with premature ejaculation, after hearing the Advanced Medical Institute advertise its services on the radio. He recalls that the doctor asked him about his general health and the medication he was taking, but she did not examine him. The doctor recommended and prescribed Mr A with a nasal spray, which was an Advanced Medical Institute medication. Mr A was told to squirt the nasal spray up his nose. He was not provided with information about other treatment options, and was not advised that the medication was being prescribed on an "off-label" basis. Mr A said he felt pressured to sign the contract for treatment with the Advanced Medical Institute.

3. Mr A contacted the Advanced Medical Institute about three days after he received the nasal spray to advise that it was burning his nostrils. The Advanced Medical Institute sent him some pills instead. Mr A contacted the Advanced Medical Institute again to advise that he had trouble sleeping when he took the pills, and the Advanced Medical Institute prescribed him lozenges.

4. At no stage did the Advanced Medical Institute inform Mr A's general practitioner that Mr A had been prescribed Advanced Medical Institute medication.

5. In 2011 Mr A injured his back and began taking pain medication. The Advanced Medical Institute advised Mr A that he should "maybe not take [the medication] together". Mr A tried to cancel his contract but was unable to do so. Accordingly, he put his contract with the Advanced Medical Institute on hold between April and October 2011. In May 2012, Mr A's general practitioner prescribed him with citalopram for depression. In September 2012, Mr A told his GP that he was taking Advanced Medical Institute medication. Mr A's general practitioner advised him of the risks of taking the Advanced Medical Institute medication with citalopram, and Mr A recalls that his general practitioner advised him to check with the Advanced Medical Institute about the appropriateness of taking the medications together. Mr A attempted to contact the Advanced Medical Institute, but did not get a response.

Decision summary

6. Mr A was not informed: that the treatment the Advanced Medical Institute recommended for him was not the accepted "first line" treatment for his condition; that the medication was being prescribed on an "off-label" basis; about the relative risks, benefits, and costs of alternative treatment options; or of how to best take his medication. Mr A was also not provided with information about the range of treatment options, including options not offered by the Advanced Medical Institute. This was information that Mr A could reasonably have expected to be provided with

prior to consenting to treatment. The Advanced Medical Institute's failure to provide that information to Mr A was a breach of Right 6(1)[1] of the Code. Because Mr A did not receive adequate information about the medication being recommended and prescribed for him, he was unable to give his informed consent to treatment. Accordingly, the Advanced Medical Institute also breached Right 7(1)[2] of the Code.

7. The Advanced Medical Institute failed to ensure the continuity of services to Mr A because it did not seek Mr A's permission to share with his general practitioner information about the Advanced Medical Institute medications Mr A had been prescribed, and did not explain to him the benefits of doing so. In this respect, the Advanced Medical Institute breached Right 4(5)[3] of the Code.

8. The Advanced Medical Institute's failure to respond to Mr A's queries about the appropriateness of taking his Advanced Medical Institute medication with medication prescribed by his general practitioner was inadequate and a breach of Right 4(1) of the Code. Mr A's follow-up care was also inadequate and a breach of Right 4(1) of the Code.

9. Mr A felt pressured to sign a contract with the Advanced Medical Institute in November 2010. When he attempted to withdraw his consent to services and cancel his contract with the Advanced Medical Institute when he injured his back in 2011, he was unable to do so. The Advanced Medical Institute coerced and exploited Mr A, and breached Right 2[4] of the Code.

10. The Advanced Medical Institute's failure to engage with HDC to facilitate the resolution of Mr A's complaint showed a disregard for Mr A's rights and its responsibilities as a provider of health services. The Advanced Medical Institute breached Right 10(3) of the Code.[5]

Complaint and investigation

11. The Commissioner received a complaint from Mr A about the services provided by the Advanced Medical Institute. The following issue was identified for investigation:

- *The appropriateness and adequacy of the care provided to Mr A by the Advanced Medical Institute (NZ) Ltd.*

[1] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."
[2] Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent …"
[3] Right 4(5) of the Code states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."
[4] Right 2 of the Code states: "Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation."
[5] Right 10(3) of the Code states: "Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints."

12. An investigation was commenced on 8 February 2013. The investigation was extended on 11 October 2013 to include the following issue:

- *Whether the Advanced Medical Institute (NZ) Ltd facilitated the fair, simple, speedy, and efficient resolution of Mr A's complaint.*

13. The parties directly involved in the investigation were:

Mr A	Consumer
Advanced Medical Institute (NZ) Ltd	Provider

14. Independent clinical advice was obtained from HDC's in-house clinical advisor, general practitioner Dr David Maplesden, and is set out in **Appendix A**.

Information gathered during investigation

15. This section of the report sets out general information about the service offered by the Advanced Medical Institute, and its policies and procedures, before setting out the factual background to Mr A's complaint about the services he received from the Advanced Medical Institute.

16. The Advanced Medical Institute did not provide a response to Mr A's complaint, this investigation, or the provisional report, despite being given numerous opportunities and extensions to do so. Accordingly, the general information regarding the Advanced Medical Institute's business practices and processes is derived from information the Advanced Medical Institute previously provided to HDC for the purposes of resolving other complaints about its services.[6]

The Advanced Medical Institute

The service

17. At the time of the events in question, the Advanced Medical Institute was a wholly owned subsidiary of Advanced Medical Institute Australia Holdings Pty Ltd, an Australian-based company.[7] The Advanced Medical Institute advertised its treatments for erectile dysfunction and premature ejaculation widely throughout New Zealand. The Advanced Medical Institute stated on its website:

[6] See Decisions 09HDC00905, 09HDC01077, 09HDC01082 and 09HDC01540 available at www.hdc.org.nz.

[7] The Advanced Medical Institute advised HDC that it is no longer operating in New Zealand, and the Advanced Medical Institute (NZ) Ltd is no longer owned by AMI Australia Holdings Pty Limited. The New Zealand Companies Register website, as at 16 December 2013, lists AMI Australia Holdings Pty Ltd as holding 100% of the shares and therefore the sole shareholder of Advanced Medical Institute (NZ) Limited. The Australian Securities and Investments Commission website, as at 16 December 2013, provides that the company formerly known as AMI Australia Holdings Pty Ltd is now known as A.C.N. 095 238 645 Pty Ltd.

> "Advanced Medical Institute focuses on delivering safer, faster acting and lower dosage treatments to people suffering from erectile dysfunction and premature ejaculation. AMI's strategy is to provide new methods of treatment and delivery systems that provide a practical non-invasive method of drug delivery to the body to treat premature ejaculation and erectile dysfunction, marketed directly to the public."[8]

18. Based on information previously provided to HDC, initial contact between a consumer and the Advanced Medical Institute would generally occur in a telephone conversation between the consumer and a call centre agent. They would discuss the consumer's problem, and the call centre agent would then either arrange a suitable time for the consumer to attend an appointment at an Advanced Medical Institute clinic, or have a doctor call the consumer back. Advanced Medical Institute clinics are staffed by doctors who are contracted by the Advanced Medical Institute to provide services,[9] and clinical co-ordinators.

19. The Advanced Medical Institute previously provided HDC with the following description of the role of the doctors and clinical co-ordinators in discussing medication, length of programme and costs with patients:

> "The role of doctors is to assess patients, determine what treatments (if any) are suitable for the patient, determine the length of treatment with the patient, prescribe any proposed treatment, advise patients regarding the use of treatments and their potential side effects, answer any questions raised by patients and conduct any necessary follow up relating to patients. The role of clinical coordinators is to agree financial arrangements with patients."

20. The Advanced Medical Institute previously provided HDC with a copy of its standard *Engagement as Consultant* agreement. The Agreement requires its "consultants" to:

> "(a) Perform the services competently and in accordance with best medical practices and comply with all legal requirements and medical customs applicable to the Services;
>
> (b) Comply with Advanced Medical Institute's lawful directions and published policies and procedures in performing the Services; …"

Advanced Medical Institute medications

21. The Advanced Medical Institute supplies its patients with its own medications.

22. Companies wishing to sell a medicine in New Zealand must make an application to Medsafe for approval. Medsafe then reviews the application, including information about the quality, safety and efficacy of the medicine concerned, and makes a recommendation to the Minister of Health as to whether the medicine should be approved.

[8] http://www.amiaustralia.com.au (as at 15 December 2010).
[9] The Advanced Medical Institute previously advised HDC that its doctors are independent contractors.

23. Medicines are approved for particular indications, dosages and routes of administration, as specified on the approved New Zealand data sheet. Approved medicines may legally be used in ways other than as specified on the data sheet — a practice that is termed "off-label" use.

24. The medications that the Advanced Medical Institute supplies are generic medications that have been approved for use in New Zealand. However, these medications have not been approved for the purpose of treating sexual dysfunction or for the method by which they are administered (for example, in a nasal spray or lozenge formulation). Accordingly, the use of those medications in this manner by the Advanced Medical Institute is an "off-label" use.

25. With regard to informing consumers that its medications are being provided on an "off-label" basis, the Advanced Medical Institute previously advised HDC:

> "All of [Advanced Medical Institute's] contractors and staff are advised that [Advanced Medical Institute's] medications are being provided on an off-label basis and the obligation to advise the patient of this is an obligation of the consulting doctor. The use is, however, not experimental and is well supported in literature (in the case of injectable medication) and by a combination of literature and extensive clinical experience (in the case of nasal spray medication)."

26. However, the Advanced Medical Institute previously provided HDC with a disk containing "all training literature as supplied to all the Doctors who commence working for the Advanced Medical Institute". On that disk were two articles on the use of "off-label" medications. The first article stated that "off-label" medications were commonly used in treating sexual disorders, but did not mention discussing "off-label" use with patients.[10] The second article does consider whether doctors should discuss "off-label" use with patients.[11] The article states:

> "This article argues that the doctor's decision to inform the patient of the 'off-label' status of the prescription is not relevant to the physician's standard of care for an informed consent case. … Therefore, doctors should not be branded with the additional duty of disclosing non-pertinent information, such as the [Food and Drug Administration's] medically irrelevant distinction, to their patients."[12]

27. One of the Advanced Medical Institute's medication booklets for patients states: "To overcome many drawbacks of existing drug delivery systems Advanced Medical Institute has developed new Transnasal and Troche (Lozenges) Medication Delivery Technologies utilising existing drugs that have been approved by regulatory authorities and have known safety and efficacy profiles."

[10] Fallon, B. (2008). "'Off-label' drug use in sexual medicine treatment", *International Journal of Impotence Research* (20), 127–134.
[11] Meadows, W.A. & Hollowell, B.D. (2008). "Off-label" drug use: an FDA regulatory term, not a negative implication of its medical use", *International Journal of Impotence Research* (20), 135–144.
[12] Words underlined in pdf copy of the article provided by the Advanced Medical Institute.

28. The Advanced Medical Institute advised that copies of the medical booklet for patients and the Nurse Reference Folder are provided to each of the Advanced Medical Institute's doctors. The Advanced Medical Institute provided no other evidence of how it instructs its contracting doctors to advise patients that its medications are prescribed on an "off-label" basis.

29. In relation to the manner in which its medications are prescribed, the Advanced Medical Institute previously advised HDC that:

> "… clients medications are provided on an individual prescription basis, may only be provided after a patient has been assessed by a doctor and no treatments are able to be issued by the prescribing pharmacy without a prescription signed by a licensed doctor".

30. The Advanced Medical Institute further explained that:

> "[a]ll medications which are prescribed to consumers are prescribed by registered doctors. Once a prescription is entered into the computer it is then printed, signed by the doctor and forwarded to the pharmacy in NZ for the medication to be made. Once the medication is made it is sent from the pharmacy either to the patient directly or to the clinic and the patient collects the medication from the clinic."

31. The Advanced Medical Institute previously advised HDC that it provides two information booklets to its patients with their medications. It said that each booklet contains the Advanced Medical Institute's "Satisfaction and Privacy Policy". The policy states:

> "There is a range of treatment options and delivery methods which can include:
>
> - Nasal Spray
> - Troches (Lozenges)
> - Intra Urethral Gel
> - Self Injection Therapy
>
> A doctor from [Advanced Medical Institute] will diagnose and prescribe the most appropriate form of treatment available to assist you.
>
> Advanced Medical Institute experience shows that between 60% and 70% of patients obtain immediate results and are well satisfied following their first course of treatment.
>
> If required [Advanced Medical Institute] doctors will work with you to achieve a successful outcome by adjusting your prescribed medication, varying your medication options or by trying an alternative delivery method."

Follow-up care offered by Advanced Medical Institute

32. The Advanced Medical Institute previously explained that it also provides follow-up services to patients as part of its treatment programme, from "nurses, Customer

Service and re-order staff". Patients should contact the Advanced Medical Institute every three months to re-order more medications, and "on this occasion the Customer Service and Re-Order staff take the opportunity to ask the patients whether the medication is working for them and make sure that the patients are not suffering any side effects from the medication".

Cost and terms of treatment programme

33. The Advanced Medical Institute previously advised HDC that "[a]ll patients are provided with detailed information regarding the cost of treatment prior to committing to those treatments with [Advanced Medical Institute]". The Advanced Medical Institute said that the cost of its programmes includes medication and medical services, and "the length of treatment programs and the associated cost of those programs is determined by agreement between the patient and [Advanced Medical Institute]".

34. The Advanced Medical Institute's "Satisfaction and Privacy Policy" states:

> "**Satisfaction**
> The following terms are agreed by both parties:
>
> 1. You agree to try at least one option from each of the treatment methods as prescribed by your [Advanced Medical Institute] doctor before a refund case can be considered.
>
> 2. If you are still unable to overcome your current problem using all [Advanced Medical Institute] treatment methods as prescribed by the [Advanced Medical Institute] doctor and an [Advanced Medical Institute] doctor decides that the treatment has not been successful and that further treatment options and methods under the program are inappropriate or unavailable to you, then [Advanced Medical Institute] will refund the cost of the treatment incurred by you, less a 15% administration fee and less the cost of the medication supplied to you.
>
> …
>
> 6. Where a refund is either in dispute or needs further clarification it will be passed onto a case manager in the Refund Department who will review the case and discuss the various options available. The Case Manager will pass on his recommendation to the Refund Manager for final determination."

35. The Advanced Medical Institute also previously advised HDC that:

> "[the Advanced Medical Institute] commits to clients that it will provide them with an effective treatment for a specified period or provide them with a refund. Where an initial treatment is ineffective a replacement treatment is provided at no extra cost and the period in which treatment is provided is for the period commencing on the date on which effective treatment is provided."

Mr A

Background

36. Mr A, aged 24 years, consulted his general practitioner on 20 May 2009 for anxiety related issues, and a history of possible premature ejaculation was discussed. An appropriate history was taken (including a history of recent urine infection) and treatment options were discussed, including physical methods of treating the issue and the possible use of selective serotonin reuptake inhibitors (SSRIs). The clinical records for that consultation indicate that Mr A would consider the use of SSRIs, but did not want the medication at that point.

37. A week later, Mr A had further urinary symptoms, and a repeat urine sample was positive for infection. He consulted his general practitioner on 2 June 2009, and a physical examination was undertaken, which was normal, and the infection was treated. There is no evidence that Mr A discussed the issue of premature ejaculation with his general practitioner again until September 2012 (see below), although Mr A had frequent consultations with his general practitioner for back pain and anxiety.

Initial consultation with the Advanced Medical Institute

38. Mr A advised HDC that he heard the Advanced Medical Institute advertising its services on the radio. He called the 0800 number, and was given an appointment at an Advanced Medical Institute clinic for assistance with premature ejaculation.

39. Mr A advised HDC that he attended an Advanced Medical Institute clinic in November 2010, and was assessed by a female doctor. He did not recall the name of the doctor he consulted, but he recalls that she said she worked for the Advanced Medical Institute, that she was a doctor, and that she was the Auckland contractor for the Advanced Medical Institute.

40. Mr A recalls that he met the doctor in her office. Mr A said that the doctor did not examine him. He recalls that she asked him about his general health and the medications he was taking (he was not taking any medications at that time).

41. Mr A said that they discussed the benefits of medication and how medication could help him. Mr A recalls that the doctor spoke to him about a nasal spray medication. She told him that there was other medication he could try if the nasal spray did not work, but she did not discuss the other medication. Mr A said that the doctor prescribed him the nasal spray. Mr A did not recall being shown how to use the nasal spray, other than that "maybe he was told to squirt it in the nose".

42. Mr A advised that the doctor did not talk about other treatment options, including treatment options not offered by the Advanced Medical Institute. In addition, the doctor did not advise him that the medication would be prescribed on an "off-label" basis.

43. Mr A recalls that he discussed the payment plan with the doctor, and he was told that there was a service he could call if he had any problems, needed advice, or needed to change medications. Mr A said that he was reluctant to sign the contract, but the doctor assured him that it was "all good" and told him that he needed to decide at that

time, otherwise he would not be able to see her for another month or so. Mr A said he felt pressured to sign the contract. The contract required Mr A to pay $3000 for a year's supply of medication. Mr A recalls that he paid about $300 upfront, and he did not receive a copy of his contract.

44. Mr A does not recall receiving any written documentation from the Advanced Medical Institute following his consultation in November 2010, including written information about the medications he was being prescribed, or the "Satisfaction and Privacy Policy".

Subsequent events

45. Mr A said that the nasal spray was sent to him, and came with instructions on how to use it. He said that the nasal spray was burning his nostrils, so about three days after he received the spray he contacted the Advanced Medical Institute. Mr A recalls that the person he spoke to at the Advanced Medical Institute informed him that the Advanced Medical Institute would send him different medication. Mr A cannot recall to whom he spoke at the Advanced Medical Institute.

46. Mr A recalls that about a week later, he received some pills in the mail. Mr A advised HDC that when he took the pills he had trouble sleeping. At some stage, Mr A rang the Advanced Medical Institute and told the person who answered the call about the problems he was having with the pills. Mr A was prescribed lozenges, and he recalls that before he was given the prescription he was asked whether he was taking any other medication. Mr A said he was not advised how to take the lozenges, but he did receive a DVD with the lozenges when they arrived in the mail.

47. Mr A said that on the pack of lozenges it said he should take a lozenge 30 minutes prior to sexual activity. Mr A said that he called the Advanced Medical Institute and advised that the lozenges were not working well. Mr A recalls that he was then told by the person who answered the phone that he should take two to three lozenges, two hours before sexual activity.

48. In 2011, Mr A injured his back and was taking pain medication including Panadol, tramadol, Nurofen and anti-inflammatory medication, prescribed by his general practitioner. Mr A put his contract with the Advanced Medical Institute on hold between April and October 2011, owing to his back injury. He advised that he tried to cancel his contract at that time, but was unable to. He recalled discussing with the Advanced Medical Institute whether it was okay to take the pain medication for his back in conjunction with his Advanced Medical Institute medication, and that the person to whom he spoke was not sure, and said that he should "maybe not take it together".

49. In May 2012 Mr A was prescribed citalopram for depression by his general practitioner. Between 2011 and 2012, Mr A had also on occasion been taking both clonazepam for anxiety and Seroquel for sleep.

50. Mr A consulted his general practitioner on 3 September 2012. His general practitioner recorded that Mr A was taking tramadol troches from the Advanced Medical Institute. The notes of that consultation state:

> "[I]t seems to work,
> I have warned him re risks while taking Citalopram.
> It has cost him $2000 so far and is contracted for another $1000 in the next yr
> I think there are some serious consumer rights issues going on here.
> Showed him the report of the HDC investigation into this company."

51. Mr A recalls that his general practitioner informed him that he would need to check with the Advanced Medical Institute as to whether he could continue to take the Advanced Medical Institute medication in conjunction with his other medication. Mr A said that he tried to call the Advanced Medical Institute on a number of occasions over two to three months to get an answer to his question. Mr A recalls that he was advised that someone would ring him back, although no one ever did, or that he should call again. Mr A recalls that he was then told that there were no longer any doctors to help him.

52. Mr A is concerned that he has paid for more medication than he has received.

Opinion: Advanced Medical Institute (NZ) Ltd

Introduction

53. As this Office has previously stated, when attending a specialist clinic like the Advanced Medical Institute, consumers are entitled to have services provided in accordance with the Code, which includes having an appropriate history taken, an appropriate examination undertaken, and information provided about the risks, benefits, options, and costs of treatment before treatment is recommended and/or prescribed.[13]

54. The Advanced Medical Institute has not responded to this investigation or the provisional report, and has not provided HDC with the names of any individual staff or contractors involved in providing services to Mr A. The Advanced Medical Institute is a healthcare provider for the purposes of the Health and Disability Commissioner Act 1994, and it is responsible for the services that it provides to consumers both directly and through its employees and agents. This opinion examines the responsibility of the Advanced Medical Institute for the services it provided to Mr A.

55. I am concerned about several aspects of the services that Mr A received from the Advanced Medical Institute, as set out below.

[13] Opinion 08HDC02899, 08HDC05986, 08HDC07100, 08HDC09984 (18 December 2008), available at www.hdc.org.nz.

Adequacy of assessment — No further action

56. In November 2010 a doctor who was contracted to the Advanced Medical Institute (an Advanced Medical Institute doctor) prescribed Mr A medication for premature ejaculation. The Advanced Medical Institute doctor asked Mr A about his general health and the medications he was taking before recommending and prescribing an Advanced Medical Institute medication for him, but she did not examine Mr A.

57. My expert advisor, general practitioner Dr David Maplesden, advised that there are a number of factors to consider when assessing the adequacy of the Advanced Medical Institute doctor's assessment of Mr A prior to prescribing him with Advanced Medical Institute medication for premature ejaculation. In particular, the features obtained in the history taking are important in directing the degree of physical examination required. Dr Maplesden stated that, in general, if there was no indication from the history taken to suggest that Mr A had systemic or urogenital disease, and if Mr A's history of anxiety had been obtained, it may have been reasonable for the Advanced Medical Institute doctor to prescribe Mr A medication for premature ejaculation without first undertaking a physical examination. However, had it been established that Mr A's premature ejaculation was of recent onset rather than longstanding, coupled with a history of genitourinary infection (which Mr A had in May/June 2009), a prostate examination should have been undertaken to determine whether there were any physical signs of prostatitis, which is a potential cause of premature ejaculation. In addition, if there was a history of erectile dysfunction, a physical examination would have been indicated.

58. Although the Advanced Medical Institute doctor asked Mr A about his general health and the medications he was taking, the adequacy of the history that she obtained from Mr A prior to recommending and prescribing medication for him is not clear, as the Advanced Medical Institute has failed to provide HDC with any information or documentation relating to that examination.

59. In the circumstances, I am unable to make a finding whether the Advanced Medical Institute breached the Code with regard to its doctor's assessment of Mr A.

Adequacy of information provided — Breach

Information provided to Mr A

60. In accordance with Right 6 of the Code, consumers need to be provided with all the information that a reasonable consumer, in that consumer's circumstances, would expect to receive before making an informed choice about which (if any) treatment to have.

61. In my view, the Advanced Medical Institute did not provide Mr A with the information that a reasonable consumer in his circumstances would expect to receive, prior to consenting to the nasal spray, pills, and lozenges treatment. In particular:

- the Advanced Medical Institute did not provide Mr A with information about the range of treatment options, including treatment options not offered by the Advanced Medical Institute;

- there is no evidence that the Advanced Medical Institute advised Mr A that the medication it was recommending and that it prescribed for him was not the accepted "first-line" treatment for his condition;

- Mr A was not advised that the medication he was being prescribed was being prescribed on an "off-label" basis;[14]

- Mr A received inadequate information about how to take his medication. In November 2010 he was advised to squirt the nasal spray in his nose, and he was not advised how to take the lozenges at the time they were prescribed for him (although he did receive a DVD with the lozenges); and

- the relative risks, benefits, and costs of alternative treatments other than those supplied by the Advanced Medical Institute were not discussed with Mr A. As noted by Dr Maplesden, an SSRI would have been available to Mr A at a significantly lower cost than the Advanced Medical Institute medications.

62. The Advanced Medical Institute previously submitted to HDC that it is the responsibility of the prescribing doctor to advise patients regarding the use of treatments, their potential side effects, and the "off-label" use of those medications. Nevertheless, in my view, in these circumstances, the Advanced Medical Institute is also responsible for these failures.

63. I have previously found[15] that the Advanced Medical Institute failed to provide sufficiently clear information to the doctors it contracted with regarding the fact that the medications offered by the Advanced Medical Institute constituted an "off-label" use of that medication. The Advanced Medical Institute stated that it advised its staff and contractors that its medications were being provided "off-label" through its publicly accessible website, patient booklet, and training materials (DVD). In my view, the materials it relied upon to inform its doctors that its medications were "off-label" were not sufficiently detailed or specific. Indeed, the DVD training material suggested that doctors were not required to advise patients that a medication was being used "off-label" (see above, paragraph 26). In addition, the Advanced Medical Institute's medication booklets for patients also fail to explain that the medications offered are not approved in that form. There is no evidence that the Advanced Medical Institute provided information to consumers, or directed its doctors to provide full information to consumers, about treatment options other than those offered by the Advanced Medical Institute, or the risks, benefits, and costs of different treatment options. Furthermore, there is no evidence that the Advanced Medical Institute provided information to consumers, or directed its doctors to provide full

[14] Right 6 of the Code gives consumers the right to information that a reasonable consumer, in that consumer's circumstances, would want to receive. In many instances this will include being told if a particular medication is being used in an unapproved way. Medsafe advises that, while there may be some limited circumstances where this is not required, in general terms, a medical practitioner should advise the patient that the proposed use is unapproved (in accordance with Right 6 of the Code) (see: http://www.medsafe.govt.nz/profs/RIss/unapp.asp). Providers need to be mindful of their obligations under Right 6 of the Code when prescribing "off-label" medications.

[15] See: 09HDC00905, 09HDC01077, 09HDC01082 and 09HDC01540, available at www.hdc.org.nz.

information to consumers, that the medication it provides is not the accepted "first-line" treatment for premature ejaculation.

64. The Advanced Medical Institute should have ensured that it provided the above information to Mr A, either directly or through its contracted doctor, before recommending and prescribing its medication to him. Its failure to do so was a breach of Right 6(1) of the Code.

65. Because Mr A did not receive adequate information about the medication being recommended and prescribed for him, he was unable to give his informed consent to that treatment. Accordingly, I also find that the Advanced Medical Institute breached Right 7(1) of the Code.

Information provided to Mr A about sharing information with his general practitioner

66. In November 2010 an Advanced Medical Institute doctor prescribed Mr A with a nasal spray to treat premature ejaculation. The Advanced Medical Institute subsequently prescribed Mr A with pills and tramadol lozenges.

67. There is no evidence that the Advanced Medical Institute sought Mr A's permission to, and explained the benefits to him of, sharing with his general practitioner information about the Advanced Medical Institute medications Mr A had been prescribed.

68. In my view, it is important that when a specialist clinic like the Advanced Medical Institute prescribes medication to a consumer, it advises that consumer of the benefits of sharing information about that prescription with the consumer's general practitioner. General practitioners have a vital role in maintaining the continuity of medical care provided to consumers under their care.[16] As I have previously noted, consumers will often move from one part of the healthcare system to another, and back again, as they access the various services they need.[17] It is essential that, when this happens, providers take sufficient steps to ensure that the consumer receives a safe and seamless service as he or she moves between the different providers.

69. The Advanced Medical Institute did not have a discussion with Mr A regarding the benefits of sharing information about his prescription of Advanced Medical Institute medication for premature ejaculation with his general practitioner. As noted by Dr Maplesden, the Advanced Medical Institute's failure to do so in this case led to a situation of potential harm, when Mr A was later prescribed citalopram by his general practitioner in May 2012.

70. In my view, the Advanced Medical Institute failed to ensure the continuity of services to Mr A, and breached Right 4(5) of the Code.

[16] Medical Council of New Zealand, *Good Medical Practice: A Guide for Doctors* (2011).
[17] Hill, A., "Consumer-centred Care: Seamless Service Needed", *NZ Doctor* (24 August 2011). Available at www.hdc.org.nz.

Follow-up care — Breach

71. The Advanced Medical Institute previously advised HDC that it provides follow-up services to consumers as part of its treatment programme. It advised that patients contact the Advanced Medical Institute every three months to re-order medication and, on those occasions, the Advanced Medical Institute will "take the opportunity to ask the patients whether the medication is working for them and make sure that the patients are not suffering any side effects from the medication".

72. I am not satisfied that the Advanced Medical Institute provided adequate follow-up care to Mr A. Mr A has reported that he had extreme difficulty contacting anyone at the Advanced Medical Institute to discuss his medication, particularly when he had questions about whether there were any contraindications to taking the Advanced Medical Institute prescribed medication in conjunction with the medication prescribed by his general practitioner. Mr A recalls that he was advised that someone would ring him back, but no one ever did. The Advanced Medical Institute's failure to respond to Mr A's queries, and his follow-up care, were clearly inadequate, and in this case led to the situation where a potential drug interaction went unrecognised. In my view, the Advanced Medical Institute breached Right 4(1) of the Code for failing to adequately follow up on and monitor Mr A while prescribing medication to him.

Treatment programme — Breach

73. In a previous decision, this Office commented that when first-time patients are seeking assistance with a sensitive problem such as erectile dysfunction or premature ejaculation, particular care is needed to ensure that they understand their treatment options and do not feel pressured to purchase a recommended treatment.[18] Mr A said that he felt pressured to agree to the treatment programme during his appointment with the Advanced Medical Institute doctor in November 2010. The Advanced Medical Institute has not provided any information to suggest that Mr A was not pressured to agree to its treatment programme, and in these circumstances I accept Mr A's account.

74. Under its "Satisfaction and Privacy" policy, the Advanced Medical Institute requires its patients to agree to try at least one option from each of its four treatment methods before the patient may be eligible for a refund (see above, paragraph 34). I agree with comments made by my expert advisor, Dr Maplesden, in previous cases relating to the Advanced Medical Institute regarding the Advanced Medical Institute's Satisfaction and Privacy Policy.[19] In particular, that:

> "[t]he terms of this policy are unduly restrictive in terms of demanding that a client trial treatments other than those to which they have initially agreed, before being entitled to a refund if they are dissatisfied with the initial treatment. I believe this demand is unethical and unreasonable and would meet with disapproval from my peers."

[18] Opinion 08HDC02899, 08HDC05986, 08HDC07100, 08HDC09984 (18 December 2008), available at www.hdc.org.nz.
[19] See: 09HDC00905, 09HDC01077, 09HDC01082 and 09HDC01540, available at www.hdc.org.nz.

75. Mr A attempted to withdraw his consent to services and cancel his contract with the Advanced Medical Institute when he injured his back in 2011. However, he advised that he was unable to do so. I agree with Dr Maplesden that it is unethical and unreasonable that a consumer cannot stop treatment and seek a refund if he or she is dissatisfied with the treatment being provided or if his or her medical condition changes so as to make ongoing treatment inappropriate or unnecessary.

76. In these circumstances, I find that the Advanced Medical Institute coerced and exploited Mr A, and breached Right 2 of the Code.

Complaints management — Breach

77. Pursuant to Right 10(3) of the Code, the Advanced Medical Institute is required to facilitate the fair, simple, speedy, and efficient resolution of complaints.

78. Despite numerous requests from my Office, the Advanced Medical Institute failed to respond to Mr A's complaint or my investigation into his complaint. The Advanced Medical Institute failed to respond to written requests and, despite verbal assurances from the Chief Financial Officer and the Senior Manager that a written response would be provided, no such response has been received.

79. The Advanced Medical Institute's failure to engage with this Office to facilitate the resolution of Mr A's complaint shows a disregard for Mr A's rights. In my view, the Advanced Medical Institute breached Right 10(3) of the Code for failing to respond to Mr A's complaint.

Conclusion

80. The Advanced Medical Institute's purpose is clearly to promote and sell its own treatment programmes. While the Advanced Medical Institute's products may assist some men with premature ejaculation, the system the Advanced Medical Institute set up to provide its service is not consumer-centred. In addition, the Advanced Medical Institute's failure to respond to this complaint shows a worrying disregard of its responsibilities as a provider of healthcare services. Mr A was let down by the Advanced Medical Institute.

Recommendations

81. I recommend that the Advanced Medical Institute provide a written apology to Mr A. The apology is to be sent to HDC by **24 January 2014**, for forwarding to Mr A.

82. The Advanced Medical Institute has advised HDC that it is no longer providing services in New Zealand. I recommend that the Advanced Medical Institute advise HDC by **24 January 2014** of the number of consumers in New Zealand it is currently providing services to, and details of the steps it has taken to ensure that those consumers have, and continue to receive, adequate follow-up and monitoring, and information about their medication and treatment options.

83. Before the Advanced Medical Institute resumes providing services in New Zealand, if ever, I recommend that it provide a written summary to HDC of the steps it has taken to review its New Zealand operating procedures and policies in light of this report, and the reports 09HDC00905, 09HDC01077, 09HDC01082 and 09HDC01540. I recommend that the Advanced Medical Institute provide HDC with an undertaking by one month of the date of this report, to do so.

Follow-up actions

84.
- My concerns about the Advanced Medical Institute in relation to its breaches of the Code in this case, as well as in cases 09HDC00905, 09HDC01077, 09HDC01082 and 09HDC01540, will be reported to the Director-General of Health.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case and the Advanced Medical Institute (NZ) Ltd, will be sent to the Medical Council of New Zealand, the Medical Board of Australia, the Royal New Zealand College of General Practitioners, and the Royal Australian College of General Practitioners, with a cover letter recommending that they advise their registrants and members of the potential issues that may arise when providing services as a contracting doctor to the Advanced Medical Institute (NZ) Ltd.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case and the Advanced Medical Institute (NZ) Ltd, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent general practitioner advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden:

"1. Thank you for requesting advice on this file. You have provided the following facts:

(i) The consumer, [Mr A], said that he consulted an AMI doctor in November 2010 for premature ejaculation. [Mr A] could not recall the doctor examining him, although he recalled that she asked him about his general health and the medications he was taking (he was not taking any medications at that time). [Mr A] said that they discussed the benefits of medication and how medication could help him. [Mr A] recalled that the doctor spoke to him about a nasal spray medication. She told him that there was other medication he could try if the nasal spray did not work, but she did not discuss the other medication. [Mr A] said that the doctor prescribed him the nasal spray. [Mr A] did not recall being shown how to use the nasal spray, other than that 'maybe he was told to squirt it in the nose'.

[Mr A] advised that the doctor did not talk about other treatment options, including treatment options not offered by the Advanced Medical Institute. In addition, the doctor did not advise him that the medication would be prescribed on an 'off-label' basis.

(ii) [Mr A] said that the nasal spray burned his nostrils, so about three days after he received the spray he contacted AMI and he was sent some pills instead. [Mr A] was not asked about his condition or general health during that phone conversation. [Mr A] said that when he took the pills he had trouble sleeping, so he rang AMI again. In response, AMI sent him their lozenges. He recalled that before he was prescribed the lozenges he was asked whether he was taking any other medication. He said he was not advised how to take the lozenges. He followed the instructions on the packet, which was to take one lozenge 30 minutes prior to sexual activity. However, this did not work well and he contacted AMI again, who advised him to take two to three lozenges, two hours before sexual activity.

(iii) Additional information I have gained from a transcription of the HDC interview with [Mr A] includes:

a. [Mr A] was on no regular medications at the time he was assessed by the AMI doctor (November 2010). However, he was using PRN Tramadol for back pain and PRN clonazepam for anxiety attacks since at least 2007. He had used an SSRI (Fluoxitene) in the past, stopped in March 2010.

b. In June 2011 [Mr A] recommenced regular clonazepam for anxiety/panic attacks and in May 2012 the SSRI citalopram was commenced. GP prescriptions

for oral tramadol (for back pain) had been discontinued prior to commencement of Fluoxitene.

c. On 3 September 2012 [Mr A's] GP has noted that the patient was receiving Tramadol troches from AMI for treatment of PE and has documented warning [Mr A] about the potential interaction between this drug and the citalopram he was taking. This is the first and only reference to the GP being aware [Mr A] was receiving treatment from AMI.

d. On 20 May 2009 [Mr A] saw his GP for anxiety related issues and a history of possible PE was raised. A reasonable history is documented including that latency time (see below) could last from 1–10 minutes, and [Mr A's] partner at the time was not particularly concerned. [Mr A] had had a urine infection treated recently and results of a follow-up urine test were awaited. Physical methods of controlling PE were discussed as was the possible use of SSRIs which [Mr A] would consider but did not want to use at that point. A week or so later he had further urinary symptoms and a repeat urine sample was positive for infection. A physical examination, including genital examination (normal) was performed on 2 June 2009 and the infection was treated. There is no documentation to suggest the issue of PE was raised with the GP again (until September 2012) although there were relatively frequent consultations for back pain and anxiety symptoms review in the interim.

(iv) AMI have not responded to the complaint. There are no AMI records available for review. Based on [Mr A's] complaint, the medication he eventually ended up taking was Tramadol troches. It is unclear what medication was prescribed in the form of a nasal spray in the first instance.

2. You ask: *Would you expect a doctor to physically examine a patient presenting with premature ejaculation, prior to prescribing medication for that purpose? If you would expect a physical examination, would you regard the failure to do so as a mild, moderate or severe departure from the expected standard?*

[Mr A] was essentially a physically healthy male in his mid-20s. At the time of his AMI interview he was not taking any regular medications. I cannot comment on the adequacy of the history undertaken. In general, if there was no indication from the history taken to suggest systemic or urogenital disease, and noting [Mr A's] history of chronic anxiety (if that history was obtained), I think it would be reasonable to forgo a physical examination in this instance. The epidemiology of PE is quite different to that of ED which is why a different standard applies. The relevant European guidelines include: *Diagnosis and classification of PE is based on medical and sexual history. It should be multidimensional and assess intravaginal ejaculatory latency time* (IELT — time between vaginal penetration and ejaculation), *perceived control, distress and interpersonal difficulty due to the ejaculatory dysfunction.* I note these features had been assessed by the GP in 2009. *Physical examination <u>may</u>* (my emphasis) *be necessary in initial assessment of PE to identify underlying medical conditions that may be associated with PE or*

other sexual dysfunctions, particularly ED. Routine laboratory or neurophysiological tests are not recommended. They should only be directed by specific findings from history or physical examination. Features obtained in the history are therefore important in directing degree of physical examination required. Had it been established the PE problem was of recent onset rather than longstanding (and I am not sure which was the case here), coupled with a history of documented genitourinary infection (which [Mr A] did have in May/June 2009), a prostate examination should have been undertaken to determine whether there were any physical signs of prostatitis, a potential cause of recent onset PE. If there was a history of ED (which can lead to PE if erections are very short-lived) a physical examination would have been indicated. However, as the history obtained cannot be confirmed I must say the failure to perform a physical examination, on the basis of the information available to me, was not a departure from expected standards.

3. You ask: *I would appreciate your comments on the appropriateness of AMI prescribing pills and lozenges to [Mr A] over the telephone in these circumstances (see 1(ii)), and the failure to advise him how to take the lozenges. If you consider that it was inappropriate for AMI to prescribe pills and lozenges to [Mr A] over the telephone in these circumstances, and to advise him how to take the medication, would you regard those failures as a mild, moderate, or severe departure from the expected standard?*

In making the following comments, I am assuming the AMI providers giving telephone advice were clinical and had access to [Mr A's] AMI clinical notes. These notes apparently recorded the absence of any current co-prescribing. My expectations are also dependent somewhat on the quality of information provided to [Mr A] at his face-to-face AMI consultation, and whether the medication prescribed in the lozenges (troches) (Tramadol) was the same as that present in the nasal spray, the use of which had evidently been discussed to some degree with [Mr A]. If the medication was being provided in a different form (lozenge versus nasal spray) but was otherwise the same, I think it was reasonable to provide the different form of medication through a telephone consultation. However, such a conversation should have included explicit instructions (even if these were to be included on the product labelling), and advice on any potential common side effects and interactions if this had not been discussed at the initial visit (again assuming the same drug was being prescribed). I comment further below on the information given to [Mr A] but in answer to your specific question, I think the failure to give [Mr A] explicit instructions over the phone on how to take his Tramadol lozenges, given this was a new form of medication for him, was a mild departure from expected standards while the actual provision of the medication per a telephone consultation was probably not (based on the assumptions discussed) a departure from expected standards. I have assumed also that product labelling was consistent with regulation 23 of the New Zealand Medicines Regulations 1984.

4. The Medical Council of New Zealand comments on expected standards of prescribing in their publication *Good prescribing practice*[20]. Some extracts relevant to my subsequent discussion are:

(i) *Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, side effects, benefits and costs of each option. Satisfy yourself that the patient understands how to take any medicine prescribed and is able to take it.*

(ii) *Periodically review the effectiveness of the treatment and any new information about the patient's condition and health if you are prescribing for an extended period of time. Continuation or modification of treatment should depend on your evaluation of progress towards the objectives outlined in a treatment plan.*

(iii) *In most circumstances there should be timely and full information flow between general practitioners, hospital doctors and other relevant health practitioners about the indications and need for particular therapies. If you are the prescribing doctor and you make a change to treatment, you must notify your colleague(s) of the change and the rationale for it. If the change has significant implications for the patient and his or her care, you must also make sure that this information is received by your colleague(s).*

(iv) *You may prescribe unapproved medicines or prescribe medicines for a purpose for which they have not been approved but, if you decide to do so, you should take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment… You should also inform the patient: whether there are any other options available; of any risks, side effects, costs or benefits; that the medicine being prescribed is for an unapproved use…*

5. The current European guidelines[21] on treatment of PE do not include Tramadol in their treatment algorithm (see [Figure below]) and note *research suggests that the alpha-1 adrenergic antagonists, terazosin and alfuzosin, and tramadol may have some efficacy in PE. However, further research is needed to investigate their role fully. Currently they are not recommended in clinical practice.* However, I note the drug has been used nationally and internationally as an ED treatment option since about 2000[22]. Dapoxetine has been approved for the on-demand treatment of PE in New Zealand since around 2009 (patient funded) and is the only drug approved for such an indication. Therefore, use of any agent other than dapoxetine for treatment of PE is 'off-label' use of that agent.

[20] Available at: *www.**mcnz**.org.nz*
[21] European Association of Urology. Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. 2013. Available at: http://www.uroweb.org/guidelines/online-guidelines/
[22] Hellstrom w. Update on Treatments for Premature Ejaculation. Int J Clin Pract. 2011;65(1):16–26

6. Internationally, the consensus of the American Urological Association (AUA) committee that drafted the American guidelines for PE management was that although oral antidepressants and topical anaesthetic agents are not approved by the FDA for PE, they have been shown to delay ejaculation in men with PE and have a low side effect profile when used at the lower doses commonly used for the treatment of PE. The treatments recommended by the AUA are as follows:

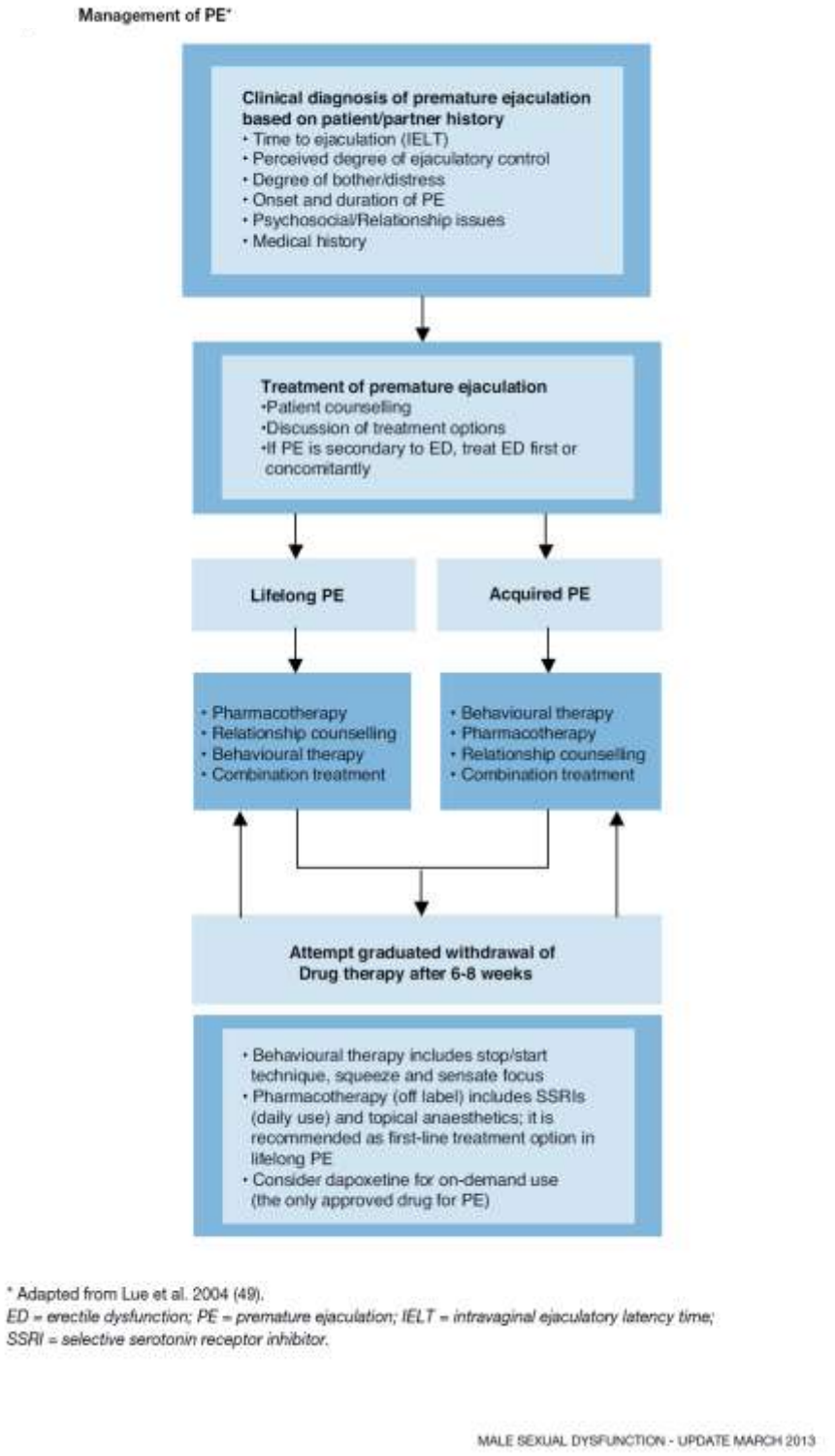
- Serotonergic antidepressants, including the selective serotonin reuptake inhibitors (SSRIs) fluoxetine, paroxetine and sertraline, and the tricyclic antidepressant clomipramine. (The antidepressants nefazodone, citalopram and fluvoxamine are not effective in treating PE.)

- Topical lidocaine–prilocaine cream

These recommendations are consistent with those contained in the European Guidelines and noted in [the figure below]. The use of non-drug methods of PE management also deserve discussion and consideration in some cases (less so for lifelong PE), and some methods had evidently been discussed with [Mr A] by his GP in 2009, as had the concept of SSRI use — the recommended first line pharmaceutical treatment in both guidelines discussed.

7. With respect to [Mr A's] complaint, the following issues are apparent: the medication prescribed by AMI was not accepted 'first-line' treatment for ED and this was not discussed with [Mr A]; alternatives to the medications prescribed by AMI, including treatments with a more robust evidence base and international acceptance than those prescribed by AMI, were not discussed with [Mr A]; the fact that Tramadol was being used 'off-label' was not discussed with [Mr A]; the relative risks, benefits and costs of alternative treatments versus those supplied by AMI were not discussed with [Mr A] (an SSRI would have been available to him at a cost of $3 per 3-month prescription if had elected to use this option, while AMI treatment was very significantly more expensive); there was apparently no formal report made to [Mr A's] GP regarding the introduction of a prescribed medication (Tramadol) — this led to a situation of potential harm when [Mr A] was later prescribed Citalopram by his GP although there is no evidence of actual harm; there was inadequate communication with [Mr A] from AMI with respect to monitoring over the months during which repeat prescriptions for Tramadol were provided meaning the potential drug interaction went unrecognised; there was inadequate information given to [Mr A] regarding how to take his medication (as discussed above). While any of these features in isolation probably represents a mild departure from expected standards (referring to the discussion in section 4) I think cumulatively they represent a very slack approach to prescribing and appropriately informing the consumer and are a moderate departure from expected standards."

Figure: From: European Association of Urology. Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. 2013. Available at: http://www.uroweb.org/guidelines/online-guidelines/



* Adapted from Lue et al. 2004 (49).
ED = erectile dysfunction; PE = premature ejaculation; IELT = intravaginal ejaculatory latency time; SSRI = selective serotonin receptor inhibitor.

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