General Practitioner, Dr E
General Practitioner, Dr F
Advanced Medical Institute (NZ) Ltd

A Report by the
Health and Disability Commissioner

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Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary....1
Investigation process....2
Part 1: Information gathered during investigation — Advanced Medical Institute...4
1.1 Advanced Medical Institute (NZ) Ltd....4
1.2 Contractors....6
1.3 Orientation and training....7
1.4 Written policies and procedures....10
1.5 Information for patients....12
1.6 Complaints procedure....14
Part 2: Information gathered during investigation — patients....15
2.1 Mr A....15
2.2 Mr B....19
2.3 Mr C....23
2.4 Mr D....25
2.5 Actions taken by providers....28
Part 3: Opinion — doctors....30
3.1 Opinion: Breach — Dr E....30
3.2 Opinion: Breach — Dr F....33
3.3 Adverse Comment — Dr F....34
Part 4: Opinion — Advanced Medical Institute (NZ) Ltd....34
4.1 Introduction....34
4.2 Advanced Medical Institute systems....36
4.3 Mr A....40
4.4 Mr B....42
4.5 Mr C....43
4.6 Mr D....44
4.7 Conclusion....45
Recommendations....46
Follow-up actions....46
Appendix 1: Clinical advice from general practitioner Dr David Maplesden....47
Appendix 2: Code Rights, Relevant standards, Medsafe Guidelines....77

Executive summary

1. This case is about four men who received poor care from the Advanced Medical Institute (NZ) Ltd (the Advanced Medical Institute) between November 2007 and early 2009. The Advanced Medical Institute specialises in the treatment of sexual dysfunction. At the time of the events in question, the Advanced Medical Institute (NZ) Ltd was a wholly owned subsidiary of Advanced Medical Institute Australia Holdings Pty Ltd. The four cases have been reported together because of the complexity and similarity of the issues raised.

2. In all four cases, an Advanced Medical Institute-contracted doctor recommended and/or prescribed medication or a medication programme without undertaking a proper clinical assessment of the patient. The Advanced Medical Institute did not have robust systems in place to ensure patients received a face-to-face consultation, were adequately examined, or were given full information about the medication and treatment options before medications were recommended and/or prescribed. The Advanced Medical Institute also had a poor and ineffective complaints procedure.

Mr A

3. Mr A was examined by Dr E in a New Zealand clinic. Dr E did not undertake an adequate physical examination or obtain a full medical history before recommending a treatment programme for Mr A. Dr E also failed to provide Mr A with information about alternative treatment options, including costs. Dr E breached Rights 4(1) and 6(1)(b) of the Code. The Advanced Medical Institute was held vicariously liable for Dr E's failure to conduct an adequate physical examination and failure to provide information about treatment options because it did not take all reasonably practicable steps to prevent those failings.

Mr B

4. Mr B was examined by Dr F in a New Zealand clinic. Dr F inappropriately prescribed Mr B an injectable medication without first conducting an adequate physical examination to determine whether the medication was contraindicated and did not appropriately record the medication she prescribed. Dr F breached Right 4(1) of the Code. The report also criticises Dr F for failing to tell Mr B that the medication prescribed was an "off-label" use of that medication. The Advanced Medical Institute was not vicariously liable for the doctor's breaches of the Code; however, it breached Rights 10(3) and 10(6) of the Code for not having an appropriate complaints procedure.

Mr C

5. Mr C spoke with a doctor in Australia by telephone. The doctor recommended that Mr C undergo a 12-month treatment programme without Mr C undergoing a face-to-face consultation and proper clinical assessment with a New Zealand doctor. Mr C did not consent to the programme recommended but his credit card was charged. The Advanced Medical Institute breached Right 4(1) of the Code by having deficient practices and procedures for ensuring that Mr C was seen by a doctor before being recommended a treatment programme, and for failing to give Mr C adequate information about the treatment programme. The Advanced Medical Institute also

breached Rights 10(3) and 10(6) of the Code by not having an appropriate complaints procedure to facilitate the timely resolution of Mr C's complaint.

Mr D

6. Mr D spoke with a doctor in Australia by telephone and, following the call, was prescribed and charged for medication which was subsequently sent to his home. He did not have a face-to-face consultation and was not clinically assessed. The Advanced Medical Institute breached Right 4(1) of the Code by having deficient practices and procedures for ensuring that Mr D was seen by a doctor before being prescribed (and receiving) medication. The Advanced Medical Institute also breached Rights 10(3) and 10(6) of the Code for not ensuring that Mr D's complaint was appropriately handled and resolved in a timely manner.

Investigation process

7. Between 8 June 2008 and 6 April 2009, the Health and Disability Commissioner (HDC) received four complaints about the services provided by the Advanced Medical Institute. An investigation was commenced on 3 August 2009.

8. Information was obtained from:

Mr A, consumer/complainant
Mr B, consumer/complainant
Mr C, consumer/complainant
Mr D, consumer/complainant
Dr E, general practitioner
Dr F, general practitioner
Ms G, clinical co-ordinator, Advanced Medical Institute (NZ) Ltd
Mr H, pharmacist
Advanced Medical Institute (NZ) Ltd, provider
Dr I, general practitioner
Dr J, Mr A's general practitioner
Dr K, Mr C's general practitioner

Also mentioned in this report:

Dr L, medical director
Dr M, CEO
Dr N, doctor

9. Clinical advice was obtained from general practitioner Dr David Maplesden, and is set out in **Appendix 1**.

10. The following issues were identified for investigation:

Mr A

- *The appropriateness of care and the adequacy of the information provided to Mr A by Dr I in January 2009.*
- *The appropriateness of care and the adequacy of the information provided to Mr A by the Advanced Medical Institute in December 2008 and January 2009.*
- *Whether the Advanced Medical Institute coerced and/or attempted to financially exploit Mr A.*

Mr B

- *The appropriateness of care and treatment provided to Mr B by Dr F in February 2009.*
- *The adequacy of the information provided to Mr B by Dr F in February 2009.*
- *The appropriateness of care and treatment provided to Mr B by the Advanced Medical Institute in February 2009.*
- *The adequacy of the information provided to Mr B by the Advanced Medical Institute in February 2009.*
- *Whether the Advanced Medical Institute appropriately managed and resolved Mr B's complaint.*
- *Whether the Advanced Medical Institute coerced and/or financially exploited Mr B.*

Mr C

- *The appropriateness of care and the adequacy of the information provided to Mr C by the Advanced Medical Institute in November 2007.*
- *Whether the Advanced Medical Institute obtained Mr C's informed consent prior to charging him for medication in November 2007.*
- *Whether the Advanced Medical Institute appropriately managed and resolved Mr C's complaint.*
- *Whether the Advanced Medical Institute coerced and/or financially exploited Mr C.*

11. In response to the notification, Dr I informed HDC that he was not the doctor who saw Mr A. The Advanced Medical Institute confirmed that Dr E saw Mr A on 7 January 2009. On 4 September 2009, the Commissioner decided to take no further action against Dr I, and the investigation was expanded to include:

- *The appropriateness of care and the adequacy of the information provided to Mr A by Dr E in January 2009.*

12. On 7 September 2009, the investigation was further expanded to include Mr D's complaint in regard to the following:

- *The appropriateness of care and the adequacy of the information provided to Mr D by the Advanced Medical Institute in April 2008.*
- *Whether the Advanced Medical Institute obtained Mr D's informed consent prior to supplying him with medication in April or May 2008.*
- *Whether the Advanced Medical Institute effectively managed and resolved Mr D's complaint.*
- *Whether the Advanced Medical Institute coerced and/or financially exploited Mr D.*

Part 1: Information gathered during investigation — Advanced Medical Institute

1.1 Advanced Medical Institute (NZ) Ltd

13. At the time of the events in question the Advanced Medical Institute (NZ) Ltd (the Advanced Medical Institute) was a wholly owned subsidiary of Advanced Medical Institute Australia Holdings Pty Ltd, an Australian-based company.[1] The Advanced Medical Institute advertises its treatments for erectile dysfunction and premature ejaculation widely throughout New Zealand. The Advanced Medical Institute stated on its website:

> "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."[2]

14. When asked to describe the services the Advanced Medical Institute provides to its clients, the Advanced Medical Institute stated that it "arranges for patients to be provided with medical services and treatments relating to the treatment of erectile dysfunction and premature ejaculation". The Advanced Medical Institute explained that:

> "[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

[1] The Advanced Medical Institute advised HDC that Advanced Medical Institute (NZ) Ltd is no longer owned by AMI Australia Holdings Pty Limited. The New Zealand Companies Register website, as at 2 April 2012, lists AMI Australia Holdings Pty Ltd as the current owner and shareholder of Advanced Medical Institute (NZ) Limited. The Australian Securities and Investments Commission website, as at 2 April 2012, provides that the company formerly known as AMI Australia Holdings Pty Ltd is now known as A.C.N. 095 238 645 Pty Ltd.

[2] http://www.amiaustralia.com.au (as at 15 December 2010).

and the period in which treatment is provided is for the period commencing on the date on which effective treatment is provided."

15. The Advanced Medical Institute supplies its patients with its own medications. These 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 injectable formulation). The use of medications in this manner is commonly referred to as "off-label" use. The provision of medication on an "off-label" basis is not illegal in New Zealand; however, Medsafe has issued guidelines for the use of unapproved medicines in New Zealand (see Appendix Two). The Advanced Medical Institute stated:

> "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)."

16. In relation to the manner in which its medications are prescribed, the Advanced Medical Institute stated 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".

17. 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."

18. The Advanced Medical Institute explained that it 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".

19. The following information sets out what I was able to ascertain regarding the system the Advanced Medical Institute has set up to provide these services, particularly the

way it contracts its workforce, the orientation and training provided to staff, any written policies and procedures, and how information is provided to patients.

1.2 Contractors

Administrative staff and clinical co-ordinator

20. Based on the information provided by the Advanced Medical Institute and the consumers involved in these complaints, 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.

21. Consumers who attended an Advanced Medical Institute clinic would initially be greeted by reception staff and asked to complete a patient information sheet. The consumer would then be taken to see a doctor.

22. After seeing the doctor, patients discussed the cost of the recommended treatment programme with the clinical co-ordinator. Clinical co-ordinators are paid on commission and, if a patient is refunded, the commission paid on that sale is deducted from future payments to the clinical co-ordinator. The Advanced Medical Institute explained that the clinical co-ordinator involved in these complaints, Ms G, "contracts to [Advanced Medical Institute] through [another service] and is not an employee of [Advanced Medical Institute]".[3] The Advanced Medical Institute provided copies of the invoices setting out the remuneration for the clinical co-ordinator, and a copy of a confidentiality obligation. However, the Advanced Medical Institute did not provide any contractual agreement or job description for the clinical co-ordinator role.

23. Ms G said that she had been working for the Advanced Medical Institute for approximately six to seven years on a contract basis. She explained: "My role is to speak to the patients about the treatment program that has been recommended to them by their consulting doctor and to discuss the cost of the program and the various payment plans that are available." She confirmed that she has no relevant qualifications or membership of any professional bodies.

Medical practitioners

24. In response to my request for information about the employment status of the doctors involved in this investigation, the Advanced Medical Institute advised that Dr F and Dr E were independent contractors. The Advanced Medical Institute provided a copy of its standard *Engagement as Consultant* agreement. The Agreement requires its "consultants" to:

[3] This service is registered in Australia but not New Zealand.

> "(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; …"

25. The Advanced Medical Institute also supplied copies of invoices from Dr F and Dr E in relation to services provided to two of the consumers involved in this investigation.

26. The Advanced Medical Institute was subsequently asked to provide copies of the written agreements it had entered into with Dr F and Dr E. In response, the Advanced Medical Institute explained that it was unable to provide copies of the doctors' contractual agreements, stating that it believes "a previous staff member has misplaced these records". The Advanced Medical Institute explained that despite extensive efforts to locate copies of the written agreements it had been unable to do so.

27. Dr E and Dr F both advised that they did not have any written contractual agreement with the Advanced Medical Institute. However, both accepted that the services they provided to the Advanced Medical Institute's patients were undertaken in the capacity of them being an independent contractor (in the case of Dr F) and as a subcontractor through an arrangement with another one of the Advanced Medical Institute's contracted doctors (in the case of Dr E).

28. Based on the information that has been provided to me I am satisfied that the services provided by doctors E and F were performed in their capacity as agents of the Advanced Medical Institute.

1.3 Orientation and training

29. The Advanced Medical Institute has provided varying accounts of the orientation and training it provided to Dr E and Dr F. Initially, the Advanced Medical Institute provided a disk containing "all training literature as supplied to all the Doctors who commence working for the Advanced Medical Institute". The disk contains approximately 50 items, ranging from scientific journal articles, book chapters, websites, newsletters, and newspaper and magazine stories. The items were published or updated between 1991 and 7 April 2009.

30. The Advanced Medical Institute later stated:

> "Each doctor is provided with assessment forms to use to assess patients. They are also provided with literature, … and coaching by another doctor when they first start contracting to [Advanced Medical Institute]. In addition to this, [Advanced Medical Institute's] practice is to hold regular telephone meetings with all doctors to discuss issues relevant to the treatment of patients (ie weekly or monthly).

> Furthermore, [Advanced Medical Institute's] medical director ([Dr L]) and CEO ([Dr M]) are available by telephone at any time to discuss any issues which doctors have in relation to the treatment of patients."

31. When asked to provide evidence of the Advanced Medical Institute's "regular telephone meetings" with doctors, the Advanced Medical Institute stated that it does not take written notes or minutes of the regular doctors' conferences. The Advanced Medical Institute provided HDC with a copy of a sworn affidavit from an Australian registered doctor contracted to the Advanced Medical Institute in Australia that regular meetings with doctors were held. However, it was unable to provide any documentary evidence, or a detailed description, of the teleconferences between the Advanced Medical Institute and Dr E and/or Dr F.

32. On the disk provided by the Advanced Medical Institute 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.[4] The second article does consider whether doctors should discuss off-label use with patients.[5] 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."[6]

33. 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."

34. 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 advised Dr E and Dr F to advise patients on its off-label medications.

Dr E

35. When initially asked about Dr E's orientation, the Advanced Medical Institute stated:

[4] Fallon, B. (2008). "'Off-label' drug use in sexual medicine treatment", *International Journal of Impotence Research*, (20), 127–134.
[5] 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.
[6] Words underlined in pdf copy of the article provided by the Advanced Medical Institute.

> "[Dr E] underwent a 2 week training and orientation program prior to commencing work for the Advanced Medical Institute. All doctors who commence working for the Advanced Medical Institute undergo such training and orientation."

36. However, Dr E explained that his first day working for the Advanced Medical Institute came about when he agreed to fill in for a colleague (Dr I) for one day. In light of this, the Advanced Medical Institute subsequently acknowledged that its initial statement was made in error and apologised for this. As it transpired, Dr I subsequently fell ill and Dr E continued to fill in for him. Dr E explained that, with regard to orientation, he was provided with only a protocol for practice from one of the Advanced Medical Institute's clinics (see paragraph 51). The Advanced Medical Institute initially denied authorising this protocol.

37. Dr E also advised that he did not have any meetings or teleconferences with the Advanced Medical Institute. He stated that there was "no clinical supervision in place to support my practice at [Advanced Medical Institute]" but he was told that he could contact senior doctors at the Advanced Medical Institute in [NZ] and [Australia] if necessary.

38. In response to my provisional opinion the Advanced Medical Institute advised that, in addition to the items on the disk, doctors are "generally provided with ongoing training regarding the role they perform", which "generally consists of on the job training and regular meetings of all doctors engaged by [Advanced Medical Institute] to discuss relevant issues". However, Dr E's training was "limited as he was subcontracted by Dr I on short notice without prior reference to [Advanced Medical Institute], which resulted in Dr E not being provided with the usual training provided to contracted doctors". The Advanced Medical Institute also confirmed that when Dr E commenced as a contractor he was not provided with his own login for the Advanced Medical Institute's computer system. The Advanced Medical Institute has advised me that it has since altered its practice such that all contracted doctors have their own separate login at the clinic, as is its standard practice elsewhere.

Dr F

39. Dr F explained her training as follows:

> "I undertook my initial training with [Dr L], an Australasian College urologist. Thereafter he was a significant point of clinical contact, if I required assistance or a second opinion. We would discuss medication indications, contraindications and side effects for erectile dysfunction, premature and retarded ejaculation, and literature issues/searches. He was available by telephone to help with any difficult clinical decisions around medicines or clinical findings and frequently we would together decide to send patients away for additional investigations and/or non-[Advanced Medical Institute] management paths where indicated.
>
> I also accessed local clinical support via liaison with other GPs, registrars, specialists etc. as would regularly occur in any primary healthcare setting.

> Advanced Medical Institute's initial training and DVDs were also quite informative on the topics of erectile dysfunction, premature and delayed ejaculation and other issues about sexual function in men and women."

40. Dr F explained:

> "Communication avenues included verbal communication within the NZ office, and faxes, and telephone calls. Also, [the Advanced Medical Institute] shorthand computer log constituted some communication with Head Office. There were also staff visits Trans-Tasman as required.
>
> Topics discussed with other [Advanced Medical Institute] personnel were generally about logistical issues, such as which patients required appointments, availability of nurse chaperones, lengths of consultation lists, when medication scripts would be processed by the pharmacy, ensuring medications were securely locked away once received, etc."

41. I note that on the issue of her understanding of off-label use of medication, Dr F stated:

> "I accept that I did not use the terminology of 'approved' or 'unapproved' because I thought that would require an additional level of explanation about what approved and unapproved means. … My present approach has arisen from the several times I have been guided by [DHB] senior consultants over the years to communicate with the patients in lay terms that they will understand, hence my approach of talking about the 'different' use or method of delivery."

1.4 Written policies and procedures

42. The Advanced Medical Institute, Dr F and Dr E were each asked to provide copies of relevant policies. Ms G was also asked to provide any policies and procedures supplied by the Advanced Medical Institute and/or her employer.

Information provided by the Advanced Medical Institute

43. In response to my request for any policies, the Advanced Medical Institute provided a copy of its *Record Keeping Policy*, dated 20 January 2010, which reminds staff of their record-keeping obligations. This was the only policy or procedure the Advanced Medical Institute provided.

44. The Advanced Medical Institute also provided a copy of pages 8, 9 and 11 to 20 of its *Nurse Reference Folder*, dated 28 April 2009. The pages from the folder contain information on each of the medications supplied by the Advanced Medical Institute, including: the ingredients, method of action, method of use, contraindications and side effects. Some of the information on the medications is different to that provided by Dr E (see paragraph 51). None of the documents provided corresponded to the time

period under investigation; however, the Advanced Medical Institute advised that the documents in place at the time of these events were similar.

Information provided by Dr E

45. The Advanced Medical Institute advised that "[n]o directions were given by [Advanced Medical Institute] to its consulting doctors as to how to conduct their examination of patients".

46. Dr E provided a copy of a note he had been given by Dr I, which stated:

> "All we require from yourself is that you perform a general check-up upon Mr… This is in terms of:
>
> 1. A check of blood pressure
> 2. Check of the heart and lungs
> 3. Check of the abdomen.
>
> Once these checks have been carried out we please ask you to forward us the bill for the patient that you have examined as you will be reimbursed by the company ... Also we would appreciate if you could call our staff … to confirm with ourselves that you have seen the patient and to provide us with feedback of the check-up.
>
> If you require any more information on dosing protocols or effects of the medications please do not hesitate to contact our Doctors on [an 0800 number].
>
> Thank you
>
> [Dr F]
> Advanced Medical Institute"

47. Dr E understood from this note that his role was "limited to ensuring the patient was healthy enough to take the medication [Advanced Medical Institute] recommended".[7]

48. Dr I recalls providing Dr E with this note, and is confident that Dr F gave it to him. Dr F denied writing the note, and pointed to the incorrect spelling of her first name as evidence that she did not write the note.

49. Dr E also provided an email dated 10 November 2008 from an Advanced Medical Institute employee,[8] which stated: "Doctors must not discuss cost of the programs or

[7] Dr I, who worked at one of the Advanced Medical Institute's clinics, explained his role in a similar way: "My role and responsibility as the Doctor at [the clinic] is *strictly* to assess the patient's *medical status* and make sure that there are *no contraindications* to any of the treatments which I recommend for the patient."

anything else only give medical assessment and recommend 12–18 months programs." Dr E stated that he was therefore given to understand that, on the direction of the Advanced Medical Institute, he should not discuss the cost of the treatment with a patient, and his role was simply to perform a general check-up on the patient and ensure that patients did not have any contrindications.

50. The Advanced Medical Institute stated:

> "In terms of the email provided by [Dr E] to the commission, that email was not authorized by [Advanced Medical Institute's] CEO, [Dr M], and does not reflect [Advanced Medical Institute's] corporate policy. The average length of [Advanced Medical Institute's] treatment programs is approximately 4.5 months. There is a range of independent clinical data which suggests that the chronic or longer term use of medication to treat both erectile dysfunction and premature ejaculation is beneficial for patients however [Advanced Medical Institute] does not have a corporate policy that treatment programs are to be of a particular length and [Advanced Medical Institute] is able to provide material verifying the average length of its treatment programs if necessary. Furthermore, [Advanced Medical Institute] has standard pricing for treatments of 3, 6, 9 and 12 months, which is inconsistent with the suggestion that [Advanced Medical Institute] has a corporate policy of patients being provided with 12–18 month treatment programs. The length of the treatment programs is determined based on a recommendation by the treating doctor and agreement with the relevant patient."

51. Dr E also provided a four-page document headed "Advanced Medical Institute", which set out: contact information for key staff in New Zealand and Australia, clinic hours, daily pay rate,[9] computer log on instructions and data to be input, and information on medications supplied by the Advanced Medical Institute. It also stated "generally prescribe [medication] for 12–18 months".

Information provided by Dr F

52. Dr F stated that she had not previously seen any of the information provided by Dr E, and that, when working for the Advanced Medical Institute, she "did not see any policies or procedures authorised by [Advanced Medical Institute's CEO]".

1.5 Information for patients

Cost and terms of treatment programme

53. The Advanced Medical Institute stated 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

[8] Described on the Advanced Medical Institute's January 2009 organisational chart as "NZ administration staff" and in the four-page document Dr E was given headed "Advanced Medical Institute" as "NZ Manager".
[9] $1,200 a day.

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]".

54. The Advanced Medical Institute has provided 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."

55. As mentioned earlier, Ms G has explained that as clinical co-ordinator it was her role to discuss the treatment programme that had been recommended by the consulting doctor, and to discuss the cost of the programme and the various payment plans available. As will be discussed later in this report, Dr E and Dr F have confirmed their understanding of the Advanced Medical Institute's process: that the clinical co-ordinator, not the doctor, discussed the issue of costs with a patient.

56. The Advanced Medical Institute provides two information booklets to its patients with their medications. 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.
>
> **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."

57. Dr F provided a blank *Advanced Medical Institute Authorisation Agreement*, which has spaces for the doctor's name, the length of the programme, the amount of the deposit and total cost of the programme, whether the patient will collect the medication from the clinic or have it sent to the patient, the patient's name and signature, and an Advanced Medical Institute staff member's signature. Dr F also provided a copy of the Advanced Medical Institute's satisfaction policy with a space at the bottom for patients to sign. However, the Advanced Medical Institute was unable to supply copies of these agreements for any of the four consumers involved in this investigation.

1.6 Complaints procedure

58. The Advanced Medical Institute stated that it had "an internal complaints process where all complaints are handled by the Customer Care department and acted upon accordingly". Dr E and Dr F provided copies of the Advanced Medical Institute's satisfaction and privacy policy (see above, para 56). Dr F stated: "To the best of my knowledge and belief [Advanced Medical Institute] does not have a formal complaints policy." Dr F said she had suggested to the Advanced Medical Institute that it create a patient complaint form available online "so that mishaps and any other issues can be detected earlier and rectified". However, the Advanced Medical Institute said that it does have a complaints handling system in place, and "has several full time staff engaged to perform this function", although it conceded that it could improve its complaint handling process.

Part 2: Information gathered during investigation — patients

2.1 Mr A

59. In December 2008, Mr A (then aged 71 years) rang the Advanced Medical Institute, after seeing its advertisement in a newspaper.

60. Mr A has a significant medical history, including type 2 diabetes, depression and a previous transient ischaemic attack.[10] The medication he was taking at the time included: metformin and gliclazide for diabetes, Aropax (paroxetine) for depression, a low-dose aspirin, and a glyceryl trinitrate (GTN) spray for angina.[11] Mr A was also having difficulty urinating, and was concerned about the reduced size of his penis. He had been dissatisfied with the advice he received from his own GP and a local diabetes nurse.

61. Mr A made an appointment to see an Advanced Medical Institute doctor at an Advanced Medical Institute clinic on 7 January 2009. When making the appointment, Mr A asked about treatment costs but was told that the cost depended on what the doctor prescribed.

Consultation — 7 January 2009

62. At 2pm on 7 January 2009, Mr A arrived at the Advanced Medical Institute clinic. Mr A spoke to three young women in the reception area before being taken in to see Dr E.

63. Mr A recalled that Dr E diagnosed him as having a prostate problem after discussing his symptoms, but Mr A did not recall any physical examination. Mr A's recollection of his consultation with Dr E was that the conversation was mostly off topic. They discussed cars, careers and a doctor they both knew.

64. Dr E recorded on the Advanced Medical Institute's computer system:

> "Main problem is when passing urine due to small penis and scattered flow. Rx Viagra but never used them. His problem is minor sexual dysfunction, but more prostatic illness. Advised to get the prostate problem investigated by his GP. But he wants his penis to become a bit longer with erection as his lady friend might have been disappointed and wants to try spray AM 140/85. Heart ok, pulse 68/m, chest clear. Suffers from diabetes mellitus on Metformin."

65. Dr E also recalled performing an abdominal examination while Mr A was standing, to check his liver, spleen and kidneys. Dr E later stated:

[10] A change in the blood supply to a particular area of the brain, resulting in brief neurological dysfunction that persists, by definition, for less than 24 hours. If symptoms persist longer, then it is categorised as a stroke.
[11] Angina is chest pain due to an inadequate flow of blood to the heart muscle.

> "It was not a full examination, as the Advanced Medical Institute rooms were not set up for a full clinical examination to take place. The consultation room could be seen by the adjoining buildings and there was no examination bed. I checked [Mr A's] pulse, blood pressure and heart rate and respiratory system."

66. The Advanced Medical Institute advised that it has three consultation rooms in this clinic, one of which has blinds. However, Dr E stated that he was not aware that there were three rooms for consultations, and pointed out that, even if other rooms were available, he could not have done a rectal examination in the absence of an examination bed. The Advanced Medical Institute confirmed that examination beds were not available in the clinic, and submitted that a detailed assessment was not required because the prostate treatment provided by the Advanced Medical Institute was limited to a herbal treatment. The Advanced Medical Institute advised that patients with "serious problems" are referred to third parties.

67. Dr E explained that initially when he saw Mr A, he recommended that Mr A see his GP about his possible prostatic hypertrophy. Mr A then left the consultation room, but returned after speaking to the nurse and requested a trial of the nasal spray. Dr E advised:

> "I told him that I could not vouch for the efficacy of the medications as I had not tried it, but the published reports seemed to indicate that it was effective. The recommendation from [Advanced Medical Institute] for over 70 year olds was a nasal spray containing apomorphine[12] and Max[o]lon,[13] which I advised him to try if he wished.
>
> The information I gave him included a detailed description of how to use the nasal spray, the dosage and side effects, and the action he had to undertake in the event of a side effects [sic]. He was given the telephone number to contact a doctor in [Australia] if he needed any further information."

68. Dr E did not document the medication (apomorphine and Maxolon nasal spray) dosage, frequency, volume and time period on the patient assessment form or in his clinical notes. He explained that his understanding was that he had no ability to adjust the dosage, frequency or volume, which was based on the Advanced Medical Institute's recommendation. Dr E advised that he did not feel he was in a position to be able to document details about the medication, which he expected would be done by the nursing staff. He stated:

> "It was my recommendation that he take the nasal spray, but not on my prescription. I do not recall ever signing any prescription form."

[12] Apomorphine is a relatively non-selective dopamine receptor antagonist. It works by stimulating arousal in the brain. Apomorphine is also a potent emetic (a drug that induces vomiting).
[13] Maxolon (metoclopramide) is a dopamine receptor antagonist, which helps to relieve nausea and vomiting.

69. In the course of the consultation regarding Mr A's erectile disfunction Dr E did not ask Mr A whether he was using a glyceryl trinitrate (GTN) spray, the presence of which would determine that first-line phosphodiesterase medications such as Viagra would have been contraindicated. Dr E stated that he "would never have prescribed Viagra to [Mr A]", and that his understanding was that he had a limited range of treatment options and delivery methods and Viagra was not one of those options. Dr E also did not elicit information about Mr A's history of depression, although Mr A's list of current medications included an antidepressant. Mr A's Advanced Medical Institute questionnaire template was not fully completed.

70. The Advanced Medical Institute stated that "[t]he selection of treatments for use by particular patients is a matter to be determined by the individual treating doctor and is a matter which is solely for determination by the treating doctor in accordance with their legal and ethical duties to the patient". The Advanced Medical Institute advised that "[i]n terms of the interaction of nitrates (such as GTN sprays) and PDE5 inhibitors, [Advanced Medical Institute] regularly reminds consulting doctors about the potential for severe adverse consequences which could arise from such interactions". The Nurse Reference Folder and patient information booklet refer to contraindications. The Advanced Medical Institute advised that these documents are provided to its contracted doctors.

71. There is no record in Dr E's notes that he advised Mr A that while apomorphine and Maxolon are approved medicines in New Zealand, they have not been approved for the purpose of treating sexual dysfunction or for use in a nasal spray formulation.[14] Dr E cannot now recall whether he provided that information or not. There was no documented plan for medical review or follow-up, except that Mr A was told that he could call the Advanced Medical Institute if the nasal spray did not work. The nasal spray was to be delivered to Mr A in a week's time.

Costs

72. Mr A said that the doctor did not discuss costs during the consultation. Dr E confirmed that he did not discuss costs, and advised that the reason for this was that he "was prohibited by the terms of employment to discuss the cost, which was delegated to [the] nurse".[15] Dr E commented:

> "I was not aware of how much the medication would cost, at this point in time. Subsequently I gathered it was an expensive affair for patients and therefore, **I recommended to patients whom I saw later that they should try it for a**

[14] The guidance provided by Medsafe for prescribers (available at http://www.medsafe.govt.nz/profs/RIss/unapp.asp) states: "The *Code of Health and Disability Services Consumers' Rights* places obligations on the provider of services. The consumer has the right to treatment of an appropriate ethical and professional standard, and the provider has the responsibility to ensure treatment, whether approved or unapproved, meets this standard. The consumer also has the right to be fully informed. If the use of a medicine is unapproved, the consumer should be so advised and the provider should be frank about the standard of support for the use and any safety concerns."

[15] Dr E was not "employed" but was in a contractual relationship with the Advanced Medical Institute.

> **shorter period of three months instead of the 12 months recommended by Advanced Medical Institute if they wanted to use it.**"[16]

73. Mr A has provided me with a copy of an invoice from the Advanced Medical Institute in relation to a 12-month medication programme in the amount of $3,795. Mr A explained that this was presented to him by one of the women in the reception area. Mr A was shocked by the amount, but filled out a cheque for the amount. Mr A cannot recall much of what was discussed with the clinical co-ordinator (who the Advanced Medical Institute identified as Ms G) that day, but said that he was not offered a choice of treatment programme lengths. Ms G cannot recall the details of her conversation with Mr A, and the Advanced Medical Institute was unable to provide a copy of the contractual agreement he signed.

74. The Advanced Medical Institute stated that Mr A "voluntarily agreed to the relevant term and voluntarily signed a cheque for the contract amount. [Mr A] could have requested a different contract term or different contract amount at any time."

75. Mr A's bank telephoned him the next day (as he did not have enough funds available in his account) and Mr A cancelled the cheque. Mr A rang the Advanced Medical Institute to advise that he had cancelled his cheque.

Complaint

76. On 17 February 2009, Mr A made a complaint to HDC regarding his experience and concerns about the amount the Advanced Medical Institute had wanted to charge him for the treatment programme. The Advanced Medical Institute's response to the complaint included naming medical practitioner Dr I as the doctor who saw Mr A.[17] The Advanced Medical Institute subsequently confirmed that Dr E was the doctor who saw Mr A. The Advanced Medical Institute explained that the doctor's role was "to examine the patient and has no involvement in the business side of the program". The Advanced Medical Institute stated:

> "[Mr A] wished to enter a rehabilitation program which is not simply the supply of medication; the treatment program offers access to doctors, nurses and various treatment options. They are also given the direct number for the staff services to use if there are any problems. If, further, the medication initially prescribed was ineffective, there are other medications."

77. The Advanced Medical Institute then stated that it was "in the process of organising to give free medication" to Mr A. However, on 21 May 2009, the Advanced Medical Institute confirmed that no such offer was made.

[16] Emphasis in original.

[17] The Advanced Medical Institute initially named Dr I as the doctor who saw Mr A. However, after Dr I was notified of the investigation he explained that he was not the doctor who saw Mr A, as he was on leave on 7 January 2009. Dr I had asked his colleague, Dr E, to cover for him that day, and Dr E had logged onto the Advanced Medical Institute system with Dr I's logon.

78. The Advanced Medical Institute advised that, as a result of Mr A's complaint, it "introduced new training for all our clinical coordinators to ensure that they clearly explain to patients the cost of treatment programs to ensure that there are no confusions".

79. On 9 April 2010, Dr E provided an apology to Mr A.

2.2 Mr B

Consultation — 19 February 2009

80. On 19 February 2009, Mr B (then aged 75 years) attended an Advanced Medical Institute clinic after seeing its advertisement in the newspaper.

81. Mr B recalled seeing a young woman, who asked him a series of questions about his health and erectile dysfunction, then advised him that prostaglandin[18] injections were the most appropriate treatment for his condition.

82. The Advanced Medical Institute's records show that Dr F saw Mr B on 19 February. Mr B's computer-generated patient assessment form documents under "doctor comments": "fit; no meds; recent hip replacement; for apm N/S [nasal spray] 12–18 MONTHS". The patient assessment form provided by the Advanced Medical Institute for Mr B did not identify the doctors or nurses who saw Mr B or the date this occurred.

83. In her handwritten notes, Dr F noted that she saw Mr B that day after he had spoken with administrative staff. She recorded that she discussed Mr B's medical history with him and reviewed the patient assessment form. Dr F stated that her opening conversation with all patients, not necessarily recorded in the notes, was to ask why the patient had approached the Advanced Medical Institute. The purpose of this question was to "elicit their awareness and understanding of [erectile dysfunction], its aetiologies, and the treatments and options that might be of assistance". She stated that Mr B told her that he understood all about the Viagra-type drugs and their side effects. She advised:

> "My initial session with [Mr B] lasted almost an hour and traversed all the treatments available but he had come because he wanted to know about the latest Advanced Medical Institute products."

84. Dr F advised that she attempted to engage Mr B about first-line medications,[19] but he wanted to know about the Advanced Medical Institute products and wanted

[18] Prostaglandins regulate the contraction and relaxation of smooth muscle tissue. Prostaglandin injections into the penis relax the smooth muscle of arteries in the penis resulting in an erection.

[19] In his report on this matter my Clinical Advisor explained that the first-line medication for the treatment of erectile dysfunction is tablets containing PDE-5 inhibitors, these being commercially available under the brand names Viagra, Cialis and Levitra. He advised. that "oral PDE-5 inhibitors

medication. She discussed the aetiology of sexual dysfunction and contributing factors, performed a cardiovascular examination, and recorded Mr B's blood pressure (156/97) and pulse (72). She noted anxiety as a contributing factor.

85. Dr F's response, which was detailed in four separate letters to the HDC[20] provides the following explanation of her discussions with Mr B during the consultation on 19 February 2009. She advised that she explained to Mr B that the Advanced Medical Institute's treatments were not a "quick fix" but a graded course of treatment starting with the least invasive treatment, a nasal spray, then lozenges, gels and injectables. She suggested the nasal spray as an option in the first instance on the basis that while it could at times be of limited efficacy, the side effects and systemic effects are less pronounced than first-line Viagra-type medications. She went on to explain to Mr B that by virtue of his age he might require a combination of medications that were more invasive than the nasal spray, including Viagra-type drugs, phosphodiesterase inhibitors,[21] and phentolamine. Dr F also explained that the injectable medications were the final medications the Advanced Medical Institute offered as they were the most invasive. She clarified that the injectables had different combinations and dosages of prostaglandins and phentolamine and other vasodilating medications. Patients start off with the lowest dosages and tiny volumes. Dr F advised Mr B that injectables "more or less" guaranteed an erectile response and are "often the safest with the older man and people with co-morbidities" because of the limited site of application. Dr F documented that Mr B was keen to try the injectable medication but she encouraged him to start with the nasal spray. Dr F recommended an apomorphine, phentolamine[22] and Maxolon (APM) nasal spray for 12–18 months. Dr F documented that she discussed the side effects of the nasal spray.

86. Dr F documented that she explained her "independent GP situation" to Mr B, and told him that the Advanced Medical Institute's medications were imported from Australia "under the necessary legal sections". Dr F explained how the nasal spray worked and advised Mr B to contact the Advanced Medical Institute within two weeks to report the efficacy of the medication. She told him to discontinue using the nasal spray if he was not tolerating it, and to contact the Advanced Medical Institute to replace it with an alternative medication. Dr F told Mr B that delivery in a nasal spray was a "different" use of the medications than the usual way of delivering them, "the main benefits of which were the ability to use them in smaller amounts, thereby reducing the risk of the usual side effects, and the convenience of this combination nasal spray, in the circumstances they would be required". Dr F did not inform Mr B that, while

remain, unless contraindicated, the standard first line of pharmacological treatment of [erectile dysfunction]".

[20] Letters dated: 26 November 2009, 31 March 2010, 16 September 2010, and 11 April 2011.

[21] Phosphodiesterase inhibitors are drugs that block the enzyme phosphodiesterase, and include Viagra (sildenafil) and Cialis (tadalafil). These drugs enhance blood vessel expansion in the penis and are used to treat erectile dysfunction.

[22] Phentolamine is a non-selective alpha-adrenergic antagonist. It causes blood vessels to expand, thereby increasing blood flow. When injected into the penis, it increases the blood flow, resulting in an erection.

apomorphine, phentolamine and Maxolon are approved medicines in New Zealand, they are not approved for use in nasal sprays.

87. Dr F did not document the dosage, frequency and volume of the APM medication on the patient assessment form or in her clinical notes. Dr F explained that this was "simply an omission or oversight", which probably occurred "because the documenting was always done on the script and [she] was aware that Advanced Medical Institute's pharmacy APM was the only one called APM, and has one particular dosage which had a safe therapeutic range". She further stated: "There was one [Advanced Medical Institute] NZ compounding pharmacist to which the scripts were sent and he himself makes up the nasal spray, according to the preset dosages, which is also recorded on the prescription."

88. Dr F did not document any discussion about costs. She later stated:

> "[W]hile I did not give [Mr B] a specific number, which I myself had no knowledge of, I told him it would not be cheap. I was also aware that it was [Advanced Medical Institute's] process to have a full discussion with the patient about the costs and for him to choose the treatment or length of course, which he felt he was prepared to pay for, given the advice I gave him about the treatment options, their effectiveness and side effects and how they worked."

89. On 20 February 2009, Mr B spoke with Advanced Medical Institute clinical co-ordinator Ms G, and advised that he would prefer to use the injections. An Advanced Medical Institute administrator noted that the clinical co-ordinator was checking with Dr F to make sure Mr B could use the injections. Ms G noted that a doctor should explain how to use the injections prior to him picking up the medications. Mr B came into the clinic and paid a $300 deposit for a programme costing $1,810.

Consultation — 24 February 2009

90. On 24 February 2009, Mr B returned to the Advanced Medical Institute clinic and was seen by Dr F. Dr F recorded that Mr B did not have an appointment but she "pushed him in". Dr F noted that Mr B was not happy with starting with just the nasal spray and wanted to try the injectable as well. However, as there was limited time she told Mr B to come back for further education by the nurses, after watching the educational DVD that was to be enclosed with the medications. She prescribed injectable prostaglandin for Mr B and added it to the script for the nasal spray that she was already processing.[23]

91. Mr B cannot recall anyone at the Advanced Medical Institute clinic telling him about side effects of the medications or what to do if he was not satisfied.

92. The Advanced Medical Institute's Nurse Reference Folder states that contraindications for all its injectable medications include: penile deformity, scarring

[23] Dr F confirmed this prescription on 3 March 2009.

and recent bend. Dr F did not conduct a physical examination of Mr B's penis. After reading the advice from HDC's expert advisor that a penile examination should have been performed, Dr F said that when Mr B returned for his training, the "doctor/nurse team of the day" would have conducted a penile examination (to exclude any signs or symptoms of Peyronie's disease).[24] She stated that she was aware of the need to conduct an examination to "ensure [Mr B's] safety before the medication was released to him". However, she stated that Mr B was not going to have access to the medicines until a genital examination had been conducted. She explained:

> "[T]he plan was that he would return to the clinic to have his injection training and genital exam with the appropriate male nurse chaperone and myself prior to commencing the injectable trial. I therefore requested the medication to be sent to the clinic to tie in with that expected examination, so it could all be done at the same time."

93. Dr F later stated:

> "(a) [I]t is my practice to ensure that I conduct a physical examination of patients;
> (b) that I considered that a physical examination of [Mr B] was appropriate;
> (c) that on the day in question, I did the most appropriate assessment that one could do, under the circumstance with no nurse available as a chaperone for the patient's support to enable the physical examination to be conducted in the most sensitive and appropriate manner;
> (d) that in these circumstances, it is my usual practice, and it was my intention in this instance, to conduct the physical examination when the patient returned to the clinic for the nurse education regarding use of the medication;
> (e) [Mr B's] injectable medication was to be sent to the clinic where it would be provided to [Mr B] for the training, only after the physical examination had been conducted and after he had attended the comprehensive nurse education regarding use."

94. At the end of his consultation, Mr B paid a further $300 deposit by cheque.[25]

Delivery of medication

95. Mr B said he was told that the two medications would be dispatched to his mailbox within two weeks. The Advanced Medical Institute's computer records for Mr B show that his medications were to be couriered "direct by post to patient". The Advanced Medical Institute has not been able to provide a copy of Mr B's contractual agreement

[24] Peyronie's disease is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis, and affecting a small percentage of men. The disease may cause pain; hardened, big, cord-like lesions (scar tissue known as "plaques"), or abnormal curvature of the penis when erect.
[25] The Advanced Medical Institute's computer system (on 19 and 20 February 2009) shows that Mr B signed up for a six-month programme for $1,800. However, Dr F's entry in the computer system on 3 March 2009 states a programme length of 12 months for both medications.

with the Advanced Medical Institute, which would have stated whether his medications were to be sent to Mr B or the clinic, and the length of his programme.

96. On 25 February 2009, an Advanced Medical Institute administrator noted that Dr F had not recorded what injectable medications she had prescribed for Mr B, and was going to check with Dr F. On 3 March 2009, Dr F visited the clinic and confirmed Mr B's prescriptions.

97. Mr B said that he contacted the Advanced Medical Institute clinic twice in March 2009 to enquire about the whereabouts of his medication, and the Advanced Medical Institute advised him that the medication was in the process of being forwarded to him from Australia. The Advanced Medical Institute's computer record shows that medications were sent on 12 March 2009. However, a mistake was made regarding Mr B's medication courier tracking number,[26] and this medication was not sent. Mr B's medication was apparently dispatched from Australia on 16 March on a second courier tracking number. Courier tracking information shows that the medication was signed for on 9 April 2009 by "[Mr H]" (Mr H is a pharmacist for the Advanced Medical Institute). At that time the Advanced Medical Institute believed that the medications were received by Mr B.

98. Mr B never received the medication.

Complaint

99. On 1 April 2009, Mr B complained to HDC.

100. Following contact from HDC, the Advanced Medical Institute offered Mr B a full refund. The Advanced Medical Institute also advised HDC that it was organising a free injectable medication for Mr B for one year. However, the Advanced Medical Institute later confirmed that no such offer had been made, and apologised to Mr B for the "inconvenience caused" to him.

2.3 Mr C

Telephone consultation

101. On 2 November 2007, Mr C (then aged 53 years) rang the Advanced Medical Institute's 0800 number after hearing its advertisement on the radio. Mr C had previously seen his own GP and trialled a treatment for erectile dysfunction; however, that treatment was ineffective.

[26] Mr H, pharmacist, provided a copy of a fax he received from the Advanced Medical Institute's head office on 10 March 2009. This shows the names of the Advanced Medical Institute clients for whom he was to receive consignments, together with their addresses, medications and the respective courier tracking numbers. Mr B was the only client without a courier tracking number, and one of the numbers previously supplied by the Advanced Medical Institute was for the patient directly above Mr B's name. Mr H said he had not received any medications or a prescription for Mr B.

102. The Advanced Medical Institute advised that Mr C had spoken to a vocationally registered general practitioner in Australia. The Advanced Medical Institute's computer records for Mr C note that he had a problem with premature ejaculation, and that tramadol nasal spray was to be prescribed by the vocationally registered general practitioner.[27] Mr C denies discussing any particular problems or medications with an Advanced Medical Institute doctor.

103. The Advanced Medical Institute stated that Mr C agreed to visit an Advanced Medical Institute clinic. However, Mr C recalled that the Advanced Medical Institute told him to see his own doctor to get a clearance to use its medications. During the telephone conversation, the Advanced Medical Institute asked for Mr C's credit card details, as proof of method of payment. Mr C said that he had asked only for information and was expecting to be sent a pamphlet. The Advanced Medical Institute did not tell him that his credit card would be charged following the call.

104. A few days later Mr C received direct debit forms for a 12-month programme costing $2,495. The Direct Debit Service Agreement recorded that a $1,200 deposit had been paid. Mr C discovered that his credit card had been charged $1,200 on the day of his call to the Advanced Medical Institute. The direct debit forms include the statement: "I acknowledge that I have read and accepted the terms and conditions of this contract including those set out in the attached Advanced Medical Institute 'Satisfaction and Privacy Policy'." However, the "Satisfaction and Privacy Policy" was not attached. Mr C was not sent any medications or any information about Advanced Medical Institute medications.

105. On discovering the credit card charge, Mr C's wife rang the Advanced Medical Institute to advise that they did not want to purchase anything from the Advanced Medical Institute. Advanced Medical Institute staff (appropriately) refused to talk to Mr C's wife without his permission owing to privacy requirements. On 20 November 2007, Mr C faxed through his permission with a copy of his and his wife's driver licences. Mr C said that the Advanced Medical Institute initially continued to refuse to talk to his wife until an Advanced Medical Institute staff member said she would contact the refund department and someone would contact Mr C in a few days' time.[28]

106. On 5, 7, 15 and 22 November 2007, Dr F recorded queries in the Advanced Medical Institute's computer system about whether she was to see Mr C face-to-face or whether he was going to see his general practitioner.

107. On 23 November 2007, an Advanced Medical Institute administrator noted that Mr C wanted to cancel his programme, and that his wife had his permission to speak on his behalf. It was also noted that his general practitioner had advised him not to go on the

[27] Tramadol is a central-acting analgesic used primarily in the treatment of moderate to moderately severe pain. It has a recognized off-label use in the treatment of premature ejaculation.
[28] On 30 November 2007 an Advanced Medical Institute administrator noted the receipt of Mr C's fax of 20 November 2007.

programme. However, on 26 November 2007, an Advanced Medical Institute administrator noted: "NON 48 Hour… NO REFUND… Awaiting outcome from Dr F f2f." Later that day another administrator entered: "Refund Decision: Rejected by Case Manager … Approval Amount: 0."

108. On 3 December 2007, Dr F noted: "[W]ill go back to his dr, [Dr K] who told him not to do ami? so awaiting [refund]." Mr C said that the Advanced Medical Institute contacted him and, when he confirmed that he did not need anything for erectile dysfunction, he was told he needed to get a medical certificate from his GP to verify that this was the case, and fax it to the Advanced Medical Institute. Mr C visited his GP on 5 December 2007 and obtained a medical certificate, which he faxed to the Advanced Medical Institute. The Advanced Medical Institute noted receipt of this fax on 7 December 2007.

109. The computer record entry on 12 December states: "Refund Decision: Rejected by Case Manager … Approval Refund Amount: 0 … NON 48 HOUR … REFUND … NZ$1,200. Pt unsuitable for meds as per drs letter." The Advanced Medical Institute advised that Mr C's refund was approved on this date but "due to a clerical error" the refund was not sent.

110. On 1 January 2008, Mr C wrote to the Advanced Medical Institute asking for a refund but did not receive a reply.

Complaint

111. On 1 April 2009, Mr C complained to HDC as he had received no response to his request for a refund.

112. Following contact from HDC, the Advanced Medical Institute offered Mr C a full refund and an apology. The Advanced Medical Institute also offered Mr C free treatment if he visited a clinic, but Mr C declined.

113. The Advanced Medical Institute could not offer an explanation for why Mr C was charged for a medication programme without a face-to-face consultation. The Advanced Medical Institute later agreed that Mr C should not have been charged, and stated that Mr C was charged owing to a "process error", which has since been rectified.

2.4 Mr D

Telephone consultation

114. On 15 April 2008, Mr D (then aged 50 years) rang the Advanced Medical Institute's 0800 number after seeing an item on television. Mr D had erectile dysfunction and a prostate problem. Mr D spoke to an Advanced Medical Institute telephonist, who told him that a doctor in Australia would telephone him.

115. Later that day Mr D was telephoned by a man who identified himself as a doctor. The Advanced Medical Institute stated that Mr D spoke with one of their doctors in Australia, Dr N. The doctor asked Mr D some basic questions about his health. Mr D told the doctor that he wanted a face-to-face consultation with one of the Advanced Medical Institute's local doctors to examine him and to assess whether his prostate problem might be worsened by its treatment or the treatment would be ineffective because of it. Mr D recalls being told only about the nasal spray and not the other medications. Mr D cannot recall being told about side effects as he was adamant that he wanted to see a doctor first.

116. The Advanced Medical Institute computer-generated record for 15 April 2008, logged as "Doctor's comments", states:

> "Benign enlarged prostate. BPH ED and PE vardenafil spray for ED — PQ spray. In a few weeks add tramadol for PE for a combined spray. Injection therapy discussed as an option. *Note clomipramine is not indicated due to prostate."[29]

117. Mr D asked to be sent information, and said that the Advanced Medical Institute refused to send him a brochure about the treatments it offers, but said that the local doctor would be able to provide him with information.

118. On 16 April, Mr D was telephoned back by a New Zealand telephonist, who told him he had an appointment with a doctor on 7 May 2008. Mr D said that the Advanced Medical Institute telephonist then asked Mr D for his credit card details so that his treatment could be processed as soon as he had seen the doctor. Mr D recalls discussing only the monthly cost of treatment, and was under the impression that he would therefore be able to cancel his monthly payments at any time. Mr D is clear that he did not agree to pay a lump sum for a treatment programme.

119. On 30 April 2008, according to the Advanced Medical Institute's computer-generated records, an Advanced Medical Institute administrator faxed Mr D's prescription to the pharmacist in New Zealand, Mr H. The records contain the entry, "script faxed to pharmacy. [Mr H] to get signed script from [another] clinic — done for [another employee]". However, the prescription was signed by Dr N. The Advanced Medical Institute explained:

> "[A] script was generated in error and sent to the New Zealand pharmacy. The pharmacy again in error dispatched the medications to [Mr D]. The script was signed by an Australian Doctor and was obviously a mistake. We have since taken steps to ensure that this error does not occur and implemented a new system whereby all scripts sent to the NZ pharmacy are first checked by a designated person to ensure that all scripts have been signed by a New Zealand doctor."

[29] Vardenafil is a phosphodiesterase inhibitor. It is closely related in function to sildenafil citrate (Viagra) and tadalafil (Cialis).

The Advanced Medical Institute stated that no treatment decisions or clinical assessments were made in respect of Mr D.

120. On 2 May 2008, nasal spray medication for erectile dysfunction, and the Advanced Medical Institute's instruction booklet, were delivered to Mr D's home. Mr D then discovered that his credit card was charged $2,880 on the same day as his call to the Advanced Medical Institute (15 April 2008).

121. On 7 May 2008, Mr D went to his Advanced Medical Institute scheduled appointment with the doctor. However, the doctor's clinic had no record of an appointment for Mr D. The doctor was not working at that time and was not expected back for about a month. Mr D rang the Advanced Medical Institute and was told that it would make another appointment for him, but never did.

122. The Advanced Medical Institute's computer records logged Mr D's call and asked its New Zealand customer services to contact Mr D urgently to avoid a cancellation. Mr D said that he made several calls to the Advanced Medical Institute's 0800 number. The Advanced Medical Institute's computer records show that Mr D contacted the Advanced Medical Institute on 7, 12, 19 and 21 May 2008. Mr D said that he was then told that the Advanced Medical Institute did not have any doctors in that city. The Advanced Medical Institute later said that the nearest doctor contracted to work for them was in another city.

123. Mr D was told that the Advanced Medical Institute would not cancel the charge to his credit card. On at least four occasions Mr D was assured that someone from the Advanced Medical Institute would ring him, first to arrange an appointment, and then to discuss his complaint. However, no one from the Advanced Medical Institute called Mr D.

124. Mr D later discovered that the Advanced Medical Institute required him to try all the medications before he would be eligible for a refund. Mr D stated that the Advanced Medical Institute said that all telephone conversations were recorded but, when he asked for a copy of the 15 April recording, the Advanced Medical Institute said a record of his telephone calls could not be located. The Advanced Medical Institute's computer records (on 29 May 2008) state that Mr D's voice could not be heard during the recording.

125. In June 2008, Mr D contacted his bank, which reversed the charge to his credit card. The Advanced Medical Institute did not challenge the reversed charges.

Complaint

126. On 8 June 2008, Mr D complained to HDC. His complaint was originally referred to the Ministry of Health, as it raised public safety concerns in regard to sending prescription medication to patients without a medical examination. Mr D was happy with this provided that his complaint was a one-off. Aspects of Mr D's complaint relating to improper prescribing practice were investigated by Medsafe and Medicines

Control. On 31 July 2009, Mr D confirmed that he wished his complaint regarding Advanced Medical Institute to be reopened since HDC had received complaints similar to his.

127. On 8 June 2010, the Advanced Medical Institute acknowledged that Mr D should not have been charged for any medication. The Advanced Medical Institute stated that Mr D was charged owing to a "process error", which has since been rectified.

2.5 Actions taken by providers

Dr E

128. Dr E said that over time he became concerned that the Advanced Medical Institute's practice was not "patient-focussed". Dr E stated:

> "Advanced Medical Institute made it clear to me that I was not there to offer treatment but to make sure that the treatments that were being provided by Advanced Medical Institute were not contra-indicated and that the medications were safe for the patients. However, I never really felt comfortable in this role. It was for this reason that I suggested to [**Mr A] that he did not really need anything for the problems that he had and that he would be better off going to see his GP about his poor urinary flow.**
>
> …
>
> I never really felt comfortable in that environment, where our options were restricted by Advanced Medical Institute."[30]

129. Dr E ceased working for the Advanced Medical Institute in mid-2009.

Dr F

130. Dr F recognised the following improvements to the care she delivers:

> "(a) conscious and aware of the need to ensure that dosages are recorded in my clinical notes at all times;
> (b) prepared to take steps to ensure that I explain the approvals process more fully, if necessary and I am more than willing to now use the professional terms as well, rather than the layman's language if you think that is better;
> (c) prepared to take steps to clarify with my patients that they accept that they have been given full information about costs, particularly where I in part expect that information, to be given to them by another person."

131. At the beginning of 2010, Dr F ceased working for the Advanced Medical Institute.

132. Dr F explained that she:

[30] Emphasis in original.

> "experienced some cognitive dissonance and concerns in my discussions with [Advanced Medical Institute] and the full ethical implications of the practitioner's role, but I sought to the best of my ability to honestly and empathically inform and support the patients in all respects from the clinical side, to counselling support role that I often ended up providing, and to the quite common recommendation to stay with the Viagra they had used previously, and all in the context of a sometimes difficult clinical situation due to nursing recruitment problems and trans-Tasman administrative or communication glitches.
>
> …
>
> If I was still working for Advanced Medical Institute … I would be continuing to press Advanced Medical Institute to ensure that nurses are available to act as chaperones to enable physical examinations to take place at the first consultation. I note that while I was with Advanced Medical Institute that was something I was constantly campaigning for even as they struggled with recruitment."

Advanced Medical Institute

133. The Advanced Medical Institute advised that it:

> "has made numerous changes to [its] procedures since these complaints have come [to] light. In relation to refunds and claims [Advanced Medical Institute] now has one centralized refund department which deals with all customer complaints in a timely manner and ensures that all customer refunds are processed in a timely manner. In relation to procedures relating to scripts [Advanced Medical Institute] has now adopted a script checking policy to ensure that each script generated is signed by the correct doctor and the medications are dispatched in a timely manner through the correct channels. [Advanced Medical Institute has] also provided its staff with extensive training in relation to dealing with customers on all levels. [Advanced Medical Institute] is also in the process of considering the training provided to staff and contractors with a view to improving the services provided to patients."

It also advised that it was "unaware" of the "requirement for doctors to specifically advise patients where treatments are being used on an off label basis" and it "has now instructed doctors that they need to advise patients of these matters in further detail and are updating their internal procedures to fully comply with these requirements".

Supporting Information

134. Expert advice provided by Dr David Maplesden is attached as **Appendix 1**.

135. The rights in the Code of Health and Disability Services Consumers' Rights and guidelines and standards relevant to this complaint are attached as **Appendix 2**.

Part 3: Opinion — doctors

3.1 Opinion: Breach — Dr E

136. Mr A (then aged 71 years) sought treatment for erectile dysfunction from the Advanced Medical Institute. He has a significant medical history, and was taking a number of medications. His Advanced Medical Institute records note that he had been prescribed Viagra previously, but had never used it. On 7 January 2009, Mr A attended an Advanced Medical Institute clinic and saw Dr E.

Standard of care

137. My expert advisor, general practitioner Dr David Maplesden (see Appendix 1), advised that there were some deficiencies in Dr E's assessment of Mr A. In particular, the questionnaire template was not fully completed, and Dr E did not elicit Mr A's history of depression even though an antidepressant was listed in his current medications. As erectile dysfunction can have a psychological cause, Dr E should have recorded and explored Mr A's psychological state.

138. Dr E did not complete a full physical examination of Mr A. Recordings are noted for blood pressure, pulse and chest auscultation,[31] and Dr E said he also checked Mr A's abdomen. Mr A does not recall any physical examination, and Dr E made no clinical notes about an abdominal examination. Dr E diagnosed Mr A with minor sexual dysfunction, but also prostatic enlargement (about which Dr E advised Mr A to see his GP). My expert advisor, Dr Maplesden, commented that it is unclear on what basis Dr E determined that Mr A had prostatic enlargement, given that he had not performed a rectal examination.

139. Dr Maplesden advised that Dr E should have performed an abdominal and genital examination on Mr A. Dr Maplesden pointed to European and Australian guidelines for GPs on erectile dysfunction, which state that patients must be given a physical examination focused on the genitourinary (penile, testicular and rectal examination), cardiovascular (blood pressure, heart rate, waist circumference, abdominal aortic aneurysm, carotid bruits, foot pulses), and neurological (focused neurological examination) systems.[32] Dr Maplesden advised that, while the physical examination undertaken by Dr E was sub-optimal, the lack of suitable facilities to conduct such an examination (discussed below) was a mitigating factor in this case. Nonetheless, Dr E

[31] Listening to chest sounds.

[32] Andrology Australia, "Erectile Dysfunction: Diagnosis and Management: GP Clinical Summary Guide 9" (July 2007). The 2010 updated version of these guidelines is available at: www.andrologyaustralia.org/wp-content/uploads/clinical-summary-guide09_May20101.pdf. On 26 April 2012 my expert, Dr Maplesden, advised HDC, "The revised Andrology Australia guidelines are not substantially different to the 2007 guidelines quoted with respect to recommended examination and treatment options and remain consistent with the European guidelines quoted initially". Wespes E et al., "Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation" (European Association of Urology, March 2009), available at http://www.uroweb.org/gls/pdf/Male%20Sexual%20Dysfunction%202010.pdf.

must also take responsibility for not performing an adequate physical examination on Mr A. As a medical practitioner, with a responsibility to provide services with reasonable care and skill, Dr E should not have recommended a treatment programme if he was unable to complete the appropriate examinations.

140. In my expert's opinion, the medication Dr E recommended (apomorphine/ Maxolon in nasal spray form) was reasonable for Mr A. However, due to his co-morbidities, his chances of success were "likely to be somewhat limited" and Mr A should have been advised of this.

141. Dr E's assessment of Mr A also did not reveal that Mr A had been prescribed a glyceryl trinitrate (GTN) spray for angina. Dr Maplesden advised that there could be significant implications if a phosphodiesterase medication, such as Viagra, was prescribed for Mr A with concurrent use of GTN spray. Dr Maplesden advised that "use of this type of medication needs to be asked about specifically rather than waiting for the patient to volunteer such information as its use is often intermittent and it may not be viewed by the patient as a "'regular' medication". While I acknowledge that Dr E did not recommend a medication that was contraindicated with the GTN spray, I accept Dr Maplesden's advice that failure to obtain this relevant information in a consultation relating to erectile dysfunction was a departure from accepted standards.

142. Overall, I consider that the standard of care Dr E provided to Mr A departed from expected standards.

Adequacy of information

143. Mr A's recollection of his consultation with Dr E was that the conversation was mostly off-topic. Mr A recalls discussing the nasal spray but none of the other medications. He thinks he may have been told about side effects and was told to ring the Advanced Medical Institute if there were any problems. Mr A was not provided with any written information, as this was to be sent with the medication.

144. Dr E said that he gave Mr A a detailed description of how to use the nasal spray, the dosage and side effects, and the action he had to undertake in the event of a side effect. Dr Maplesden said that while Dr E states that he had given Mr A verbal and written information regarding the treatment, it is not apparent that there was any discussion regarding the treatment programme which, he advised, "has the potential to be somewhat more complex than trying a single medication for a limited period".

145. It is clear that the process at the Advanced Medical Institute clinic was for the doctor to recommend a treatment to the patient, and the patient would then discuss the length of the programme and costs with administrative staff (see discussion below). I accept that Dr E understood that the clinical co-ordinator would be discussing costs with Mr A, so did not provide Mr A with any information about costs. In a previous opinion, the clinical advisor commented that "where a doctor is aware that a recommended course of treatment will be expensive, some information in that regard should be

provided by the prescribing doctor".[33] I consider that the cost of the programme Mr A was offered was important information that he needed in order to make an informed decision about whether to proceed with treatment. Given that the doctor advises the patient on what length of treatment programme would be appropriate, including the risks and benefits of choosing a particular programme length, some information about the different costs involved should have been provided before Mr A chose which (if any) treatment option he would consent to. Therefore, in order to fulfil his obligation to provide information that a reasonable consumer, in that consumer's circumstances, would expect to receive, Dr E should have included an explanation of the options available to Mr A along with an assessment of the risks, benefits, side effects, and costs of those options. That discussion should also have included an explanation of the Advanced Medical Institute's treatment programme, and the option of other medications and counselling, even if not offered by the Advanced Medical Institute.

146. Dr E recommended approved medicines (apomorphine and Maxolon) for an unapproved purpose and method of administration. There is nothing in the clinical record to suggest that Dr E discussed this with Mr A. On the basis of the information before me I am unable to determine whether or not that information was in fact provided to Mr A. In that regard I note that Medsafe[34] 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).[35] 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. Providers need to be mindful of their obligations under Right 6 of the Code when prescribing off-label medications.

Conclusion

147. In my opinion, by his failure to undertake an adequate physical examination, his failure to elicit Mr A's history of depression, and his failure to establish Mr A's use of GTN spray, Dr E failed to provide Mr A services with reasonable care and skill, and therefore breached Right 4(1) of the Code. By failing to provide information to Mr A about treatment options available to him Dr E did not provide Mr A with information that a reasonable consumer in Mr A's circumstances would expect to receive, and therefore breached Right 6(1)(b) of the Code.

148. By Dr E's own admission, he had concerns about the Advanced Medical Institute's practice. I accept that Dr E saw Mr A on his first day working for the Advanced Medical Institute, as a favour to his colleague. Accordingly, he may not have been

[33] Opinion 08HDC02899, 08HDC05986, 08HDC07100, 08HDC09984 (18 December 2008), available at www.hdc.org.nz.
[34] Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.
[35] Available at http://www.medsafe.govt.nz/profs/RIss/unapp.asp

fully aware of the Advanced Medical Institute's policies and procedures at the time that he saw Mr A. However, medical practitioners always have a responsibility to ensure that services are provided in accordance with the Code.

3.2 Opinion: Breach — Dr F

149. In February 2009, Mr B (then aged 75 years) sought treatment for erectile dysfunction from the Advanced Medical Institute. He saw Dr F on two occasions.

Standard of care

150. At Mr B's appointment on 19 February 2009, Dr F recorded a detailed clinical history, performed a cardiovascular assessment of Mr B, and recorded his blood pressure and pulse. My expert advisor, Dr Maplesden, stated that the general assessment of Mr B "appears to have been mostly adequate with standard erectile dysfunction questionnaire completed and a basic physical examination undertaken, although there is no genital examination recorded".

151. On 24 February 2009, Dr F saw Mr B again at the Advanced Medical Institute clinic, as Mr B wanted to try the injectable medication. Dr F explained that, as there was limited time, she told Mr B to come back for further education by the nurses, after watching the educational DVD that was to be enclosed with the medications. Dr F stated that she prescribed injectable prostaglandin for Mr B with the intention that he would return to the clinic to pick it up and to receive training on using the injections.

152. Dr F did not conduct a physical examination of Mr B's penis. It was only after she read my expert advisor's advice that she should have conducted such an examination that she said she was aware of the need to do so, and had intended to do so. Dr F subsequently explained that she did not have the time or a male chaperone to undertake an examination of Mr B's penis at the second appointment, and that she intended to perform the examination when Mr B returned for training and before the medication was released to him.

153. Dr Maplesden advised that observation of Peyronie's disease would have been a contraindication to prescribing the injections, so Dr F should have checked for this before prescribing the medication. He pointed out the distinction between the training required for penile injections (which could quite reasonably be deferred until the patient had received his prescription, and which could reasonably be undertaken by a male nurse), and the requirement to exclude contraindications to the use of the medication (in this case, Peyronie's disease) before prescribing the medication. It is not appropriate for a patient to be offered and prescribed medication, pay for the medication, and have education sessions arranged, prior to establishing that the patient has no contraindications to the use of that medication. Dr Maplesden advised that the failure by Dr F to undertake a genital examination on Mr B, either at her original consultation with him or at least before prescribing him injectable medication, was a mild to moderate departure from expected standards (even if Dr F intended to

undertake an examination when Mr B presented for training in the injection technique).

154. Dr F did not document the dosages and volumes of the medications she prescribed. Dr F accepted this failing, and advised that she will ensure it will not happen in future.

155. Dr Maplesden advised that "the overall management of [Mr B] by [Dr F] departed from expected standards to a mild to moderate degree". In my view, by not conducting a penile examination and not appropriately recording medication prescribed, Dr F failed to provide Mr B services with reasonable care and skill, and breached Right 4(1) of the Code.

3.3 Adverse Comment — Dr F

156. Dr F prescribed approved medicines (apomorphine, phentolamine and Maxolon) for an unapproved purpose and method of administration. Dr F told Mr B that the Advanced Medical Institute complied with medicine regulations but did not advise him that while the medications were approved for use in New Zealand their use for the purpose of treating sexual dysfunction and their administration by way of nasal spray formulation was not an approved use. I do not accept Dr F's assertion that "different" use is an adequate explanation of the concept of unapproved use. Mr B should have been made aware that prescribing the APM nasal spray for erectile dysfunction was an "off-label" use of the medication not currently included in relevant erectile dysfunction management guidelines,[36] and not generally recognised as the first step in treatment for erectile dysfunction.

157. When undertaking such prescribing a medical practitioner must be mindful of his or her obligations under Right 6 of the Code. There will be occasions when a medical practitioner will need to advise a patient that the proposed use is unapproved. In my view, a reasonable consumer, in Mr B's circumstances, would expect to receive an explanation of the nature of the unapproved "use" (ie, indication, dosage or route of administration), as well as the degree and standard of support for the use of the medicine, and of any safety concerns, warnings or contraindications regarding its use.

Part 4: Opinion — Advanced Medical Institute (NZ) Ltd

4.1 Introduction

158. The Advanced Medical Institute provides treatments to people suffering from erectile dysfunction and premature ejaculation, and markets directly to the public. Section 3(k) of the Health and Disability Commissioner Act 1994 (the HDC Act) states that a

[36] See above, footnote 32 (Andrology Australia).

health care provider includes any person who provides, or holds itself out as providing, health services to the public. Given that health services include treatment services, the Advanced Medical Institute falls within the definition of health care provider. As a provider of health care services, the Advanced Medical Institute is subject to the duties set out in the Code, in particular to provide services of an appropriate standard (Right 4), to provide information that a reasonable consumer, in that consumer's circumstances, would expect to receive (Right 6), and to respond to complaints in accordance with its obligations under Right 10 of the Code.

159. Furthermore, as a health care provider, the Advanced Medical Institute is also an "employing authority",[37] and therefore may be vicariously liable for acts and omissions by an employee, an agent, or a member.[38] I acknowledge that most people providing services on the Advanced Medical Institute's phone lines or at the Advanced Medical Institute clinics are independent contractors. I also note that the Advanced Medical Institute template contract with "Consultants" states that the consultant "is not and will not represent that he is" an employee, servant or agent of the Advanced Medical Institute. Despite this, there are circumstances in which the actions of the parties can lead to a relationship of agency being implied. While an organisation is usually not vicariously liable for the acts or omissions of independent contractors, in some cases an independent contractor may be considered an agent of the person or organisation with whom he or she contracted. This has been recognised in previous HDC opinions relating to private hospitals contracting doctors.[39]

160. As noted by the Court of Appeal:[40]

> "The legal principles relating to ostensible or apparent agency are well settled. A person who by words or conduct has allowed another to appear to a third party to be his or her agent cannot afterwards repudiate that agency."

161. In my opinion, the Advanced Medical Institute allowed its contractors to appear to be its agents. The clinics that Mr A and Mr B attended were "Advanced Medical Institute" clinics, with signs on the door stating "Advanced Medical Institute (New Zealand)". The Advanced Medical Institute advertises its 0800 number as the Advanced Medical Institute's "Confidential Advice Line", and members of the public can call this number to speak with a person about the Advanced Medical Institute's products. Consumers may reasonably assume that they are dealing with the Advanced Medical Institute representatives both on the telephone and in the clinics. No steps were taken to notify consumers otherwise. Accordingly, I am satisfied that the persons involved in providing services to Mr A, Mr B, Mr C and Mr D were acting as agents of the Advanced Medical Institute.

[37] HDC Act, section 72(1).
[38] HDC Act, sections 72(2), 72(3) and 72(4).
[39] For example, Opinions 99HDC06799, 04HDC04456, and 06HDC00096.
[40] *Arthur Watson Savage v Kathleen Taylor*, unreported, 19 March 1996, Richardson P, CA 103/95.

162. Section 72(3) provides that anything done or omitted by a person as the agent of an employing authority shall, for the purposes of the Act, be treated as done or omitted by that employing authority as well as by the first-mentioned person, unless it is done or omitted without that employing authority's express or implied authority, precdent or subsequent.

163. Accordingly, the next question is whether the actions or omissions of the agents were with the Advanced Medical Institute's express or implied authority, precedent or subsequent, which involves consideration of whether the agent's acts are sufficiently connected with acts that are expressly authorised. I am satisfied that the actions of the persons working on the Advanced Medical Institute phone line and in the Advanced Medical Institute clinics were sufficiently connected to their expressly authorised roles (as Advanced Medical Institute contractors). This includes Dr E who, at the time of his consultation with Mr A, was working as a sub-contractor for Dr I. It is well recognised at law that agency–principal relationships can be created through subsequent ratification,[41] and, in my view, AMI subsequently ratified its agency–principal relationship with Dr E when it allowed Dr E to continue to work at its clinic after being put on notice of the sub-contractor arrangement.

164. Under section 72(5) of the Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the breach of the Code.[42] At a practical level, this generally translates into having good robust systems in place, providing appropriate training, guidance and support, and ensuring ongoing audit and review.

4.2 Advanced Medical Institute systems

165. When asked to describe the clinical services the Advanced Medical Institute offers, the Advanced Medical Institute stated:

> "[Advanced Medical Institute] arranges for patients to be provided with medical services and treatments relating to the treatment of erectile dysfunction and premature ejaculation. The medical services are provided by fully registered medical doctors such as [Dr F] and the treatments are provided by a registered pharmacy."

166. The Advanced Medical Institute offers only a limited service. It offers its own medications to patients and does not provide any information to patients about other treatment options, or any psychosexual counselling. My expert advisor, general practitioner Dr David Maplesden, commented that "psychogenic causes make a

[41] Hubbard, J., Thomas, C., and Varnham, S., *Principles of Law for New Zealand Business Students* (third edition) (Pearson Education New Zealand, 2006) p464; Burrows, Finn, and Todd., *Law of Contract* (eighth edition) (Butterworths, Wellington New Zealand, 1992) p484.

[42] While the defence set out in section 72(5) refers to "employees", it is generally considered to be available in respect of agents (see *Totalisator Agency Board v Gruschow* [1998] NZAR 528).

significant contribution to the aetiology of [erectile dysfunction], and may be treated by counselling with or without [erectile dysfunction] medication". For men with erectile dysfunction or premature ejaculation, the Advanced Medical Institute offers an escalating range of treatments until patients either achieve their desired results or exit its services (at a financial penalty).

167. Professor of Health Care Policy, Dr Donald Berwick, is often quoted as saying, "every system is perfectly designed to achieve the results it achieves".[43] On the basis of these four cases, it is clear to me that the Advanced Medical Institute had poorly designed systems, which resulted in the provision of a poor standard of services to consumers. This is evidenced by the Advanced Medical Institute not having an adequate orientation or training process for its contractors; not providing appropriate guidance to its contractors (in the form of written policies or procedures); not providing adequate information to consumers; and having poor record-keeping systems.

Orientation and training

168. While I accept that the Advanced Medical Institute should have been able to rely on the doctors it contracts to provide services of a professional standard, as an employing authority the Advanced Medical Institute still has a responsibility to orientate contractors to its service and to provide appropriate support to its contracted doctors.

169. The Advanced Medical Institute provides its doctors with a Nurse Reference Folder, a medication booklet for patients, and a DVD. In my view, the training material the Advanced Medical Institute provided on a disk to its doctors should be backed up with clear policies and/or position statements from the Advanced Medical Institute about the treatment programmes it offers, including contraindications, the information expected to be provided to consumers, and the costs of these programmes. Dr Maplesden advised that the material provided is "probably sufficient to give providers a reasonable overview of the treatments they are prescribing". However, he commented that, in the training material provided, there "is a dearth of meta-analyses or systematic reviews of techniques and I would regard the overall presentation of the literature as somewhat biased in nature". In response to my provisional opinion, the Advanced Medical Institute asked HDC to provide an example of the types of analyses and reviewes that HDC would consider appropriate. It is not for HDC to prescribe what types of analyses and reviews should be included in the Advanced Medical Institute's training material. However, it is my job to state the obvious: training material should be clear, accurate, unbiased, and accurately reflect the clinical and legal environment in which services are being provided. At the least, the article arguing that patients do not need to be informed of the off-label status of medications should be replaced with relevant information from Medsafe (see Appendix 2).

170. The Advanced Medical Institute has provided conflicting accounts of the ongoing training it provided to the doctors, and it has not been able to provide any documented

[43] Berwick, D., "A primer on leading the improvement of systems" (1996) 312(7031) *BMJ* 619.

evidence of the training it provided to Dr E or Dr F. As mentioned, the Advanced Medical Institute has provided the sworn affidavit of an Australian registered doctor, which was prepared in relation to an unrelated matter before the Supreme Court of New South Wales. In her affidavit the doctor describes herself as being a consultant to the Advanced Medical Institute Australia Holdings Pty Ltd and of speaking to the practices of that entity as well as Advanced Medical Institute Pty Ltd. She notes that she is not aware of the difference between those (Australian) entities. There is no suggestion in her affidavit that she has ever been contracted to the Advanced Medical Institute New Zealand Ltd or as to what, if any, interaction she might have had with doctors contracted to the Advanced Medical Institute here in New Zealand. As such, the affidavit makes no mention of either Dr F or Dr E. In light of these factors I do not consider that the evidence contained in her affidavit assists me greatly in resolving the issue of what training Dr F and Dr E recieved while contracted to the Advanced Medical Institute (NZ) Ltd. Dr E said that he did not have any meetings or teleconferences, and Dr F described her initial training comprising conversations with Dr L and of DVDs which had been provided by the Advanced Medical Institute. She advised that Dr L was available by telephone if she required assistance or a second opinion. In the absence of any documentary evidence that the Advanced Medical Institute had regular training meetings or teleconferences with Dr E and Dr F, I have formed the opinion that such training meetings or teleconferences did not occur.

171. *Written policies and procedures*

The Advanced Medical Institute denies that it authorised the information provided to Dr E, including instructions on how to conduct physical examinations, and directions not to discuss costs and to recommend treatment programmes of 12 to 18 months. However, it has been unable to provide a copy of similar information it did authorise, aside from its *Nurse Reference Folder*. The information Dr E received also included information that conflicts with some of the information in the *Nurse Reference Folder* and includes relevant information that is not contained within the copy of the folder provided. For example, I note that in the Advanced Medical Institute's *Nurse Reference Folder* there is no stated contraindication for recommending clomipramine to someone with prostate problems, but this contraindication is included in the information provided to Dr E.

172. The Advanced Medical Institute's *Engagement as Consultant* agreement requires doctors to "[c]omply with [Advanced Medical Institute's] lawful directions and published policies and procedures". The only policy the Advanced Medical Institute was able to provide following my request was a copy of its Record Keeping Policy, dated January 2010 and not applicable to the time of these events. In my opinion, the information provided to Dr E, while it may not have been authorised by the Advanced Medical Institute, filled a gap that should have been filled by the Advanced Medical Institute's "published policies and procedures". While Advanced Medical Institute-contracted doctors should obviously fulfil their legal and ethical obligations to patients, in order to fulfil those requirements they needed access to information that only the Advanced Medical Institute held, including information on the medications

and costs of programmes. The Advanced Medical Institute has not satisfied me that it provided sufficient information to Dr E and Dr F. The lack of comprehensive policies and procedures for staff and contractors is surprising and further demonstrates the Advanced Medical Institute's poor administration systems.

Information for patients

173. The information in the Advanced Medical Institute's medication booklets for patients is generally good. However, I consider that the information on the unapproved use of Advanced Medical Institute medications is misleading. I am also concerned that patients are not provided with these booklets until they receive their medication. The booklets cannot be relied upon as part of the informed consent process, however, which requires consumers to be provided with information about the medication options *before* making a choice about treatment. In accordance with Right 6 of the Code, patients need to be provided with all 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.

174. The Advanced Medical Institute supplies its own medications to its patients. These medications use generic brand drugs which have been approved for use in New Zealand albeit not for the purpose of treating sexual dysfunction. Similarly, its nasal spray and injectable delivery methods have not been approved in New Zealand. 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, these materials were not sufficiently detailed or specific. The Advanced Medical Institute has been unable to provide categorical evidence that sufficient information was provided to Dr E and Dr F about the status of the medication and contractor obligations to fully inform their patients about that status. Indeed, the DVD training material suggested that doctors were not required to advise patients that a medication was being used "off-label" (ie, for an unapproved use). This is contrary to Medsafe Guidelines[44] and may, depending on the circumstances, constitute a breach of Right 6 of the Code.

175. In a previous decision, this Office commented that when first-time patients are seeking assistance with a sensitive problem such as erectile dysfunction, particular care is needed to ensure that they understand their treatment options and do not feel pressured to purchase a recommended treatment.[45] Information about costs is especially important when an expensive course of treatment is recommended (see above, para 145). I am concerned that both Dr E and Dr F understood that they were not expected to discuss costs with patients before recommending and prescribing medication to those patients.

[44] See Appendix 2.
[45] Opinion 08HDC02899, 08HDC05986, 08HDC07100, 08HDC09984 (18 December 2008), available at www.hdc.org.nz.

176. Under its "satisfaction" 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, para 56). I agree with my expert advisor, Dr Maplesden, 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."

177. In December 2010 the Advanced Medical Institute altered its refund policy so that patients are no longer required to try each treatment method before being eligible for a refund.

Record-keeping

178. Advanced Medical Institute's patient assessment forms do not identify the doctors and clinical co-ordinators who see each patient. Dr E did not have a separate computer log-on, and the Advanced Medical Institute did not conduct a thorough enough internal investigation to identify from its records that Dr E saw Mr A.

179. The Advanced Medical Institute was also unable to provide copies of the agreements Mr A and Mr B signed, and does not have any clinical records for Mr C's telephone consultation. This demonstrates that the Advanced Medical Institute had poor administration and record-keeping systems. I acknowledge that the Advanced Medical Institute has subsequently stated that it has made improvements to its processes.

4.3 Mr A

Information about service

180. When Mr A first contacted the Advanced Medical Institute, he enquired about the costs of its treatments but was told that it would depend on the treatment the doctor prescribed. As is the Advanced Medical Institute's practice, Mr A was not informed of the cost of the treatment programme recommended until after his consultation with the doctor. Mr A said he was told that the treatment programme was for 12 months, and he was not given any choice of treatment programme lengths. Clinical co-ordinator Ms G advised that her standard practice is to discuss the various payment plans for the treatment programme recommended by the doctor.

181. The Advanced Medical Institute has not been able to provide any direct evidence that Mr A was provided with a range of treatment options, including treatment options not offered by the Advanced Medical Institute, before he consented to treatment and before medication was prescribed for him. Instead, the Advanced Medical Institute submitted that Mr A could have declined to proceed, or requested a different contract term or amount, at any time. In my view, this position disregards the Advanced

Medical Institute's responsibility under Right 6(1)(b) of the Code to ensure that consumers are provided with an explanation of the treatment options available, including the expected risks, side effects, benefits and costs of each option, before consenting to a particular treatment option.

182. For reasons I have set out earlier (see paragraph 145), the cost of the treatment programme is a factor that will generally influence the consumer's decision on the length of the treatment programme he or she consents to, and therefore the consumer needs to be informed of the benefits, risks and costs of choosing a longer or shorter treatment programme length.

183. In my opinion, Mr A was not provided with sufficient information, including information about the cost of the treatment options available to him. Mr A also said that he was not told about the Advanced Medical Institute's "satisfaction" policy, and the Advanced Medical Institute has been unable to provide a copy of its satisfaction policy signed by Mr A. In light of this, I conclude that Mr A was also not provided with sufficient information about the details of the treatment programme he was entering into, in particular the requirement to trial each Advanced Medical Institute treatment method before a refund of any payment would be considered.

184. 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 constitute an "off-label" use of that medication. As discussed above, such information should generally be provided to patients when discussing treatment options. The Advanced Medical Institute responded that all of its "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". However, the Advanced Medical Institute has been unable to demonstrate how doctors were directly informed of this, and has provided training material that suggests doctors are not required to advise patients that a medication was being used off-label (see above, paragraphs 32–34). The Advanced Medical Institute's medication booklets for patients also fail to explain that the medications offered are not approved in that form (see above, paragraph 33).

Lack of appropriate facilities

185. Dr Maplesden advised that the facilities available at the Advanced Medical Institute's clinic for undertaking a physical examination of Mr A (basic physical examination as recommended in the relevant guidelines) "were inadequate and below the standard one would expect in general practice or a specialist [erectile dysfunction] service". Dr Maplesden also pointed to the lack of an examination bed and hand washing facilities.

186. The Advanced Medical Institute stated that examination beds are not required to undertake the types of physical examinations required. However, in its own *Engagement as Consultant* Agreement it states that its services include "diagnosing, managing and treating patients with sexual dysfunction and prostate problems".

Although the Advanced Medical Institute has submitted that the treatments provided by it for prostate problems are limited to herbal treatments to mitigate against urination problems, I note that prostate examinations are normally carried out with the patient leaning or lying on an examination bed. In addition, as stated earlier, Dr Maplesden has pointed to European and Australian guidelines for GPs on erectile dysfunction, which state that patients must be given a physical examination focused on the genitourinary (penile, testicular and rectal examination), cardiovascular (blood pressure, heart rate, waist circumference, abdominal aortic aneurysm, carotid bruits, foot pulses), and neurological (focused neurological examination) systems. On that basis he has advised me that, in the case of Mr A, the lack of an abdominal and genital examination meant that the care provided fell below expected standards. This was not helped by the fact that the Advanced Medical Institute did not supply adequate facilities to allow Dr E to carry out an appropriate examination. Accordingly, in my view, the Advanced Medical Institute is vicariously liable for Dr E's omission.

187. In response to my provisional opinion, the Advanced Medical Institute advised that examination beds have now been installed in the clinic.

Conclusion

188. Dr Maplesden advised that, in his opinion, the standard of care provided to Mr A by the Advanced Medical Institute departed from expected standards to a moderate degree.

189. Given that the Advanced Medical Institute did not provide appropriate facilities to enable full physical examinations, I am not satisfied that the Advanced Medical Institute took all reasonably practicable steps to prevent Dr E's failure to conduct an adequate physical examination of Mr A. The Advanced Medical Institute is therefore vicariously liable for Dr E's omission and breach of Right 4(1) of the Code. The Advanced Medical Institute has also not proven that it took all reasonably practicable steps to prevent the omissions in providing information to Mr A about treatment options available to him. Accordingly, the Advanced Medical Institute is vicariously liable for Dr E's omission and breached Right 6(1)(b) of the Code.

4.4 Mr B

190. I am satisfied that Dr F's breaches of the Code for failing to conduct a penile examination and not appropriately recording medication prescribed are the result of independent clinical judgement and, therefore, the Advanced Medical Institute is not vicariously liable for those breaches.

191. However, the Advanced Medical Institute should have had better systems in place to ensure that Mr B's concerns about his medication not arriving were followed up. Mr B said he made two complaints to the Advanced Medical Institute that he had not received his medication. The Advanced Medical Institute has no record of these complaints. Right 10 of the Code requires a provider to have a complaints procedure and to inform consumers of the outcome of their complaints. The Code also requires

providers to "facilitate the fair, simple, speedy, and efficient resolution of complaints". The Advanced Medical Institute did not have a documented complaints procedure, has no record of Mr B's complaints, and did not inform Mr B of the outcome of his complaints. Accordingly, the Advanced Medical Institute breached Rights 10(3) and 10(6) of the Code.

4.5 Mr C

192. Mr C contacted the Advanced Medical Institute on its 0800 phone line requesting information about the services it provides. The Advanced Medical Institute has provided no evidence that Mr C consented to any treatment programme, and has not explained why he was charged following his call. The Advanced Medical Institute has also provided no evidence that it informed Mr C that his credit card was going to be charged $1,200.

193. It is unclear how the Advanced Medical Institute agents determined over the telephone that Mr C required a $2,495 programme, particularly as the Advanced Medical Institute has not been able to provide evidence of any clinical assessments. Mr C should have first seen a doctor for an assessment, been provided with a reasonable level of information about the treatment programme, and given consent to the programme. My expert advisor, Dr Maplesden, advised that undertaking an erectile dysfunction consultation resulting in recommendation of a medication, over the telephone and without documentation of such a consultation, is a mild to moderate departure from expected standards.

194. I accept Dr Maplesden's advice. In my view, the Advanced Medical Institute agents did not provide adequate information to Mr C about the treatment programme it was offering him, either on the telephone or in writing. Mr C had specifically requested information, such as booklets or pamphlets, from the Advanced Medical Institute. The direct debit forms sent to Mr C refer to the Advanced Medical Institute's "satisfaction" policy but the Advanced Medical Institute information booklets, containing the policy, were not provided to Mr C.

195. The Advanced Medical Institute's practices and procedures should not have allowed for medication to be recommended over the telephone without a face-to-face consultation. In my view, by having deficient practices and procedures for ensuring that Mr C was seen by a doctor before being recommended a treatment programme, and for failing to give Mr C adequate information about the treatment programme, the Advanced Medical Institute failed to provide services with reasonable care and skill and so breached Right 4(1) of the Code.

196. The Advanced Medical Institute also did not appropriately handle Mr C's complaint. Mr C made several calls to the Advanced Medical Institute complaining about the charge to his credit card. Mr C stated that, when he expressed to the Advanced Medical Institute that he did not want the services offered, the Advanced Medical Institute requested he get a medical certificate from his doctor. While the Advanced

Medical Institute claimed that Mr C went to his doctor on his own initiative, in my view Mr C's account is more credible as I can see no reason for Mr C to have obtained a medical certificate of his own volition, in order to exit a treatment programme that the Advanced Medical Institute now states was generated in error. Mr C's refund was apparently authorised on 12 December 2007, but a clerical error meant that Mr C's refund was not processed. Mr C then did not get any response to his letter of complaint in January 2008.

197. I acknowledge that the Advanced Medical Institute provided Mr C with a full refund once it became aware of his complaint to HDC. However, by not having an appropriate complaints procedure to facilitate the timely resolution of Mr C's complaint, the Advanced Medical Institute breached Rights 10(3) and 10(6) of the Code.

4.6 Mr D

198. When Mr D contacted the Advanced Medical Institute on 15 April 2008, he explained that he wanted to see a New Zealand doctor before consenting to treatment, for advice on how Advanced Medical Institute medication might affect his prostate problem. However, he spoke with an Australian doctor, who recommended and prescribed medication for Mr D. During his original call to the Advanced Medical Institute, Mr D recalls being told only about the nasal spray medication and nothing about side effects. Mr D said that his request for written information was refused and he was not informed about the Advanced Medical Institute's programme and "satisfaction" policy requirements. The Advanced Medical Institute has not provided sufficient evidence of what was discussed during this phone call.

199. Following Mr D's telephone discussion with the Australian doctor, the prescription signed by the Australian doctor was sent to the pharmacy in New Zealand. The pharmacy then dispensed the medication to Mr D. The Advanced Medical Institute stated that both the prescribing and dispensing of the medication was "an error". The Advanced Medical Institute's systems should not allow such a significant error to occur. Doctors in Australia cannot lawfully prescribe medications to patients in New Zealand. These process errors are clearly the result of deficient practices and procedures for checking that medication is not recommended (or sent) before a New Zealand registered doctor has seen the consumer and prescribed the medication. In my view, by having deficient practices and procedures for ensuring that Mr D was seen by a doctor before being prescribed (and receiving) medication, the Advanced Medical Institute failed to provide services with reasonable care and skill and so breached Right 4(1) of the Code.

200. The Advanced Medical Institute advised that Mr D's experience was the result of "process errors" on its part, and has now acknowledged that no charge should have been made to Mr D. Mr D complained to the Advanced Medical Institute on a number of occasions. The Advanced Medical Institute did not have an adequate system in

place to ensure that Mr D's complaint was appropriately handled and resolved in a timely manner. Therefore the Advanced Medical Institute breached Rights 10(3) and 10(6) of the Code.

4.7 Conclusion

201. Viewing these four complaints together, the Advanced Medical Institute provided a poor standard of care in each case. Overall, the Advanced Medical Institute failed to properly treat these four men as consumers of health services in accordance with its obligations under the Code. Consistent with previous opinions, when attending a specialist clinic, consumers are entitled to services 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.[46]

202. In all four cases, an Advanced Medical Institute-contracted doctor recommended and/or prescribed medication or a medication programme without undertaking a proper assessment. I am particularly concerned that in one case medication was prescribed and dispensed without any face-to-face consultation. In another case, a patient was recommended, and charged for, a medication programme without a face-to-face consultation. These complaints indicate risks to public health and safety due to the Advanced Medical Institute not having sufficiently robust systems to ensure that a face-to-face consultation occurs, and an appropriate examination takes place, prior to prescribing medications.

203. The Advanced Medical Institute's processes also failed to ensure that sufficient information was provided to each patient, including information on charging, its "satisfaction" policy, and use of approved medications for unapproved uses. Indeed, Mr D stated that an Advanced Medical Institute agent refused to provide information he specifically requested.

204. The Advanced Medical Institute's complaints procedures, as described to me, were unnecessarily complicated. Patients were required to undergo further treatment before being eligible for a refund. I agree with my expert advisor that this practice is "unethical and unreasonable".

205. Mr A, Mr B, Mr C and Mr D received a poor service from the Advanced Medical Institute. 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 with erectile dysfunction and premature ejaculation, it is clear that the system the Advanced Medical Institute set up to provide services could do more to ensure that consumers are provided with full information about treatment options for erectile dysfunction and premature ejaculation, and ensure consumers make an informed choice about treatment. As outlined above, the service the Advanced Medical Institute

[46] Opinion 08HDC02899, 08HDC05986, 08HDC07100, 08HDC09984.

provided to these four men fell below the standard of service required in New Zealand, as provided for by the Code.

Recommendations

206. Dr E has provided an apology to Mr A (see above, para 79).

207. I recommend that Dr F:

- provide a written apology to Mr B for her breaches of the Code. The apology is to be forwarded to HDC by 30 June 2012 for sending to Mr B.

208. I recommend that the Advanced Medical Institute:

- provide written apologies to Mr A, Mr B, Mr C and Mr D for its breaches of the Code. The apologies are to be forwarded to HDC by 30 June 2012 for sending to the four men.

- review its New Zealand operating procedures and polices in light of this report and, by 31 July 2012, provide HDC with evidence of all changes it has made, particularly in regard to its:

1. training and orientation of its contractors
2. policies on provision of information to patients
3. procedures for assessing patients
4. complaint-handling procedures.

Follow-up actions

- A copy of this report with details identifying the parties removed, except the name of the Advanced Medical Institute (NZ) Ltd and the HDC expert advisor, will be sent to the Medical Council of New Zealand. The Medical Council will be advised of the names of Drs E and F.

- A copy of this report with details identifying the parties removed, except the name of the Advanced Medical Institute (NZ) Ltd and the HDC expert advisor, will be sent to the Ministry of Health, the Medical Board of Australia and the Royal New Zealand College of General Practitioners, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1: Clinical advice from general practitioner Dr David Maplesden

"**Consumers:** [Mr A]; [Mr B]; [Mr C]; [Mr D]

Provider: Advanced Medical Institute (NZ) Ltd; [Dr E]; [Dr F]

File numbers: 09/00905, 09/01077, 09/01082, 09/01540

Date: 7 December 2010

1. My name is David Vaughan Maplesden. I am a vocationally registered general practitioner having graduated MB ChB (Auckland University 1983), Diploma in Obstetrics (Auckland University 1984) and FRNZCGP (2003). I have no known conflict of interest in advising on this case. I have previously provided preliminary advice on this case (16 November 2009 and 10 December 2009).

2. I have been asked to provide independent expert advice about whether:
   - [Dr E] provided an appropriate standard of care to [Mr A];
   - [Dr F] provided an appropriate standard of care to [Mr B]; and
   - Advanced Medical Institute (NZ) Ltd (Advanced Medical Institute) provided an appropriate standard of care to [Mr A], [Mr B], [Mr C], and [Mr D].

3. I have been provided with the following documentation:
   - All correspondence with Advanced Medical Institute
   - All correspondence with [Dr F]
   - All correspondence with [Dr E]
   - Advanced Medical Institute computer records for [Mr A], [Mr B], [Mr C], and [Mr D] and [Dr F], and clinical notes for [Mr B]
   - Summary document entitled 'Information gathered during the investigation'

4. I have been asked to provide the following expert advice:

   i) **[Dr E]**
      a) Whether, in your opinion, [Dr E] provided an appropriate standard of care to [Mr A] and, if not, please outline the reasons for your views.
      b) Are there any aspects of the care provided by [Dr E] that you consider warrant additional comment?

Names have been removed (except the Advanced Medical Institute and the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

ii) **[Dr F]**
   a) Whether, in your opinion, [Dr F] provided an appropriate standard of care to [Mr B] and, if not, please outline the reasons for your views.
   b) Are there any aspects of the care provided by [Dr E] that you consider warrant additional comment?

iii) **Advanced Medical Institute**
   a) Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr A] and, if not, please outline the reasons for your views.
   b) Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr B] and, if not, please outline the reasons for your views.
   c) Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr C] and, if not, please outline the reasons for your views.
   d) Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr D] and, if not, please outline the reasons for your views.
   e) Are there any aspects of the care provided by Advanced Medical Institute that you consider warrant additional comment?

iv) If, in answering any of the above questions, you believe that [Dr E], [Dr F] or Advanced Medical Institute did not provide an appropriate standard of care, please indicate the severity of departure from the accepted standard. I note that some experts approach the question by considering whether the providers' peers would view the conduct with mild, moderate, or severe disapproval.

v) If there are any discrepancies in the facts, please express your opinion based on alternative fact scenarios.

5. Background comments and observations

(i) The Advanced Medical Institute website includes a mission statement[47]: *Advanced Medical Institute Inc. (collectively with its subsidiaries, 'AVMD') focuses on delivering faster acting and lower dosage treatments to people suffering from Impotence and Premature Ejaculation. Unlike many of our competitors, we treat the whole patient, individually and over the long term. AVMD'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 and by using existing drug products with known safety and efficacy.* On the same page the following comments are made: *Treatment options*

[47] http://www.amiaustralia.com.au/?q=node/150 Accessed 6 December 2010.

*include push button self injections, lozenges, tablets and nasal spray program options for the treatment of Erectile Dysfunction and for the treatment of Premature Ejaculation… Treatment options are generally provided under a treatment program (3–24 months) … We compete with rival treatments such as Viagra *, Cialis * and Levitra * in the Erectile Dysfunction field. AVMD does not currently have any known competitors in the Premature Ejaculation market.* When asked to describe the clinical services Advanced Medical Institute offers its clients, Advanced Medical Institute stated:

> '[Advanced Medical Institute] arranges for patients to be provided with medical services and treatments relating to the treatment of erectile dysfunction and premature ejaculation. The medical services are provided by fully registered medical doctors such as [Dr F] and the treatments are provided by a registered pharmacy.'

The impression given is that Advanced Medical Institute offers a service specialising in management of male sexual dysfunction, specifically erectile dysfunction (ED) and premature ejaculation (PE) ie, they are a specialised service. As such, my expectation would be that they are well versed in the recognised local and international guidelines applying to that specialised service, and provide a service relating to management of ED and PE that is at least equal to that offered in the generalised environment of general practice, and is consistent with the recommendations contained in the relevant clinical management guidelines.

(ii) The European Association of Urology (EAU) have developed guidelines referring to the management of ED and PE[48], updated in 2010 but not significantly different to those in force at the time the events referred to in this report occurred. Relevant excerpts from these guidelines, with reference to PE, include:

a) *An increasing number of men are seeking help for ED due to the great media interest in ED and the availability of effective and safe oral drug therapy. However, there are many physicians evaluating and treating ED without appropriate background knowledge and clinical experience. Thus, some men with ED may receive little or no evaluation before treatment and will therefore not receive treatment for any underlying disease that may be causing their ED. Other men*

[48] Wespes E et al. Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. European Association of Urology 2010. http://www.uroweb.org/gls/pdf/Male%20Sexual%20Dysfunction%202010.pdf

without ED may be requesting treatment simply to enhance their sexual performance. Given this situation, these EAU guidelines for the diagnosis and treatment of ED are a necessity.

b) *Basic work-up … The first step in evaluating ED is always a detailed medical and psychological history of patients and partners …Often it is not possible to include the partner on the patient's first visit, but an effort should be made to include the partner at the second visit. The pathophysiology of ED may be vasculogenic, neurogenic, hormonal, anatomical, drug-induced or psychogenic … and taking a medical history may reveal one of the many common disorders associated with ED.*

c) *Sexual history — The sexual history may include information about previous and current sexual relationships, current emotional status, onset and duration of the erectile problem, and previous consultations and treatments. A detailed description should be made of the rigidity and duration of both erotic and morning erections and of problems with arousal, ejaculation and orgasm. Validated questionnaires, such as the International Index for Erectile Function (IIEF), help to assess all sexual function domains (erectile function, orgasmic function, sexual desire, ejaculation, intercourse and overall satisfaction), as well as the impact of a specific treatment modality.*

d) *Physical examination — Every patient must be given a physical examination focused on the genitourinary, endocrine, vascular and neurological systems … A physical examination may reveal unsuspected diagnoses, such as Peyronie's disease, prostatic enlargement or cancer, or signs and symptoms suggesting hypogonadism (small testes, alterations in secondary sexual characteristics, diminished sexual desire and changes in mood). A rectal examination should be performed in every patient older than 50 years. Blood pressure and heart rate should be measured if they have not been assessed in the previous 3–6 months. Particular attention must be given to patients with cardiovascular disease.*

e) *Laboratory testing — Laboratory testing must be tailored to the patient's complaints and risk factors. All patients must undergo a fasting glucose and lipid profile if not assessed in the previous 12 months. Hormonal tests must include a morning sample of total testosterone … Specific diagnostic tests are indicated by only a few conditions.*

f) *Treatment options — The primary goal in the management strategy of a patient with ED is to determine the aetiology of the disease and treat*

it when possible, and not to treat the symptom alone. Erectile dysfunction may be associated with modifiable or reversible factors, including lifestyle or drug-related factors. These factors may be modified either before, or at the same time as, specific therapies are used… Most men with ED will be treated with treatment options that are not cause-specific. This results in a structured treatment strategy that depends on efficacy, safety, invasiveness and cost, as well as patient preference … To counsel patients properly with ED, physicians must be fully informed of all treatment options.

g) *Lifestyle changes and risk factor modification must precede or accompany ED treatment … When a curable cause of ED is found, the cause must be treated first … PDE5 inhibitors* [commercially available as Viagra, Cialis and Levitra tablets] *are first-line therapy … Daily administration of PDE5 inhibitors may improve results and restore erectile function … Inadequate/incorrect prescription and poor patient education are the main causes of a lack of response to PDE5 inhibitors … Testosterone replacement restores efficacy in hypogonadic non-responders to PDE5 inhibitors … Apomorphine can be used in mild-to-moderate ED or psychogenic causes or in patients with contraindications for the use of PDE5 inhibitors … A vacuum constriction device can be used in patients with stable relationship … Intracavernous injection is second-line therapy … Penile implant is third-line therapy.*

(iii) Guidelines from Canada[49] and Australia[50] have been reviewed and are consistent with the EAU guidelines. Advanced Medical Institute have quoted the Australian guidelines in their response.

(iv) A recent GP-orientated Australian article on ED[51] makes the following recommendations, also consistent with the guidelines reviewed:

Consultations around the issue of erectile dysfunction should be conducted in a relaxed, reassuring, and nonjudgmental manner. The first step is to take a full medical, sexual, surgical and psychosocial history … A focused physical examination includes:

- *a genital examination*
- *assessment of secondary sexual characteristics*

[49] Toward Optimized Practice (TOP) Program. Guidelines for the investigation and management of erectile dysfunction. Updated 2010. http://www.topalbertadoctors.org/informed_practice/clinical_practice_guidelines/complete%20set/Erectile%20Dysfunction/erectile_dysfunction_guideline.pdf

[50] Andrology Australia. Erectile Dysfunction: Diagnosis and Management. GP Clinical Summary Guide 9. July 2007. http://www.andrologyaustralia.org/docs/GPguide_09_ED.pdf

[51] Smith I et al. Erectile dysfunction: when tablets don't work. Aust Fam Phys. 2010; 39(5):301–305.

- *a digital rectal examination to assess the prostate gland.*

A cardiovascular risk assessment should be performed before commencing a patient on a PDE-5 inhibitor and advising the resumption of sexual activity …

The management of ED should follow a stepwise approach as outlined …

First line
- *Lifestyle modifications (eg. quitting smoking, exercise, weight loss)*
- *Management of cardiovascular risk factors*
- *Trial of PDE-5 inhibitors (at least four attempts with two different PDE-5 inhibitors) in the absence of contraindications*

Second line
- *Self intracavernosal injections*
- *Vacuum erection devices*
- *Hormonal therapies (eg. testosterone replacement)*
- *Combination therapy*

Third line
- *Penile prostheses*

iv) None of the guidelines or primary-care orientated material reviewed refers to the use of nasal delivery of medication for the treatment of ED. While this does not mean it is ineffective, as part of a general discussion of treatment for ED the patient should be made aware that this mode of treatment does not feature in guidelines currently in use, and oral PDE5 inhibitors remain, unless contraindicated, the standard first line of pharmacological treatment of ED.

6. [Dr E]/[Mr A]

6.1 **Chronology of Complaint**

6.11 In December 2008, [Mr A] (aged 71) phoned Advanced Medical Institute, after seeing their advertisement in a newspaper. [Mr A] had been dissatisfied with the service he was getting from his own GP regarding advice about difficulty passing urine because of the size of his penis. [Mr A] made an appointment to see a doctor on 7 January 2009. When making the appointment, [Mr A] asked how much treatment cost. [Mr A] was told that they couldn't say as it depended on what the doctor prescribed.

6.12 On 7 January 2009, [Mr A] arrived at the Advanced Medical Institute clinic at 2pm. ... [Mr A] spoke to three young women … before being

taken in to see [Dr E]. [Mr A] could not recall what he discussed with the women in the reception area. [Dr E] stated:

> 'Before the consultation, patients are taken through a printed form by the nurse. The nurse collects the past medical history from the patient. The nurse also takes information about the presenting complaint. A copy of the form was provided to me. When [Mr A] came into the room, I would go back over the questions again to confirm the information in order to make a diagnosis.'

6.13 [Dr E] told [Mr A] that he likely had a prostate problem without performing a physical examination of the area and [Mr A] could not recall having his pulse or blood pressure checked. [Dr E] stated:

> 'It was not a full examination, as the Advanced Medical Institute rooms were not set up for a full clinical examination to take place. The consultation room could be seen by the adjoining buildings and there was no examination bed. I checked [Mr A's] pulse, blood pressure and heart rate and respiratory system.
>
> As I felt that [Mr A's] complaint was suggestive of prostatic hypertrophy, and accordingly I suggested to him that he should see his GP and get it investigated.'

6.14 [Dr E] provided a letter apparently from [Dr F] (medical practitioner providing services on behalf of Advanced Medical Institute) which stated:

> 'All we require from yourself is that you perform a general check-up upon Mr … This is in terms of:
> 1. A check of blood pressure
> 2. Check of the heart and lungs
> 3. Check of the abdomen.'

6.15 [Dr E] claimed that [Mr A] left the consultation room and then returned after speaking to the nurse. [Mr A] recalled that [Dr E] may have come into the room while he was discussing the cost with one of the young women. [Dr E] claimed that [Mr A] requested to try the nasal spray. [Dr E] stated:

> 'I told him that I could not vouch for the efficacy of the medications as I had not tried it, but the published reports seemed to indicate that it was effective. The recommendation from Advanced Medical Institute for over 70 year olds was a nasal spray containing Apomorphine and Maxolon, which I advised him to try if he wished.

> The information I gave him included a detailed description of how to use the nasal spray, the dosage and side effects, and the action he had to undertake in the event of a side effects. He was given the telephone number to contact a doctor in [Australia] if he needed any further information.'

6.16 [Mr A] was prescribed a nasal spray and told that if that didn't work to contact Advanced Medical Institute and they would try him on pills. The nasal spray would be delivered to [Mr A] in a week's time. This was confirmed by [Mr A]. At 3.15pm [Mr A] was presented with an invoice for $3,795. [Mr A] was shocked by the amount. This was more than [Mr A] had in his cheque account. [Mr A] filled out a cheque for the amount. He stated that he was not offered a choice of programme lengths or being able to pay in instalments. [Dr E] stated:

> 'I was not aware of how much the medication would cost, at this point in time. Subsequently I gathered it was an expensive affair for patients and therefore, I recommended to patients whom I saw later that they should try it for a shorter period of three months instead of the 12 months recommended by Advanced Medical Institute if they wanted to use it.'
>
> 'I was prohibited by the terms of employment to discuss the cost, which was delegated to nurse.'

[Dr E] provided an email from an Advanced Medical Institute employee which stated:

> 'Doctors must not discuss cost of the programs or anything else only give medical assessment and recommend 12–18 months programs.'

[Mr A's] bank phoned him the next day and [Mr A] cancelled the cheque. [Mr A] has had no further contact with Advanced Medical Institute.

6.17 A response from Advanced Medical Institute noted that [Mr A] 'initially wanted to enter the rehabilitation programme … (which) offers access to doctors, nurses and various treatment options; … if … the medication initially prescribed was ineffective, there are other medications … [Mr A] may not have appreciated the extent the program offers with regards to its extensive support system as referred to above … In that context the cost of the rehabilitation program is reasonable if embraced by a patient'. This same response claims that Advanced Medical Institute is

organising to give free medication to [Mr A] but in a later response this claim is withdrawn.

6.18 There is confusion over which provider saw [Mr A]. Initial Advanced Medical Institute responses identify the provider as [Dr I] and the doctor responds stating 'My role and responsibility as the Doctor at [the clinic] is strictly to assess the patient's medical status and make sure there are no contraindications to any of the treatments which I recommend for the patient. I have done so in the case of [Mr A]'. The provider is later identified as [Dr E] who was working on behalf of [Dr I] as a favour and had omitted to change the log-in details when he saw the patient.

6.19 [Dr E], in his response, included a summary of his experience in general practice and managing ED. He reiterates that Advanced Medical Institute informed him that 'my role was limited to ensuring the patient was healthy enough to take the medication Advanced Medical Institute recommended. There was no clinical supervision in place to support my practice at Advanced Medical Institute' and 'Advanced Medical Institute made it clear that I was not there to offer treatment but to make sure that the treatments that were being provided by Advanced Medical Institute were not contraindicated and that the medications were safe for the patients'. Both [Dr I] and [Dr E] have withdrawn their services from Advanced Medical Institute.

6.10 [Dr E] has provided the copy of an e-mail from '[an employee]' that relates to instructions regarding the doctor's role in the Advanced Medical Institute consultation. This e-mail states 'Most important thing is to recommend to patients 12 to 18 months programs — this gives to patients good chance to be cured and forget about their (*sic*) problems. Doctors should speak with patients with great confidence about medications and opportunity to be cured if patients get 12 to 18 months programs. Doctors must not discuss cost of the programs or anything else only give medical assessment and recommend 12–18 months programs.' AMI distances itself from the e-mail, stating 'this e-mail was not authorised by [AMI's] CEO … and does not reflect [AMI's] corporate policy'.

6.2 Review of clinical records/documentation

6.21 Records from [Mr A's] regular GP are available from 11 April 2007. Diagnoses listed include type 2 diabetes, depression and previous transient ischaemic attack (TIA). Medication list includes metformin and gliclazide for diabetes, Aropax for depression, a low-dose aspirin preparation and GTN spray. A majority of entries are completed by practice nurses and relate to diabetes checks. The entry of 11 April 2007

includes the comment 'Is impotent — wants to trial Viagra — warned re spray'. The concurrent use of GTN spray and Viagra is contraindicated. An entry of 5 November 2007 states 'Has not tried Viagra — not really needed now'. There is no record of urinary problems being discussed.

6.22 A partially completed Advanced Medical Institute 'Patient Assessment Form' has been viewed. There is no date or provider details on the template provided. The template is fairly detailed and provides, if completed properly, what I would regard as an adequate pre-assessment for erectile dysfunction (ED). In [Mr A's] case the area relating to psychological history is not completed; there is no date of last rectal examination; the area related to previous ED treatments is not completed; the medication list does not include GTN spray or Cartia although the title 'Heart Disease' is checked 'Yes'. The areas for doctor use only note no contraindications to ED medications (listed as 5PDE (eg, Viagra), injectable and clomipramine). Doctors comments note 'main problem is passing urine due to small penis and scattered flow. Rx Viagra but never used them. His problem is minor sexual Dysfunction, but more prostatic illness. Advised to get the prostate problem investigate by his GP'. There is an additional comment regarding [Mr A] wanting 'to try spray AM' to increase the size of his erection. Recordings are noted for blood pressure, pulse and chest auscultation but there are no abdominal findings documented.

6.23 A further template on which the doctor has completed handwritten responses has been viewed. This is dated '1/09' and has no provider identification on it. There is further detail regarding the nature of [Mr A's] erection problems but no further elaboration on medical history or medications. Rectal examination 'Yrs ago' is noted. There are no clinical recordings or examination findings, but a comment 'His problem is benign prostate enlargement but he wants erection'. [Dr E] later stated he recalled performing an abdominal examination while [Mr A] was standing to check his liver, spleen and kidneys. [Dr E] stated 'In the course of that examination, any bladder distension would have been apparent …'.

6.24 A disk containing training literature as supplied to doctors contracted to work for Advanced Medical Institute has been viewed. This is largely a collection of monographs and journal articles which vary in quality and which generally support the prescribing of products as undertaken by Advanced Medical Institute. The articles relating to injectable therapy for ED are predominantly 10–15 years old. There is a dearth of meta-analyses or systemic reviews of techniques and I would regard the overall presentation of literature as somewhat biased in nature, but probably sufficient to give providers a reasonable overview of the

treatments they are prescribing. However there is no structured or didactic approach, such as a manual, to the assessment and treatment of ED but if a provider read a majority of the literature provided I think it is reasonable to assume they could undertake a competent assessment, advisory and treatment service relating to ED. Additional written support material outlines the medications commonly used by Advanced Medical Institute with appropriate dosage regimes and contraindications. I note that instructions regarding injectable therapy on page 3 of this publication states the therapy is injected 'at 12pm position of penis' — this instruction is contrary to instructions in other Advanced Medical Institute patient education material and contrary to accepted practice. This same material instructs in use of the computer system with a single user name and password (both '[…]') and no instruction on individual log-in facility or details.

6.25 Patient education material has been viewed (yellow and grey pamphlets entitled 'For an active lifestyle'). This material is comprehensive and generally of good quality, and gives customer support numbers in the event of problems. In terms of provision of health information to other providers the policy notes that Advanced Medical Institute 'may be required to disclose some of your health information to other healthcare professionals such as specialists or healthcare providers like pathology providers, radiology etc, this will occur only with your consent at the time'. There is no mention of information provided to the patient's GP.

6.3 Comments

6.31 There are some deficiencies in the assessment of [Mr A] by [Dr E]. Completion of the questionnaire template was incomplete and did not detect his history of depression although an antidepressant is listed in his current medications. As psychogenic causes make a significant contribution to the aetiology of ED, and may be treated by counselling with or without ED medication, the failure to document this condition in [Mr A's] case would, in my opinion, be met with mild disapproval by my peers. The use of GTN spray was not noted in either the questionnaire or the doctor's report — this could have significant implications if a PDE-5 medication[52] was being considered, and [Mr A] is listed as having no contraindication to this group of medications when concurrent use of GTN spray would require significant precautions. Use of this type of medication needs to be asked about specifically rather than waiting for the patient to volunteer such information as its use is often intermittent and it may not be viewed by the patient as a 'regular' medication. The failure to obtain this relevant information in a

[52] Phosphodiesterase-type 5 inhibitor eg Viagra.

consultation relating to ED would, in my opinion, be met with mild disapproval from my peers.

6.32 The physical assessment of [Mr A] was sub-optimal in that inadequate abdominal and no genital examination was performed (see above: Guidelines 5 (ii)(d)), nor were there adequate facilities available to undertake such an examination. It is unclear on what basis [Dr E] determined that [Mr A] had BPH as a rectal examination had not been performed. [Dr E] felt the facilities provided to him by Advanced Medical Institute precluded an adequate physical examination (see 6.13). Advanced Medical Institute responded that other rooms with blinds were available for [Dr E's] use (he states he was not aware of this) and that 'facilities were provided to consulting doctors which enable a physical examination to occur'. Photographs of the offices were provided — no office has a consultation couch, nor are handwashing facilities available in each room. While the physical examination undertaken by [Dr E] was sub-optimal, I feel the lack of suitable facilities to conduct such an examination (the responsibility of Advanced Medical Institute) was a mitigating factor in this case.

6.33 Clinical documentation was unsatisfactory in that there was no facility to accurately identify the provider (see 6.24 regarding the common log-in). This led to confusion over the actual provider in [Mr A's] case. Otherwise, the use of an extensive template did support reasonable documentation in terms of relevant functional enquiry and history, and documentation of the limited physical examination undertaken was adequate as a representation of this examination.

6.34 The medication prescribed to [Mr A] was reasonable (Apomorphine/Maxolon in nasal spray form (AM spray)). There is limited clinical information on the efficacy of this preparation of apomorphine in treating elderly men with ED, and the use of oral PDE-5 inhibitors was less desirable given [Mr A's] use of GTN spray. [Mr A] had several known potential contributors to his ED — psychological (depression), diabetes, vascular disease (previous TIA) and prostate disease. Therefore his chances of success were likely to be somewhat limited. There was no particular indication to undertake additional blood tests given the knowledge of these co-morbidities. [Dr E] states that he had given [Mr A] verbal and written information regarding the treatment but it is not apparent that there has been any discussion regarding the 'treatment programme' which has the potential to be somewhat more complex than trying a single medication for a limited period. The prescribing of AM spray to [Mr A] on a trial basis was, in my opinion, a reasonable action under the circumstances although it should have been made clear to [Mr A] that the chances of success may have been

somewhat limited given the extent of his co-morbidities and that this was an 'off-label' use of the component medications.

6.35 The written information provided to [Mr A] (assuming he received one of the leaflets described in 6.25) was reasonable from a clinical perspective.

6.36 *(i) Whether, in your opinion, [Dr E] provided an appropriate standard of care to [Mr A] and, if not, please outline the reasons for your views.*

[Dr E] was new to Advanced Medical Institute having been asked to 'fill in' for another contractor and was somewhat constrained by the Advanced Medical Institute processes which did not provide facilities for an adequate physical examination of the patient, had not provided adequate orientation ([Dr E] was logged in under another provider's name) and had apparently directed [Dr E] to undertake a limited physical examination, recommend a 12–18 month course of treatment and not to discuss cost with the patient (although Advanced Medical Institute denies these suggestions). Under these circumstances, I am of the opinion that the standard of care provided by [Dr E] to [Mr A] departed from expected standards to a mild degree, primarily related to his failure to establish use of GTN spray in a patient being considered for ED assessment and treatment, even though PDE-5 inhibitors were not prescribed. The failure to discuss the 'off-label' use of AM spray as a treatment for ED was also a mild departure from expected standards.

ii) *Are there any aspects of the care provided by [Dr E] that you consider warrant additional comment?*

I have no additional comments.

7. [Dr F]/[Mr B]

7.1 **Chronology of Complaint**

7.11 On 20 February 2009, [Mr B] (aged 75) attended [an] Advanced Medical Institute clinic after seeing their advertisement in the newspaper. [Mr B] had not discussed his erectile dysfunction problem, which he described in his complaint as 'a failing libido' with his GP. ... He was seen by a young woman, who he did not think was a doctor. The young woman asked him a series of questions about his health and erectile dysfunction then advised him that Prostaglandin injections were the most appropriate treatment for his condition. [Mr B] paid a $300 deposit for a 12 month programme costing $1,810. [Mr B] believed it is possible that he still

needed to see [Dr F] before Advanced Medical Institute would have supplied him with medication.

7.12 On 25 February 2009, [Mr B] returned to the Advanced Medical Institute clinic and was seen by [Dr F]. [Dr F] went through the same types of questions as the young woman on his previous visit. [Mr B] could not recall whether or not [Dr F] performed any physical examinations. [Dr F] prescribed an Apomorphine and Maxolon nasal spray. [Mr B] was charged $300 for a one month's supply. [Mr B] does not recall the young woman or [Dr F] telling him about side effects of the medications or what to do if he was not satisfied. Advanced Medical Institute stated that [Dr F] prescribed the injectable medication. However, only the nasal spray was recorded on the patient assessment form. The invoice dated 20 February 2009 has '[Dr F's] as the doctor's name, whereas the invoice dated 25 February 2009 has '[location] NZ'.

7.13 [Mr B] was told that the two medications would be dispatched to his mail box within two weeks. In March 2009, [Mr B] visited the Advanced Medical Institute clinic twice to enquire about the whereabouts of his medication. Advanced Medical Institute advised him that the medication was in the process of being forwarded to him from Australia. Advanced Medical Institute explained that according to their records the medications were sent to [Mr B] on 11 and 12 March 2009. […] From Advanced Medical Institute's records, their staff understood that the medications were received by [Mr B].

7.14 On 1 April 2009, [Mr B] complained to HDC. On 28 May 2009, [Mr B] received a full refund from Advanced Medical Institute. [Mr B] did not receive an apology or any offers from Advanced Medical Institute although an initial response from them stated 'We are in the process of organising a free injectable for one (1) year to satisfy him even more than he is to date'. A response from [Dr F] states 'I do not accept that there can be any question about the appropriateness of the care and treatment which I provided [Mr B]'.

7.2 Review of clinical records/documentation/[Dr F's] response

7.21 A completed Advanced Medical Institute 'Patient Assessment Form' on [Mr B] has been viewed. There is no date or provider identification on this form. The template is identical in content to that mentioned in [Mr A's] case above and the same general comments regarding the template apply. In this case most questions have been checked with either 'Yes', 'No' or N/A — the latter I take to mean not applicable and/or not asked. Of note, in relation to the initial recommendation of injection therapy, N/A is placed beside the question 'penile deformity'. There are no

apparent contraindications recorded to the ED treatments used. Clinical findings documented appear to be restricted to recordings of blood pressure (156/97) and pulse (72). There is no evidence that an abdominal or genital examination has taken place. The doctor's comments are 'Fit; no meds; recent hip replacement; For apm N/S 12–18 months'.

7.22 In her response, [Dr F] outlines how she saw [Mr B] on 19 February 2009 and undertook a 45–50 minute consultation. She summarises the content of the consultation and this is supported by comprehensive handwritten notes which were undertaken at the time of the consultation. The general assessment of [Mr B] appears to have been mostly adequate with standard erectile dysfunction questionnaire completed and a basic physical examination undertaken, although there is no genital examination recorded.

7.23 The handwritten notes and the response indicate that a number of treatment issues were discussed in some detail including an explanation that Advanced Medical Institute's treatments were not a 'quick fix' but a graded course of treatment starting with the least invasive treatment, a nasal spray, then lozenges, gels and injectables. [Dr F] documented that she discussed the side effects of the medications but did not document any discussion about medication costs, and noted the medications were compounded in Australia and imported to New Zealand 'under the necessary legal sections'. [Dr F] documented that [Mr B] was keen to try the injectable medication but she encouraged him to start with the nasal spray. She encouraged him to think about it and make his own decision. She explained how the nasal spray worked and to contact Advanced Medical Institute within two weeks to report the efficacy of the medication. [Dr F] told him to discontinue using the nasal spray if he was not tolerating it and contact Advanced Medical Institute to replace it with an alternative medication. [Dr F] did not inform [Mr B] that while apomorphine, phentolamine[53] and Maxolon (APM) are approved medicines in New Zealand, they have not yet been approved for use in nasal sprays ie they are used 'off-label'. [Dr F] went on to tell [Mr B] that by virtue of his age he may require combination medications that are more invasive than the nasal spray, including Viagra type drugs, PDE-5 inhibitors and phentolamine. [Dr F] also explained that the injectable medications were the final medications Advanced Medical Institute offered as they were the most invasive and required careful dose titration but are 'often the safest with the older man and people with co-morbidities'. According to [Dr F], [Mr B] was happy to start with the

[53] Phentolamine is a nonselective alpha-adrenergic antagonist. It causes blood vessels to expand, thereby increasing blood flow. When injected into the penis, it increases the blood flow, resulting in an erection.

nasal spray and she recommended an APM nasal spray for 12–18 months. She did not discuss cost specifically as this process was undertaken by other Advanced Medical Institute staff subsequent to the medical assessment.

7.24 [Dr F] noted 'After the initial consultation, patients were generally followed up one month later, and then there were three-monthly reviews, or as individually required. If the patient chose to trial medications, whether Advanced Medical Institute or other, then I (or another doctor) would monitor their progress at these reviews, and make whatever changes were indicated to their treatment plans. If clinically it appeared they needed to come off courses of treatment I also advocated for it, to both the patient and Advanced Medical Institute.

I also considered my role to involve patient information and education, counselling or referral as appropriate. I clinically assessed the wellness of each patient and if, for example, significant medical concerns such as psychological, urological, or other medical or cardiac issues arose, I would send them away to obtain letters from their specialist or cardiologist, verifying they were well enough to participate in treatment.'

7.25 [Dr F] did not document the dosage, frequency and volume of the APM medication on the patient assessment form or in her clinical notes. [Dr F] later explained:

> '[O]n this occasion this was simply an omission or oversight. It has probably occurred because the documenting was always done on the script and I was aware that Advanced Medical Institute's pharmacy APM was the only one called APM, and has one particular dosage which had a safe therapeutic range. There was one Advanced Medical Institute NZ compounding pharmacist to which the scripts were sent and he himself makes up the nasal spray, according to the preset dosages, which is also recorded on the prescription. I accept failing to record the dosage in my clinical notes and that was an oversight which I will ensure will not happen in the future.'

7.26 In February 2009 [Mr B] made it known to Advanced Medical Institute administrative staff that he would prefer to try the penile injections. An Advanced Medical Institute administrator noted that the clinical co-ordinator was checking with [Dr F] to make sure [Mr B] could use the injections and on 24 February 2009, [Mr B] returned to the Advanced Medical Institute clinic and was seen by [Dr F]. She noted that [Mr B] was not happy with starting with just the nasal spray and wanted to try the injectable as well. [Dr F] recorded that [Mr B] did not have an

appointment but she *pushed him in.* However, there was limited time so she told [Mr B] to come back for further education by the nurses, after watching the educational DVD that was to be enclosed with the medications. [Dr F] explained that the injectable medication came in incremental doses and prescribed injectable prostaglandin, adding it to the script for the nasal spray that she was already processing. [Mr B] does not recall any discussion about side effects or what to do if he was not satisfied. I could not find the precise dose or formulation of the injectable medication documented in [Mr B's] notes.

7.27 [Dr F] did not conduct a physical examination of [Mr B's] penis at either of the consultations she had undertaken with him. After HDC advised her that a penile examination should have been done, [Dr F] said that when [Mr B] returned for his training the 'doctor/nurse team of the day' would have excluded any signs or symptoms of Peyronie's disease before any injection training begins.[54] Advanced Medical Institute's Nurse Reference Folder states for all its injectable medications that contraindications include: penile deformity, scarring and recent bend. [Dr F] later stated:

> (i) 'it is my practice to ensure that I conduct a physical examination of patients;
> (ii) that I considered that a physical examination of [Mr B] was appropriate;
> (iii) that on the day in question, I did the most appropriate assessment that one could do, under the circumstance with no nurse available as a chaperone for the patient's support to enable the physical examination to be conducted in the most sensitive and appropriate manner;
> (iv) that in these circumstances, it is my usual practice, and it was my intention in this instance, to conduct the physical examination when the patient returned to the clinic for the nurse education regarding use of the medication;
> (v) [Mr B's] injectable medication was to be sent to the clinic where it would be provided to [Mr B] for the training, only after the physical examination had been conducted and after he had attended the comprehensive nurse education regarding use'.

[Dr F] explained further:

[54] Peyronie's disease is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis affecting a small percentage of men. The disease may cause pain; hardened, big, cord-like lesions (scar tissue known as 'plaques'); or abnormal curvature of the penis when erect.

> 'the plan was that he would return to the clinic to have his injection training and genital exam with the appropriate male nurse chaperone and myself prior to commencing the injectable trial. I therefore requested the medication to be sent to the clinic to tie in with that expected examination, so it could all be done at the same time … I can only surmise that there was a subsequent communication breakdown with staff about when he would have his genital examination with me and a male nurse chaperone, who would assist with injecting training. As a female doctor I did not undertake such injection training without a male chaperone present. This ensured there was a male nurse who would be able to continue to practice with the patient after my initiating the process, while I continued seeing other patients etc. This requirement for the male nurse chaperone did, however, lead to time delays'.

7.28 (i) *Whether, in your opinion, [Dr F] provided an appropriate standard of care to [Mr B] and, if not, please outline the reasons for your views.*

> There are marked discrepancies in [Mr B's] recollection of events and the events as recorded by [Dr F]. [Mr B] is recorded as having an examination of his cardiovascular system, lungs, abdomen and central nervous system yet he can not recall whether or not an examination occurred. He can not recall seeing [Dr F] at the first consultation. It is difficult to explain these discrepancies but the contemporaneous documentation supplied supports [Dr F's] recollection of events. There was no abdominal or genital examination undertaken (refer guidelines section above 5(ii)(d)) even though [Mr B] had expressed a desire to use injectable medication, and observation of Peyronie's disease would have immediately identified this as a contraindication had it been present. There was no testing undertaken to exclude occult diabetes or testosterone deficiency as a cause for [Mr B's] symptoms (refer guidelines section above 5(ii)(e)). The medication regime offered was not in accordance with current guidelines (see above 5(ii)(f) — I am assuming [Mr B] had not previously tried oral PDE-5 inhibitors which are the accepted first line of pharmacological treatment provided there are no contraindications. While it may be reasonable to recommend alternative non-invasive pharmacological interventions such as the APM nasal spray, [Mr B] should have been made aware this was an 'off-label' medication not currently included in relevant management guidelines, and was not generally recognised as the first step in treatment. [Dr F] discusses at some length the reasons why a genital examination was not undertaken on [Mr B] prior to her prescribing him the penile injections. Here one must make a distinction between the training required for penile injections, which could quite reasonably be deferred until the patient had received his prescription, and which could reasonably be

undertaken by a male nurse as [Dr F] states, and the requirement to exclude contraindications to the use of the medication (Peyronie's disease) before prescribing it. One must also take into account the recommended basic examination for an ED assessment and the fact that Advanced Medical Institute is offering a specialised ED and PE service. In my opinion, the failure by [Dr F] to undertake a genital examination on [Mr B] either at her original consultation with him, or at least before prescribing him (and requiring him to pay for) injectable medication, is a mild to moderate departure from expected standards even if she intended to undertake an examination when he presented for training in the injection technique. It seems inappropriate for a patient to be offered and prescribed such medication, required to pay for it, and education sessions ostensibly arranged before it has been established that the patient has no contraindications to its use. [Dr F] failed to annotate prescribing and dosages of the nasal or injectable medication in [Mr B's] notes. It would be reasonable to assume [Mr B] would receive full instructions on the use, and precautions associated with use, of the penile injections at his training session(s), although such sessions did not eventuate which is a reflection on inefficiencies in internal Advanced Medical Institute processes. In my opinion, the overall management of [Mr B] by [Dr F] departed from expected standards to a mild to moderate degree for the reasons described above.

(ii) Are there any aspects of the care provided by [Dr F] that you consider warrant additional comment?

a) I note communication to [Dr E] apparently from [Dr F] (see 6.14) stating *All we require from yourself is that you perform a general check-up upon Mr… This is in terms of*:
   4. A check of blood pressure
   5. Check of the heart and lungs
   6. Check of the abdomen.

In correspondence from Advanced Medical Institute the comment is made *[Dr F] … was not authorized to make the comments she made to [Dr E] … No directions were given by* [Advanced Medical Institute] *to its consulting doctors as to how to conduct their examination of patients.* [Dr F] denies generating this letter (in which her name is misspelt) and suggests it has come from an Advanced Medical Institute administrative source other than herself.

8. *Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr A] and, if not, please outline the reasons for your views.*

8.1 In my view the facilities available for undertaking of a physical examination of [Mr A] (basic physical examination as recommended in the relevant guidelines), were inadequate and below the standard one would expect in general practice or a specialist ED service.

8.2 The orientation of [Dr E] to Advanced Medical Institute processes was inadequate — he was not made aware that rooms offering some degree of privacy were available, and the instructions provided for log-in to the facility computer identified him as [Dr I].

8.3 [Dr E] had been given information identified as coming from Advanced Medical Institute administrative sources (e-mail regarding length of programme recommendations and not to discuss cost (6.16)) and from '[Dr F], Advanced Medical Institute' regarding nature of examination to be undertaken (6.14). While there have been attempts by Advanced Medical Institute to distance themselves as the providers of this advice, the advice was inappropriate and in my opinion was likely to negatively influence the quality of the assessment to be undertaken and the rights of the patient to be offered an estimate of programme cost at the time the length of programme was to be decided (a clinical decision between doctor and patient). Advanced Medical Institute state that the patient is always made aware of the cost of the programme before signing up for it — however this discussion occurs with an administrative staff member after the patient/doctor decision on the recommended programme length. Cost should be included at the time of the patient/doctor discussion as a factor influencing the trial period to be recommended.

8.4 Training documentation provided by Advanced Medical Institute to me included instructions regarding injectable therapy, stating the therapy is injected 'at 12pm position of penis' — this instruction is contrary to instructions in the patient education material provided and is contrary to accepted practice.

8.5 In my opinion, Advanced Medical Institute has not made it sufficiently clear to NZ contracting doctors that the medications they supply are 'off-label' and are not included in current relevant guideline recommendations, and certainly not as first-line treatments, and that such information should be provided to patients when discussing treatment options. Advanced Medical Institute has responded that 'all of our client's contractors and staff are advised that our client's medications are being provided on an off-label basis and the obligation to advise the patient of this is an obligation of the prescribing doctor'. I could find no written doctor or patient orientated material that made this situation clear.

8.6 The Advanced Medical Institute 'Satisfaction and Privacy Policy' in their patient booklet outlines the terms of a treatment 'trial'. The Guarantee portion of this policy states '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'. The patient must agree to try at least one option from each of the treatment methods prescribed before a refund can be considered and an Advanced Medical Institute doctor must decide that all available and suitable Advanced Medical Institute treatments have been tried without success before such a refund is considered. Cancellation of a direct debit request 'will only be approved if an (Advanced Medical Institute) doctor finds you are medically unsuitable for (Advanced Medical Institute) medications'. In my view, the 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. The patient should retain the right to decline medical treatment without suffering financially. We are not talking about some inanimate material object — this clause represents patients being forced to suffer financially if they elect not to continue trialling various types of medication that might be effective, include penile injections, if initial less invasive treatments are unsatisfactory. This requirement, if it is to remain, should be made explicit to patients before they commit to the services of Advanced Medical Institute.

8.6 Based on the points above, it is my opinion that the standard of care provided to [Mr A] by Advanced Medical Institute departed from expected standards to a moderate degree.

9. *Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr B] and, if not, please outline the reasons for your views.*

9.1 Points 8.3 to 8.5 apply.

9.2 I accept that the difficulties [Mr B] experienced in obtaining his prescriptions appear to relate to the contracted dispensing service rather than specific Advanced Medical Institute processes.

9.3 Training in the penile injection technique was not given to [Mr B] in a timely manner despite him having deposited significant money to commence his treatment programme. The cause of these delays were internal and unspecified.

9.3 In my opinion, the standard of care provided by Advanced Medical Institute to [Mr B] departed from expected standards to a moderate degree.

10. *Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr C] and, if not, please outline the reasons for your views.*

10.1 **Chronology of Complaint**

10.11 [Mr C] had seen his own GP and trialled a treatment for erectile dysfunction, which hadn't worked. On 2 November 2007, [Mr C] (aged 53) rang Advanced Medical Institute's 0800 number after hearing their advertisement on the radio. During the phone conversation Advanced Medical Institute took his credit card details and said they would send him a sample. [Mr C] claimed that he had only asked for information and was expecting to be sent a pamphlet. [Mr C] claimed that Advanced Medical Institute has asked for his credit card details as proof of method of payment. Advanced Medical Institute did not explain that they would be charging his credit card following the call. [Mr C] did recall a discussion of part payments.

10.12 Advanced Medical Institute stated that [Mr C] had spoken to [a] vocationally registered general practitioner in Australia about his penile erection problem and the possible medications to overcome this, and he was advised to go to a local doctor for assessment and treatment. Advanced Medical Institute's computer records for [Mr C] note that [Mr C] had a problem with premature ejaculation and a tramadol nasal spray was to be prescribed by [the vocationally registered general practitioner].[55] Advanced Medical Institute has provided no clinical records for this phone consultation. [Mr C] denied discussing any particular problems or medications with Advanced Medical Institute. Advanced Medical Institute claim that [Mr C] agreed to visit Advanced Medical Institute's clinic. [Mr C] denied this. [Mr C] claimed that Advanced Medical Institute told him to see his own doctor to get a clearance to use their medications.

[55] Tramadol is a central acting analgesic used primarily in the treatment of moderate to moderately severe pain.

10.13 A few days later [Mr C] received direct debit forms for a 12 month programme costing $2,495. [Mr C] discovered that his credit card had been charged $1200 on the day of his call to Advanced Medical Institute. The direct debit forms include the statement 'I acknowledge that I have read and accepted the terms and conditions of this contract including those set out in the attached Advanced Medical Institute 'Satisfaction and Privacy Policy', which was not in fact attached. The policy referred to requires that a person must agree to try all four treatment methods and an Advanced Medical Institute doctor decides that the person is medically unsuitable for Advanced Medical Institute medications.

10.14 [Mr C's] wife rang Advanced Medical Institute to state that they did not want to purchase anything from Advanced Medical Institute. Advanced Medical Institute refused to talk to [Mr C's] wife without [Mr C's] permission. [Mr C] faxed through his permission with a copy of his and his wife's drivers licences. Advanced Medical Institute initially continued to refuse to talk to [Mr C's] wife until an Advanced Medical Institute staff member said she would contact the refund department and someone would contact [Mr C] in a few days.

10.15 Advanced Medical Institute contacted [Mr C] who confirmed he did not need anything for erectile dysfunction. [Mr C] claimed that Advanced Medical Institute told him that he needed to get a medical certificate from his GP and fax it to them. [Mr C] visited his GP on 5 December 2009 and got a medical certificate, which he faxed to Advanced Medical Institute. Advanced Medical Institute later claimed that [Mr C] had gone to his GP who had recommended that he not take medication for erectile dysfunction. Advanced Medical Institute commented that erectile dysfunction is quite separate to the condition of premature ejaculation, which was the reason [Mr C] contacted Advanced Medical Institute.

10.16 Medication was meant to be prescribed after [Mr C] saw the doctor at [one of the Advanced Medical Institute's clinics]. [Mr C] recalled being contacted twice by a female doctor offering to clear him for treatment if he would visit [her clinic]. On 5, 7, 15 and 22 November 2007, [Dr F] recorded queries in Advanced Medical Institute's computer system about whether she was to see [Mr C] face to face or whether he was going to see his general practitioner.

10.17 On 23 November 2007, an Advanced Medical Institute administrator noted that [Mr C] wanted to cancel his programme, that his wife had his permission to speak on his behalf, and that his general practitioner had advised him not to go on the medications/programme. On 26 November 2007, an Advanced Medical Institute administrator noted 'NON 48 Hour…..NO REFUND…. Awaiting outcome from [Dr F] f2f'. Later that

day another administrator entered 'Refund Decision: Rejected by Case Manager Approval Amount: 0'. On 28 November 2007, Advanced Medical Institute sent [Mr C] a reminder letter after not getting a response to its phone calls. On 30 November 2007, an Advanced Medical Institute administrator noted the receipt of [Mr C's] fax of 20 November 2007.

10.18 Advanced Medical Institute claimed that on 12 December 2007, [Mr C's] refund had been approved but due to a clerical error the refund was not sent. On 1 January 2008, [Mr C] wrote to Advanced Medical Institute asking for a refund. On 1 April 2009, [Mr C] complained to HDC. On 27 May 2009, [Mr C] received a full refund from Advanced Medical Institute. Advanced Medical Institute offered [Mr C] free treatment if he visited [their clinic], which [Mr C] declined.

10.2 **Review of clinical records/documentation**

10.21 There is a letter dated 5 December 2007 from [Mr C's] GP and stating 'This is to certify that my patient does not require medication for erectile dysfunction'. There are no additional clinical notes.

10.3 **Comments**

10.31 There are several discrepancies between the recollections of [Mr C] and the responses of Advanced Medical Institute. Advanced Medical Institute maintains that [Mr C] was not going to be sent medication for his erectile dysfunction problem until he had been seen by an Advanced Medical Institute provider. What is clear is that [Mr C] did not receive any medication, nor did he make an appointment with an Advanced Medical Institute provider yet he had $1200 debited from his bank account by Advanced Medical Institute. The decision to debit [Mr C's] account for $1200 before providing any sort of material service was a commercial rather than clinical decision. The general standard of care in terms of failure to inform [Mr C] of what he was purchasing and the conditions of the purchase, and the failure to resolve his complaint in a timely manner, in particular a refund of his deposit, would meet with moderate to severe disapproval from a majority of my peers although some of these issues are commercial rather than clinical.

10.32 The undertaking of an ED (?PE) consultation resulting in recommendation of a medication, over the telephone and without documentation of such a consultation, is a mild to moderate departure from expected standards (refer to guidelines section 5) even though it was evidently expected [Mr C] would subsequently attend a local Advanced Medical Institute contractor at some later stage for a face to

face consultation. This is a different situation to follow-up after a face to face consultation where telephone advice and provision of medication might be appropriate if adequately documented.

10.33 Advanced Medical Institute 'agrees that no charge should have been made to [Mr C] or [Mr D] (see below) and note that it provided a full refund to each of them … the relevant charges made were due to process errors by [Advanced Medical Institute] which … have since been rectified'.

10.34 The standard of clinical care offered by Advanced Medical Institute to [Mr C] departed from expected standards to a mild to moderate degree for the reasons discussed above.

11. *Whether, in your opinion, Advanced Medical Institute provided an appropriate standard of care to [Mr D] and, if not, please outline the reasons for your views.*

11.1 **Chronology of Complaint**

11.11 On 15 April 2008, [Mr D] (aged 50) rang Advanced Medical Institute's 0800 number after seeing an item on television about their provocative bill boards. [Mr D] had erectile dysfunction and a prostate problem. [Mr D] spoke to an Advanced Medical Institute telephonist who told him that a doctor in Australia would phone him. The doctor (Dr N) asked [Mr D] some basic questions about his health. [Mr D] told the doctor that he wanted a face to face consultation with one of Advanced Medical Institute's local doctors to examine him and to assess whether his prostate problem might be worsened by their treatment or be effective. [Mr D] only recalls being told about the nasal spray. [Mr D] does not recall being told about side effects as he was adamant he wanted to see a doctor first.

11.12 [Mr D] asked to be sent information. [Mr D] claimed that Advanced Medical Institute refused to send him a brochure about the treatments they offer, but conceded that the doctor would be able to provide him with information. [Mr D] only recalls discussing the monthly cost of treatment, not that he would be charged a lump sum up front. [Mr D] was under the impression that he would therefore be able to cancel his monthly payments at any time. [Mr D] was phoned back by the New Zealand telephonist who told him he had an appointment with [a doctor] on 7 May 2008. [Mr D] claimed that Advanced Medical Institute then asked [Mr D] for his credit card details so they could process his payment as soon as he had seen the doctor.

11.13 In early May 2008, [Mr D] received a courier pack with medication for erectile dysfunction. [Mr D's] credit card had been charged $2880 on the same or the day following his call to Advanced Medical Institute.

Advanced Medical Institute stated that:

> '[A] script was generated in error and sent to the New Zealand pharmacy. The pharmacy again in error dispatched the medications to [Mr D]. The script was signed by an Australian Doctor and was obviously a mistake. We have since taken steps to ensure that this error does not occur and implemented a new system whereby all scripts sent to the NZ pharmacy are first checked by a designated person to ensure that all scripts have been signed by a New Zealand doctor.'

11.14 On 7 May 2008, [Mr D] went to his appointment with [the doctor]. The [Medical Centre] had no record of an appointment. [The doctor] had been off work for a couple of weeks and wasn't expected back for about a month. [Mr D] rang Advanced Medical Institute who said they would make another appointment for him, but never did. Advanced Medical Institute stated that the 'appointment was set up but for reasons that I could not determine the Doctor was not available at the date of his scheduled appointment'. [Mr D] made several calls to Advanced Medical Institute's 0800 number. Advanced Medical Institute's computer records show that [Mr D] contacted them on 7, 12, 19 and 21 May 2008. [Mr D] said he was told that Advanced Medical Institute did not have any doctors in [that city]. [Mr D] said that Advanced Medical Institute had told him that one of [the doctor's patients in that city] had tried the nasal spray and therefore [Mr D] was left with the impression that Advanced Medical Institute had simply tried to find any doctor in [the city]. Advanced Medical Institute later said that the nearest doctor contracted to work for them was in [another city].

11.15 [Mr D] was told that … Advanced Medical Institute would not cancel the charge to his credit card. On at least four occasions [Mr D] was assured someone from Advanced Medical Institute would ring him to firstly arrange an appointment and then to discuss his complaint; neither happened. [Mr D] later discovered that Advanced Medical Institute would require him to try all the medications before he would be eligible for a refund. [Mr D] claimed that Advanced Medical Institute encouraged him to try the medications he was sent rather than returning them. [Mr D] claimed that Advanced Medical Institute stated that they record their phone conversations, but when asked they stated that they could not locate his recording.

11.16 [Mr D] contacted his bank who reversed the charge to his credit card. The bank justified this on the basis that Advanced Medical Institute had not informed [Mr D] that they would be charging him a lump sum. Advanced Medical Institute did not challenge the reversed charges. On 8 June 2008, [Mr D] complained to HDC. His complaint was originally referred to the Ministry of Health on 27 June 2008, as it raised public safety concerns in regards to sending prescription medication to patients without a medical examination. [Mr D] was happy with this provided his complaint was a one-off. On 31 July 2009, HDC contacted [Mr D] to see if he would be interested in HDC reopening his complaint regarding Advanced Medical Institute as HDC had received similar complaints to his.

11.17 On 8 June 2010, Advanced Medical Institute acknowledged that [Mr D] should not have been charged. Advanced Medical Institute stated that [Mr D] was charged due to a 'process error' which has since been rectified. Advanced Medical Institute stated that it should have adopted different processes and procedures.

11.2 **Review of clinical records/documentation**

11.21 There is a copy of a prescription signed by an Australian doctor ([Dr N]) for Phentolamine and Vardanafil nasal spray — 'use as directed'.

11.22 The Advanced Medical Institute computer record for 15 April 2008, logged as 'Doctor's comments', states:

> 'Benign enlarged prostate. BPH ED and PE vardenafil spray for ED — PQ spray. In a few weeks add tramadol for PE for a combined spray. Injection therapy discussed as an option. *Note clomipramine is not indicated due to prostate.'[56]

11.3 **Comments**

11.31 The undertaking of an ED consultation over the telephone, resulting in medication being recommended and prescribed, is a mild to moderate departure from expected standards (refer to guidelines section 5) even though it was evidently expected [Mr D] would subsequently attend a local Advanced Medical Institute contractor at some later stage for a face to face consultation. This is a different situation to follow-up after a face to face consultation where telephone advice and provision of medication might be appropriate if adequately documented.

[56] Vardenafil is a Phosphodiesterase inhibitor. It is closely related in function to sildenafil citrate (Viagra) and tadalafil (Cialis).

11.32 It was inappropriate for medication prescribed by a GP in Australia to be dispensed in New Zealand. It was inappropriate for such medication to be delivered to [Mr D] before he had received a suitable assessment (face to face) and without, according to [Mr D's] recollections, receiving adequate information on the nature and use of the medication or adequate information on the service contract [Mr D] was entering.

11.33 Efforts by Advanced Medical Institute to facilitate a face to face consultation for [Mr D] were not timely or complete. The level of service offered by Advanced Medical Institute when [Mr D] requested a refund was inadequate.

11.34 The standard of care provided by Advanced Medical Institute to [Mr D] was a moderate departure from expected standards.

12. *Are there any aspects of the care provided by Advanced Medical Institute that you consider warrant additional comment?*

12.1 Advanced Medical Institute state 'all patients contact Advanced Medical Institute every 3 months to re-order more medications and on these occasions the Customer Service and Re-Order staff take the opportunity to ask the patients whether the medication is working for them and to make sure the patients are not suffering any side effects from the medication. If the patient is experiencing side effects the staff … will transfer them to a Registered Nurse'. In New Zealand general practice, the use of non-clinical staff to ascertain effectiveness of, or side effects from, medication use (particularly relating to a sensitive issue such as ED) would not be the norm. Such clinical enquiries are generally the realm of clinical staff such as practice nurses.

12.2 I note Advanced Medical Institute has advised that it:

> 'has made numerous changes to [its] procedures since these complaints have come [to] light. In relation to refunds and claims [Advanced Medical Institute] now has one centralized refund department which deals with all customer complaints in a timely manner and ensures that all customer refunds are processed in a timely manner. In relation to procedures relating to scripts [Advanced Medical Institute] has now adopted a script checking policy to ensure that each script generated is signed by the correct doctor and the medications are dispatched in a timely manner through the correct channels. [Advanced Medical Institute has] also provided its staff with extensive training in relation to dealing with customers on all levels. [Advanced Medical Institute] is also in the

> process of considering the training provided to staff and contractors with a view to improving the services provided to patients.'

In response to the Commissioner's provisional opinion, the Advanced Medical Institute submitted that Dr Maplesden's advice does 'not include reference to the relevant US or Dutch guidelines and does not make any reference to recent developments in the United Kingdom'. The Advanced Medical Institute provided HDC with a copy of US and Dutch Guidelines, and two 'web reports relating to Boots Pharmacy in the UK' . The Advanced Medical Institute submitted:

> 'The US guidelines relating to premature ejaculation clearly state that no physical examination is necessary in relation to the diagnosis and treatment of premature ejaculation and that such matters may be based on a review of medical history alone. The Dutch guidelines relating to erectile dysfunction make similar findings. In the United Kingdom authority has been provided to pharmacies to prescribe certain erectile dysfunction medications to the general public without the need for any prior medical consultation at all.'"

Dr Maplesden was asked to review the policies referred to by the Advanced Medical Institute, and advise whether they altered his opinion in any way. Dr Maplesden provided the following advice:

> "The US Guidelines relate to Premature Ejaculation rather than Erectile Dysfunction and therefore have relevance only to [Mr C's] case and even then there was confusion over whether he was complaining of ED or PE, and he denies being asked any questions relevant to this. There was certainly no evidence the US PE guidelines were followed with respect to the detail of questioning recommended, although I would not be particularly critical if no physical examination was undertaken in a patient complaining of chronic PE, provided a sufficiently detailed history had been undertaken to confirm this was the sole problem.
>
> The Dutch study was a small pilot study with acknowledged flaws (no control group, self-selection of patients) and I would certainly not regard it as evidence of sufficient quality to disregard national and international guidelines.
>
> The Boots programme excludes men over 65 years (who tend to have more complex causes of ED and in whom appropriate examination may be more critical than the younger age groups) and does not constitute a guideline, nor does it vindicate the actions of AMI. Furthermore, the service was provided by selected pharmacists who had undertaken formal training in assessment and management of ED patients and were required to interview the patient, check blood pressure and some biochemistry, and notify the patient's GP of all findings. While there may be a formal published appraisal of the programme

in the future, the documentation offered by AMI to date does not constitute quality evidence, nor does it give grounds for departure from recommended guidelines, particularly in complex elderly ED patients.

None of the documentation supplied has influenced the comments provided in my original advice."

Dr David Maplesden
Clinical Advisor
Health and Disability Commissioner
Auckland

Appendix 2: Code Rights, Relevant standards, Medsafe Guidelines

Code Rights

Right 4 — Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.

Right 6 — Right to be Fully Informed

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —
- (a) an explanation of his or her condition; and
- (b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
- (c) advice of the estimated time within which the services will be provided; and
- (d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
- (e) Any other information required by legal, professional, ethical, and other relevant standards; and
- (f) the results of tests; and
- (g) the results of procedures.

Right 10 — Right to Complain

…

(3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.

…

(6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that —
- (a) the complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
- (b) the consumer is informed of any relevant internal and external complaints procedures, including the availability of —
  - (i) independent advocates provided under the Health and Disability Commissioner Act 1994; and
  - (ii) the Health and Disability Commissioner; and
- (c) the consumer's complaint and the actions of the provider regarding that complaint are documented; and

(d) the consumer receives all information held by the provider that is or may be relevant to the complaint.

Relevant standards

"*Good medical practice — A guide for doctors* (Medical Council of New Zealand, October 2004)

Medical care
Good clinical care

2. Good clinical care must include:

- an adequate assessment of the patient's condition, based on the history and clinical signs and, an appropriate examination
- providing or arranging investigations or treatment when necessary
- taking suitable and prompt action when necessary
- referring the patient to another practitioner, when indicated.

3. In providing care you must:

…

- keep clear, accurate, and contemporaneous patient records that report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed

  …

- prescribe only the treatment, drugs, or appliances that serve the patient's needs and only when you have adequate knowledge of those needs

  …

- if you do not see patients face to face, be confident that a physical examination is not necessary, ie that there is no important information this would add, before you provide treatment or advice.

  …

Financial and commercial dealings

54. You must be honest in any financial and commercial matters relating to your work. In particular:

- You should provide information about fees and charges before obtaining a patient's consent to treatment, wherever possible …"

Good medical practice — A guide for doctors (Medical Council of New Zealand, June 2008)

"Keeping records

4. You must keep clear and accurate patient records that report:

- relevant clinical findings
- decisions made
- information given to patients
- any drugs or other treatment prescribed.

…

Prescribing drugs or treatment

5. You may prescribe drugs or treatment, including repeat prescriptions, only when you:

- have adequate knowledge of the patient's health
- are satisfied that the drugs or treatment are in the patient's best interests.

Usually this will require that you have a face-to-face consultation with the patient or discuss the patient's treatment with another registered health practitioner who can verify the patient's physical data and identity.

…

Giving information to patients about their condition

13. Give patients all information they want or need to know about:

- their condition and its likely progression
- treatment options, including expected risks, side effects, costs and benefits

…

Financial and commercial dealings

93. Be honest and open in any financial dealings with patients. In particular, note the following:

- inform patients about your fees and charges before asking for their consent to treatment
- do not exploit patients' vulnerability or lack of medical knowledge when making charges for treatment or services …"

Responsibilities in any relationships between doctors and health related commercial organisations (Medical Council of New Zealand, August 2008)

"Good medical practice

7. In providing care you are expected to provide effective treatments based on the best available evidence. You must adequately assess the patient's condition, taking account of the patient's history and his or her views and examine the patient as appropriate.
8. Act in your patient's best interests when making referrals and providing or arranging treatment or care. …"

Medsafe Guidelines
Regulatory Issues

Unapproved Use of Medicines

The Medicines Act 1981 permits a registered medical practitioner, dentist and midwife to prescribe, administer or arrange for the administration of medicines for the treatment of a patient in his or her care. The medicine and its use may or may not be approved. The Act also permits the sale or supply of unapproved medicines to registered medical practitioners, but requires the supplier to notify the Director-General of Health. Approval is obtained when a sponsor company has sought and received Ministerial consent to the marketing of that medicine and the indications, contraindications, etc. are set out in the current data sheet.

The *Code of Health and Disability Services Consumers' Rights* places obligations on the provider of services. The consumer has the right to treatment of an appropriate ethical and professional standard, and the provider has the responsibility to ensure treatment, whether approved or unapproved, meets this standard. The consumer also has the right to be fully informed. If the use of a medicine is unapproved, the consumer should be so advised and the provider should be frank about the standard of support for the use and any safety concerns. The Code requires written consent for experimental use of a medicine. The unapproved use of a medicine would be considered to be experimental if there is little or equivocal documented support for the use.

Use of medicines regulated by the Medicines Act
Section 25 of the Medicines Act permits use of unapproved medicines
Section 29 requires notification of sale or supply of unapproved medicines
Patients should be advised of the forwarding of information under section 29
Consumers' rights spelt out in the Code
Right to services of an appropriate standard
Right to be fully informed
Right to give informed consent
Scenario 1: Unapproved medicine
Scenario 2: Unapproved medicine
Scenario 3: Unapproved indication and route of administration
Scenario 4: Unapproved indication

Medsafe is aware that some medical practitioners are confused about their rights and responsibilities with respect to prescribing unapproved medicines, or approved medicines for unapproved uses (such as unapproved indication, dosage or route of administration). Recent correspondence has raised concerns about the legal position of the practitioner who prescribes a medicine in a situation in which it is contraindicated, or against which there are warnings in the data sheet. Examples of these situations are

the use of Depo-Medrol injection for epidural administration, and nifedipine capsules in the treatment of hypertensive crisis in pregnancy.

This article will attempt to clarify the situation with regard to the Medicines Act 1981. It will also apply the requirements of the *Code of Health and Disability Services Consumers' Rights* to the unapproved use of medicines. At the end of the article are four scenarios which illustrate the points made and describe correct procedure. The reader may find the material more accessible if the scenarios are read first.

Use of medicines regulated by the Medicines Act

The Medicines Act regulates the use of medicines in New Zealand. It requires that in order for a medicine to be marketed an application with supporting documentation must be made for the consent of the Minister. The Minister's consent is notified in the *New Zealand Gazette*, at which time the medicine, along with a set of indications, dosage instructions and route(s) of administration, is regarded as being approved. Proposed changes, including new indications and changes to the data sheet, also have to be applied for.

Because of this requirement for seeking and obtaining consent, it follows that there will be medicines that may be effective and safe, and approved in other countries, but do not have approval in New Zealand. There will also be other medicines that have been approved with a particular set of indications, but for which there are other recognised indications not applied for in New Zealand. Some unapproved medicines may be used for rare diseases, for which there are few or no treatments approved in this country.

Hence, the need to provide for access to unapproved medicines was recognised when the Medicines Act was formulated. Section 25 of the Act permits registered medical practitioners, dentists and midwives (hereafter referred to collectively as "practitioners") to procure, administer and arrange the administration of an unapproved medicine. Section 29 permits an authorised supplier or a medical practitioner to supply or sell an unapproved medicine to a medical practitioner provided the Director-General of Health is notified. Both sections of the Act need further explanation.

Section 25 of the Medicines Act permits use of unapproved medicines

The terms of section 25 are inclusive and permissive, allowing the practitioner to "procure the sale or supply of any medicine" for a particular patient in his or her care. "Any medicine" includes approved and unapproved medicines. For dentists "any medicine" applies only to medicines for dental treatment, and for midwives it applies only to medicines for antenatal, intrapartum and postnatal care (Regulation 39, Medicines Regulations 1984).

"Procure the sale or supply" refers to obtaining the medicine through the usual channels such as a pharmacy or a pharmaceutical company, and it also permits the practitioner to use other means of obtaining a medicine such as importation. However,

section 25 does not envisage bulk purchase by the practitioner. The use is to be for the treatment of a particular patient in the care of that or another practitioner.

It is worth mentioning, at this point, the use of approved medicines for unapproved uses. Section 25 permits a practitioner to use any medicine (approved or unapproved) for the treatment of a particular patient in his or her care. The Act puts no restriction on the use of a medicine, even in a situation in which it is contraindicated. However, whether the practitioner uses approved or unapproved medicines, he or she must provide care of an adequate professional and ethical standard (see the discussion of the *Code of Health and Disability Consumers' Rights* later in this article).

Section 29 requires notification of sale or supply of unapproved medicines
Section 29 of the Act permits the sale or supply to medical practitioners of medicines that have not been approved, and requires the "person" who sells or supplies the medicine to notify the Director-General of Health of that sale or supply in writing naming the medical practitioner and the patient, describing the medicine and the date and place of sale or supply.

No notification is required for an unapproved use of an approved medicine, nor is notification required if a practitioner imports a medicine to treat his or her patient. However, if an unapproved medicine is sold or supplied to a medical practitioner, that sale or supply should be notified. If the supply is from one medical practitioner to another, the supplying medical practitioner is encouraged to notify the supply, but notification of supply is not mandatory in this case.

It should be noted that section 29 specifies only medical practitioners. This means that if dentists and midwives wish to procure unapproved medicines their sources are limited to other practitioners or to direct importation.

On occasions a pharmacist working in a pharmacy may be involved in the supply of an unapproved medicine as the medical practitioner's agent. If the pharmacy has imported the medicine, it is the pharmacist's responsibility to ensure that the details of supply are sent to Medsafe. If the medicine has been obtained from a distributor for an identified patient then that distributor should be given sufficient information to enable them to report the supply to Medsafe.

Anyone who imports an unapproved medicine for supply to a doctor under Section 29 (other than a hospital or pharmacy) should ensure that they hold a licence to sell medicines by wholesale. They should also ensure that they hold the product specifications and certificates of analysis for each batch imported as required by Section 42.

Section 29 supply will be audited as part of the annual audit for a Wholesale licence.

Section 29 Notification Form (*Microsoft Word document 26KB*)

Patients should be advised of the forwarding of information under section 29
Note that under the Health Information Privacy Code, Rule 3, the medical practitioner must advise the patient that the information about supply of the medicine will be forwarded to Medsafe and recorded on a database as a requirement of the Medicines Act.

Consumers' rights spelt out in the Code
The *Code of Health and Disability Services Consumers' Rights*, which was introduced in July 1996, specifies certain rights of consumers of health and disability services and as a result places obligations on the practitioner. The Code covers the right to treatment of an appropriate ethical and professional standard, the right to be fully informed about condition and treatment options, and the right to make an informed choice.

Right to services of an appropriate standard
Right 4 of the Code refers to the right to services of an appropriate standard. This right includes:

2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

This right covers the professional standard of the service provided. Whether the medicine or use of the medicine is approved or unapproved, the practitioner must approach the decision for its administration in a professional, scientific manner which includes weighing the expected benefits and risks.

This right also applies to the situation where a patient requests the prescription of an unapproved medicine, about which the practitioner knows nothing. In such cases, the practitioner must seek to be adequately informed before assisting the patient to obtain supplies of the medicine. Only then will the practitioner be in a position to comply with Rights 6 and 7, which are discussed below.

It is conceivable that the medical practitioner will be unable to find sufficient information to convince him or her of either the efficacy or the safety of a medicine requested by a patient. The decision must then be made whether or not to assist the patient to obtain the medicine and conduct a clinical trial of one patient. In anticipation of such situations the medical practitioner needs to pre-determine what are his or her minimum criteria for regarding a medicine as a treatment option, and also what will be his or her standard of patient monitoring to minimise harm should the decision be to proceed with treatment in situations where documentation is severely limited.

Right to be fully informed
Right 6 of the Code covers the right to be fully informed.

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including...

(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;...

For an unapproved medicine or unapproved use, the consumer should be advised of the unapproved status. The consumer should also be advised of the degree and standard of the support for the use of the medicine, and of any safety concerns, or warnings or contraindications regarding its use in their particular condition. In using the phrase "Right to be fully informed", the Code requires frank disclosure of information including information that may dissuade the consumer from agreeing to use of the medicine.

The following are examples of the information that should be conveyed, as appropriate:

> The medicine is widely used for this indication and its use is supported by well conducted clinical trials;
>
> The medicine is contraindicated for use in this situation;
>
> This medicine is approved for use in adults but no studies have yet been published on its use in children;
>
> The medicine is innovative and little is known about its potential adverse effects; and
>
> The published studies of the use of this medicine for this indication do not provide consistent evidence of its efficacy.

With regard to the first point above, it is worth noting that a medicine only obtains approval if there has been an application, with adequate supporting documentation, from a sponsor company to the Director-General of Health. There may be adequate data supporting the use of a medicine, or supporting a different indication or dosage regimen, but if no company has submitted an application there can be no marketing approval in this country.

The use of medicines in certain groups, such as infants and small children, pregnant women, and frail or elderly patients can be a dilemma for the practitioner. Usually trials have not been conducted in these groups for a number of reasons including ethical ones. Therefore, the sponsor company is unwilling and unable to recommend such use in its data sheet and this becomes an unapproved indication.

Right to give informed consent
Right 7 refers to the right to make an informed choice and give informed consent:

(6) Where informed consent to a health care procedure is required, it must be in writing if...

(b) The procedure is experimental;... .

The use of an unapproved medicine, or unapproved use of a medicine will not always be experimental, but in some circumstances the requirement to obtain written consent will apply. These would include situations where:

> There is minimal evidence to support this use;
>
> The evidence of the efficacy or safety of the medicine used in this manner is equivocal; or
>
> The use is part of a clinical trial.

Prescribers need to take responsibility for thinking through the issues, deciding in each situation whether the use is experimental or not, and taking the necessary action. If the use is not judged to be experimental the consumer still has the right to make an informed choice and give informed consent to the treatment.

Note that the obtaining of written consent does not mean that the requirements of the Code have been complied with. The obtaining of informed consent is a process which involves effective communication, frank information disclosure and freely given consent. It also involves careful investigation of the clinical condition of the patient and maintaining a current knowledge of treatment options.

The following four scenarios illustrate what is permitted under the Medicines Act and what is required by both the Medicines Act and the *Code of Health and Disability Services Consumers' Rights.*

Scenario 1: Unapproved medicine
A patient comes to a medical practitioner's surgery complaining of insomnia and requesting melatonin. The patient claims that melatonin has been helpful in the past and says that it can be obtained from Company X in Auckland. The practitioner knows that melatonin is not approved and that it has recently been scheduled a prescription medicine. He has no knowledge of the safety or efficacy of melatonin. The practitioner is obliged to use the means available to him to obtain unbiased information on the efficacy and safety of melatonin in the treatment of insomnia, and be assured that it may benefit and not harm the patient. He is then able to decide whether he wishes on scientific grounds to assist the patient to obtain melatonin. He should discuss with the patient the information obtained, as well as the nature of the patient's insomnia, and other medical and non-medical treatment options.

If, after a full and frank discussion, the decision of both the medical practitioner and the patient is to use melatonin, the practitioner has three further steps to take before obtaining supplies. He should decide whether melatonin for insomnia should be

regarded as experimental, necessitating signed consent. If it is considered experimental he should agree with the patient on a suitable procedure for monitoring for safety and efficacy. Finally, he should advise the patient that it is a requirement under the Medicines Act for the information about the supply, including the patient's name, to be forwarded to Medsafe and be stored in a database.

The practitioner then contacts Company X and requests melatonin for his patient. If the medicine is procured from Company X, the company must report the supply to the Director-General.

Scenario 2: Unapproved medicine
A patient who has recently returned from two years working in Canada has been taking Medicine A for rheumatoid arthritis and has found it to be more effective in easing the pain and improving mobility than any other medicine he has used to date. He would like to continue using this medicine. His general practitioner checks the *New Ethicals Catalogue* and cannot find either the medicine or the manufacturer listed. She contacts Medsafe and is advised that it is not available in New Zealand and no application for consent has been received for this medicine.

Through the medical school library the practitioner is able to obtain some information on the efficacy and safety of Medicine A in the management of rheumatoid arthritis. She also finds that Medicine A has been available in the United Kingdom, France and Canada for about 20 years. The general practitioner also contacts a rheumatologist, who advises that she was aware of the effective use of Medicine A when she was working in the UK for a year.

After this process the general practitioner is persuaded that Medicine A could be a useful and safe medicine for this purpose, and she agrees to write on behalf of her patient to the manufacturer at the address on the bottle supplied by the patient. She also discusses the treatment with another general practitioner who has a patient with difficult to manage rheumatoid arthritis. This colleague requests some of the medicine for his patient.

When the supplies of the medicine arrive, the first medical practitioner supplies one bottle to her patient and another to her colleague. She reports to the Director-General of Health the supply of the medicine to the other practitioner, including the name of the practitioner, name of the other practitioner's patient and the date and place of supply.

Scenario 3: Unapproved indication and route of administration
A man visits a pain clinic with long term disabling back pain. The specialist he sees at the clinic believes that an epidural injection of Depo-Medrol may ease the patient's pain, and restore a degree of quality of life. She has successfully treated a number of back pain sufferers with Depo-Medrol in the past 12 months, and so have her colleagues at the same clinic. She believes that she is able to administer the injection with accuracy and skill.

However, she is aware that epidural Depo-Medrol is not an approved treatment for back pain, and the manufacturer has included a warning in the data sheet stating that "Depo-Medrol should not be administered by any route other than those listed under Indications". In addition, she is aware that the studies examining the efficacy of epidural steroid injections in the management of back pain are not well-controlled and not all show significant gains in pain relief. She also knows that some New Zealand back pain sufferers have claimed that they have been more seriously disabled following treatment with an epidural corticosteroid injection.

The specialist presents epidural Depo-Medrol to the patient as a possible treatment option. She mentions that it is not an approved treatment, that the manufacturer of the medicine warns against this use, that the evidence for its efficacy in clinical trials is not well-supported, and that some recipients treated at other clinics believed they were more seriously disabled following this treatment. She also explains that in her experience it is a valuable option for the treatment of back pain and that she has administered it successfully in the past. The patient and the specialist discuss why the manufacturer may warn against this use and why other patients may claim they have been further disabled by it. The specialist gives the patient a leaflet that discusses this and other treatments for lower back pain and invites the patient to consider the options and return to the clinic the following week.

When the patient returns, he asks a few questions and then advises the specialist he wishes to have the epidural Depo-Medrol injection. Because the documented evidence of efficacy is equivocal, the manufacturer warns against use in unapproved indications, and some patients consider they have been seriously disabled by treatment, the specialist considers the treatment should be regarded as experimental under the Code, and explains this to the patient with reasons. She asks the patient to sign a form indicating he has agreed to treatment with epidural Depo-Medrol.

Scenario 4: Unapproved indication
A patient is admitted for the placement of a coronary artery stent. The specialist routinely prescribes ticlopidine and aspirin for antiplatelet therapy after this procedure. Ticlopidine is an approved medicine, but it is not approved for antiplatelet therapy following stenting *(ticlopidine [Ticlid] is now approved for this indication). A recent large scale well-designed study demonstrated that ticlopidine and aspirin were an optimum treatment option in this indication. The specialist and his colleagues had carefully discussed the merits of the study and other knowledge they had of the treatment options, together with other views expressed in letters to the editor, and had decided to use ticlopidine and aspirin.

Before the procedure the specialist discusses the need for anticoagulant or antiplatelet therapy and the treatment options with the patient. He explains that ticlopidine is not approved for this indication but recent data have shown it to be an effective treatment with better long term outcomes than other options. He briefly discusses the nature of the data. The specialist also explains the need for biweekly blood monitoring because

of a risk of bone marrow suppression, and advises the patient to contact her general practitioner at the first sign of any infection.

The patient agrees that the combination of aspirin and ticlopidine appears to be the best choice. She is not invited to sign a consent form for ticlopidine treatment because the specialist has decided that the evidence for efficacy and safety is substantial and its use cannot be regarded as experimental.

This article has been prepared in consultation with the Health and Disability Commissioner. The reader should note that the Health and Disability Commissioner does not give advance rulings on interpretation and application of the Code, and hence it is not possible to say in advance that a particular practice is or is not in breach of the Code. This provision is to ensure that each complaint is considered impartially and with an open mind.

Disclaimer: Mention of the therapies in the scenarios described in this article should not be regarded as implied endorsement on the part of Medsafe.

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*This statement was accurate at the time this article was first published in April 1998. However, in 1999 ticlopidine (Ticlid) was approved for antiplatelet therapy following coronary artery stenting. The scenario continues to aptly illustrate the point even though it no longer applies to this indication of ticlopidine.