Medical Practitioner, Dr C

A Report by the

Health and Disability Commissioner

(Case 10HDC00986)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Names have been removed (except 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.

Executive summary

1. Dr C is a doctor who performs minimally-invasive cosmetic procedures. Dr C has general registration with the Medical Council of New Zealand, however was not registered under any vocational scope of practice at the time of these events.

2. On 24 July 2009, Mrs A, accompanied by her daughter, attended a consultation with Dr C as she wanted a cosmetic procedure to help her achieve a healthier appearance.

3. Dr C recommended a procedure called the "mid-face volumisation", which involved the injection of a dermal filler[1] into her cheeks. The dermal filler was not an approved medicine in New Zealand under the Medicines Act 1981.

4. Dr C did not inform Mrs A that the dermal filler was unapproved in New Zealand; he only informed her that the dermal filler included the same chemical compound that he had been using for the previous four years, and that he had considerable experience performing the procedure. Dr C also did not inform Mrs A about the possible side effect of granuloma formation.[2]

5. Following the procedure, Mrs A developed granulomas, which Dr C was unsuccessful in treating.

Decision summary

6. Dr C failed to ensure that the filler was safe and appropriate for use as a dermal filler, therefore breached Right 4(1)[3] of the Code of Health and Disability Services Consumers' Rights (the Code).

7. A reasonable consumer in Mrs A's circumstances would expect to receive information about the risk of granuloma formation, that the dermal filler was not an approved medicine in New Zealand, as well as independent clinical literature about the dermal filler's safety. Dr C's failure to provide that information breached Rights 6(1)[4] and 7(1)[5] of the Code.

8. Dr C failed to provide adequate follow-up care to Mrs A and breached Right 4(1) of the Code. He also failed to keep clinical records of the post-operative care he provided to Mrs A, and therefore breached Right 4(2) of the Code.

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[1] Gel-like substance that is injected into the skin to physically lift the skin. Dermal fillers are commonly used to correct wrinkles and asymmetries of the face.

[2] A granuloma is a small, benign, chronic inflammatory nodule that forms in response to foreign material. Histologically it is characterised by a tight, ball-like collection of macrophages (a type of white blood cell that ingests foreign material). In this case, granulomas would appear as skin lumps over the cheek area where the foreign dermal filler material was injected.

[3] Right 4(1) provides "Every consumer has the right to have services provided with reasonable care and skill."

[4] Right 6(1) provides "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive,"

[5] Right 7(1) provides "Services may be provided to a consumer only if the consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."

Complaint and investigation

9. On 26 August 2010, the Commissioner received a complaint from Mrs B about the services provided by Dr C to her mother, Mrs A. Mrs A provided HDC with written support for the complaint on 8 October 2010.

10. The following issues were identified for investigation:

- *Whether Dr C provided Mrs A with an appropriate standard of care, including follow-up care.*
- *Whether Dr C provided Mrs A with adequate information and obtained her informed consent in relation to the care he provided to her.*

11. An investigation was commenced on 26 July 2011.

12. The parties directly involved in the investigation were:

Mrs A	Consumer
Mrs B	Complainant and the consumer's daughter
Dr C	Provider

Also mentioned in this report:

Mr D	Medical supplies director

13. Information was reviewed from Medsafe.

14. Independent expert advice was obtained from a Cosmetic Physician and President of New Zealand College of Appearance Medicine, Dr Teresa Cattin (attached as **Appendix A**).

Information gathered during investigation

15. On 24 July 2009, Mrs A, accompanied by her daughter, Mrs B, consulted registered medical practitioner, Dr C at a beauty clinic (the clinic). Mrs A was exploring the possibility of a cosmetic facial procedure to help her achieve a healthier appearance. Dr C recommended the "mid-face volumisation" procedure, which involves the injection of dermal filler into the patient's cheeks to improve their contour and increase their fullness. While the procedure itself was not unusual, the product Dr C used as the dermal filler was new to his practice and was also not approved for use in New Zealand under the Medicines Act 1981.[6] Unfortunately, Mrs A developed granuloma formation[7] after the procedure, which required surgical treatment.

[6] 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

16. My investigation into Mrs A's complaint focused on the appropriateness of the care provided by Dr C to Mrs A, and the adequacy of the information given to Mrs A to enable her make an informed decision as to whether to give consent.

Dr C's medical practice

17. Dr C achieved general registration as a doctor in 1999. At the time of the complaint, Dr C was not registered under any vocational scope of practice with the Medical Council of New Zealand.

18. Dr C advised HDC that his medical practice was limited to minimally invasive appearance medicine, such as botox injections and dermal filler placement. Dr C practises from a clinic in a main centre, of which he is the Director. Dr C also advised HDC that he works as an independent contractor at the clinic (in a regional town) once a month.

19. Dr C advised HDC that, at the time of his consultation with Mrs A, he was an "associate" member of the New Zealand College of Appearance Medicine (NZCAM). He also stated that he had performed "some 300 [mid-face volumisation] procedures over the past six years as well as demonstrating this procedure at the New Zealand College of Appearance Medicine conference in 2008, as well [as] at International Colleges in Australia."

20. My expert advisor, Cosmetic Physician and President of NZCAM, Dr Teresa Cattin advised that Dr C joined NZCAM as an "affiliate" member in 2007 but his membership lapsed in mid 2009.[8]

21. Dr Cattin explained that NZCAM does not offer "associate" membership, and that the "affiliate" membership is offered to anyone with an interest in appearance medicine and, therefore, affiliate membership is not an assurance of the practitioner's competence or fitness to practise.

22. NZCAM also confirmed to HDC that there is no reference to Dr C in its 2008 Conference programme as a speaker or a presenter. NZCAM stated that the only contact NZCAM had from Dr C, in relation to the 2008 Conference, was an email from him saying that he was unable to attend. NZCAM further confirmed that its 2005 to 2011 Conference programmes also do not refer to Dr C as a speaker or a presenter.

The dermal filler

23. A company (the supplier) provided medical supplies to Dr C. The supplier's Director, Mr D, advised HDC that he was introduced to the dermal filler during a workshop held overseas in 2009. Mr D stated that the manufacturer demonstrated and marketed

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medicine, along with a set of indications, dosage instructions and route(s) of administration, is regarded as being approved.

[7] A granuloma is a small, benign, chronic inflammatory nodule that forms in response to foreign material. Histologically it is characterized by a tight, ball-like collection of macrophages (a type of white blood cell that ingests foreign material). In this case, granulomas would appear as skin lumps over the cheek area where the foreign dermal filler material was injected.

[8] Dr C's annual membership subscription was due in April 2009, which was not paid until October 2009. His membership lapsed again in March 2010, and has not been renewed.

the dermal filler as a cosmetic dermal filler for the face and he was given free samples to take back to New Zealand. Mr D stated that he was aware that the dermal filler was a vocal cord enhancer and was not approved as a facial filler by the United States of America, Food and Drug Administration (FDA) department, but that it was in the FDA approval process.

24. Medsafe advised HDC that, in 2009, the dermal filler was an "unapproved medicine" in New Zealand as the Minister of Health had not given his consent to the sale, distribution or advertising of the product.[9] Furthermore, the FDA has not listed the dermal filler as an approved medicine or medical device on its website.[10]

25. Mr D stated that he told Dr C about the dermal filler and gave Dr C information about the product. Mr D advised that Dr C expressed an interest in the dermal filler and therefore Mr D supplied Dr C with 12 units for trial. Mr D stated that he believed the product was being supplied under section 29 of the Medicines Act 1981.[11] However, Dr C did not receive that supply in relation to any particular patient and Medsafe advised HDC that there is no record of the supplier reporting that sale or supply to the Director General of Health pursuant to section 29.

26. Dr C advised HDC that after he was advised of the dermal filler by Mr D, he took a number of steps to ensure that the product was efficacious and safe to use. He stated that he reviewed the manufacturer's product information, which included a marketing DVD, promotional brochures and "product literature". He stated that the packaging and brochure information "appeared to legitimise the use of [the dermal filler] as an ideal dermal filler".

27. Dr C stated that he also reviewed the manufacturer's website to check whether the dermal filler had USA FDA approval. Dr C advised that because the product had FDA approval for use in vocal cord augmentation,[12] and contained the same active compound as a dermal filler (the approved filler) that he had used for the previous four years without any significant complication, Dr C believed that the dermal filler was safe and efficacious to use as a dermal filler.

28. Dr C advised that prior to Mrs A's consultation, he used the dermal filler supplied by the supplier on seven other patients.

29. Dr C stated to HDC:

[9] Medicines Act 1981, s 20.
[10] USA Food and Drug Administration website <www.accessdate.fad.gov> <last accessed 4 May 2010>.
[11] Section 29 permits the sale or supply to medical practitioners of medicines that have not been approved, and requires the person (or company) who sells or supplies the medicine to notify the Director General of Health of that sale or supply in writing naming the medical practitioner, the patient, description of the medicine, and the date and place of the sale or supply.
[12] See paragraph 25. The FDA website does not list the dermal filler as an approved medicine or medical device.

> "I understood that [the dermal filler] was available to use under section 29 of the [Medicines] Act. The distributor here in New Zealand is [the supplier] … who imported the product to expand their cosmetic product range."

Consultation with Mrs A

30. On 24 July 2009, Mrs A, accompanied by her daughter, Mrs B, attended a consultation with Dr C at the clinic. Mrs A wanted a healthier appearance and Dr C recommended the "mid-face volumisation" procedure.

31. Mrs A stated that "[Dr C] on first consultation discussed the benefits of the procedure; that he had been using these '[dermal] fillers' for at least five years and that it would be beneficial for me to fill the deep holes in my cheeks".

32. Mrs A further stated that Dr C did not name the dermal filler he would be using but advised her that he "used this product frequently" and that the product was calcium based; the advantage being that it would break down within 18 months of treatment, returning her cheeks to their original condition.

33. Mrs A said that Dr C did not, at any time during the consultation, inform her that the product was not approved in New Zealand. Mrs A stated, "If [Dr C] had [told me,] I would never have agreed to the procedure". Mrs B confirmed that Dr C did not advise Mrs A of the name of the dermal filler that he would be using or that it was an unapproved medicine.

34. In relation to the risks and benefits of the procedure, Mrs A stated that Dr C showed her before and after photos to illustrate the result of the procedure but "did not outline any risk and side effects other than that associated with poor injecting", such as bruising and slight swelling. Mrs A also stated that Dr C did not inform her of the risk of bleeding or nodule development.

35. Mrs A further advised that Dr C reassured her that he had never had any adverse side effects occur. She also stated that Dr C did not advise her that there was a risk of granuloma formation.

36. Dr C advised HDC that he explained to Mrs A that the side effects of the procedure could include bruising, swelling and tenderness, and that further correction may be needed after the procedure. Dr C acknowledged that he did not discuss the possibility of granuloma formation because it was a rare side-effect. He stated:

> "What I did not specifically identify as a risk was the possibility of granuloma formation. The reason I did not state this is that in the previous 4 years that I had been injecting [the approved filler], I had never encountered this side effect. In fact I had never in the nine years of previous injecting seen this side effect but rather had seen the side effect being presented at conferences. I had not regularly stated that granuloma formation is a side effect of dermal fillers because of its rarity."

37. Dr C agreed with Mrs A's account that he explained the benefits of using a calcium hydroxyapatite based dermal filler, but did not give her any information about the dermal filler because he believed Mrs A had total trust in his expertise. He stated:

> "I had not offered [Mrs A] information about the dermal filler. She had relied on the initial consultation and my recommendation that the product was safe to use. In addition, [Mrs A] was visiting her daughter from [overseas] and [Mrs A] had been thinking about a simple procedure to improve her appearance. I believe [Mrs A] totally trusted that I would use only safe products because I had been treating her daughter without incident (although not with dermal fillers)."

38. The consent form, dated 24 July 2009 and signed by Mrs A, records that the procedure's safety and duration were discussed, as well as the risks of "bleeding, bruising, swelling, redness", and the development of "nodules". Mrs A denies being informed of these risks, as stated above.

39. The procedure was performed without incident. Mrs A subsequently returned home.

Follow-up care

40. Mrs A advised HDC that approximately two weeks after the procedure she developed swelling and inflammation on her cheeks. She stated that Dr C recommended that she take prednisone[13] and antibiotics. Mrs A returned to New Zealand to see Dr C on 25 October 2009 as the prescribed medication did not resolve her skin condition.

41. Mrs A said that after arriving back in New Zealand, Dr C postponed the appointment for another week. Mrs A advised that during that time, a large granuloma was about to erupt on her face and so she had to see a GP in [the town] to drain the granuloma, which left "a hole by [her] cheekbone".

42. Mrs A stated that during the follow-up consultation, Dr C advised her that the lumpy lesions were likely to be granuloma reactions to the dermal filler. Dr C advised that he injected a steroid directly into the lumps on Mrs A's face, provided laser therapy in an attempt to seal the microvasculature supplying the granulomas, and further prescribed antibiotics and prednisone. He stated that he reviewed Mrs A two weeks later, repeated the above treatment, and arranged for Mrs A to be followed up by her GP [at home]. Dr C told HDC that he was happy with the improvement although "obvious swellings (approx 10-20cm) in her cheeks" were still present.

43. Mrs A subsequently returned home. She stated that she contacted Dr C several times by telephone because she did not know what her skin condition was. Mrs A states that Dr C did not seem to know either. She stated that she continued taking prednisone, which had some positive benefits, but her condition worsened whenever she stopped taking it.

44. Dr C stated that he subsequently recommended to Mrs A a "trial" of allopurinol, a drug usually used to treat gout. Dr C stated that he had read a "Journal case report" of

[13] A medicine sometimes prescribed as an anti-inflammatory.

allopurinol having a positive result on a similar reaction to a different filler compound.

45. When there was no improvement, Dr C stated that he contacted Mrs A's GP to help find a clinical solution to her condition and also attempted to refer Mrs A to a dermatologist. Dr C advised that the dermatologist referrals were unsuccessful because the dermatologists were reluctant to get involved due to the rarity of Mrs A's complication. Dr C stated that he had discussed Mrs A's condition with her GP and her brother-in-law, who was also a GP.

46. Mrs A stated that when she told Dr C that her brother-in-law had referred her to two specialists, Dr C "henceforth completely ignored [her] - much to the disgust of the two specialists – who were both appalled with the rubbish this person had injected into [her] face". Mrs A stated that Dr C's "follow-up [care] after two weeks was nil".

47. Dr C stated that in November 2010 he went overseas to see Mrs A. Mrs A stated that Dr C said that she looked like she had cancer of her face and informed her that the dermal filler that he had used was a vocal cord filler that a drug representative had sold to him.

48. Dr C advised HDC that he immediately ceased using the dermal filler after discovering the side effect experienced by Mrs A and that he was "duped" into believing the product was safe. He stated:

> "I believe with good reason that I was duped into believing that the product was safe and pending FDA approval.[14] This was because the product packaging and promotional brochure marketed the product as a dermal filler. In addition, because I had used a previous dermal filler based on Calcium Hydroxyapatite without incident, I thought I was just using a similar technology."

49. Mrs A estimates that she suffered at least nine nodular eruptions to her face. She advised that she required multiple facial lacerations to remove the lesions and the injected filler from her cheeks. Histological examination confirmed the diagnosis of necrotizing granulomas. Mrs A advised HDC that she has physical and emotional scars as a result of the procedures.

50. Mrs A and Mrs B made a complaint to HDC on 26 August 2010.

Documentation

51. HDC made several requests for Dr C to provide all clinical records of the treatment he provided to Mrs A. He provided the "Consultation Form", the "Consent form", and the "Treatment Worksheet" with an illegible date recorded. HDC requested that Dr C verify whether the records provided were the only documentation he had of Mrs A's treatment and care. To date, Dr C has not provided a response to this matter.

[14] See paragraph 25.

Response to provision opinion

52. Dr C responded that he accepts my findings "without reservations". Dr C also provided a written apology to Mrs A, as recommended in the provisional opinion.

53. Mrs A also provided some comments, which are incorporated into this report where relevant.

Opinion: Breach – Dr C

Provider's obligations when prescribing unapproved medicine

54. This dermal filler is an unapproved medicine in New Zealand. In using or prescribing an unapproved medicine, a practitioner is required to comply with the Medicines Act 1981. In addition, when prescribing an unapproved medicine to a patient, the practitioner has an obligation to satisfy themselves that the medicine is safe and efficacious. This legal obligation arises from Right 4(1) of the Code. Right 4(1) requires that services are provided with reasonable care and skill. In determining the standard of care required to fulfil Right 4(1), I may consider the standards as accepted by peers of Dr C and also relevant professional standards as set by the Medical Council of New Zealand (MCNZ).

55. The MCNZ's *Good prescribing practice* (June 2009) states that doctors who prescribe unapproved medication must meet the standards expected of doctors who provide complementary and alternative medicine. The *Statement on complementary and alternative medicine* (March 2005) provides that doctors must take steps to ensure that the complementary or alternative treatment or product is safe and efficacious for the intended use.

56. My expert advisor, Dr Cattin, advised that appropriate steps for a practitioner to take before prescribing an unapproved medication would be to carefully review independent clinical evidence, peer-reviewed journals, and to engage in discussions with more experienced colleagues. For example, if a NZCAM member wishes to trial a new product, they are required to submit the clinical data and relevant peer-reviewed articles to the NZCAM Executive. If the Executive considers that the independent information is adequate, the matter is then discussed by all NZCAM members. If a significant number of senior members do not support the use of the new product, the product is not endorsed by NZCAM.

57. Dr Cattin further emphasised that as there are over 100 different dermal fillers available worldwide, and the majority are untested and unapproved, "the [practitioner's] choice of product must be independent of 'data' provided by the manufacturer or supplier".

58. The Medsafe information sheet *Regulatory issues: Unapproved use of medicines* provides that 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".[15]

59. Dr C advised HDC that he assessed the manufacturer's product information and reviewed the manufacturer's website to ascertain whether the dermal filler is FDA approved. He also stated that he relied on the fact that the dermal filler and the approved filler share the same compound as an indication of the dermal filler's safety and efficacy.

60. Dr Cattin stated that it was neither reasonable nor safe to assume that one dermal filler would have the same safety and efficacy profile as another, even if the products appeared similar. She concluded that Dr C's decision to use the dermal filler was unreasonable as he did not seek any rigorous evidence regarding its safety or efficacy, which she viewed with severe disapproval.

61. I agree with Dr Cattin's advice. In my view, the steps Dr C took were clearly inadequate. Dr C did not obtain and assess evidence independent of the manufacturer's information and unreasonably relied on the fact that the dermal filler and an approved filler shared the same compound as an assurance of the dermal filler's safety. Accordingly, I find that Dr C did not exercise reasonable care and skill in determining the safety of the filler as dermal filler and, accordingly, breached Right 4(1) of the Code.

Information and consent

62. Dr C informed Mrs A that the side effects of the mid-face volumisation procedure could include bruising, swelling and tenderness. He also advised her about the benefits of using a product containing calcium hydroxyapatite. However, Dr C did not inform Mrs A that there was a risk that she may develop granuloma and that the dermal filler he would be using was an unapproved medicine in New Zealand.

63. Right 6(1) provides that every consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive. A reasonable consumer would expect to receive information about the expected risks, side effects, benefits, and costs of the particular procedure.

64. Furthermore, the Medsafe information sheet (see above) states that the consumer should be advised of the unapproved status of the medicine, the degree and standard of the support for the use of the medicine, and any safety concerns. It also makes clear that the information given to the consumer should be balanced; therefore, information that may dissuade a consumer from agreeing to the use of the medicine should also be provided.

65. In my view, a reasonable consumer, in Mrs A's circumstances, would expect to receive information about the risk of developing granuloma. I note that Dr C advised that he does not inform his patients the risk of granuloma because of its "rarity". However, Dr Cattin is of the view that granuloma formation is a well documented side

[15] Available from Medsafe website <www.medsafe.govt.nz> <last accessed 11 April 2011>.

effect and the risk is increased with particular dermal fillers; therefore, it ought to be disclosed as part of the informed consent process.

66. A reasonable consumer, in Mrs A's circumstances, would also expect to be informed that the dermal filler is an unapproved medicine in New Zealand, the extent to which it is safe to use in light of independent clinical literature, and the degree and standard of clinical support for the use of the medicine.[16] Such information would materially affect a reasonable consumer's view of the procedure's overall safety.

67. In any event, I consider that the information Dr C did provide Mrs A related, at least in part, to a different dermal filler to the one used. He informed Mrs A that the product he was using as the dermal filler contained calcium hydroxyapatite but that "[he] had been using this type of compound since 2005". Dr C wrote beside that comment "([approved filler])". Dr Cattin noted that while the dermal filler and approved filler both contain calcium hydroxyapatite, the pathologist reported that the dermal filler also contained other material. In my view, it was incumbent on Dr C to be clear about the information he was providing and its specific relationship to the product he was intending to use.

68. Mrs A knew that Dr C had provided treatment to her daughter without incident and therefore Mrs A placed a degree of trust in Dr C's skill and experience. In addition, Dr C had reassured Mrs A that the procedure would achieve her desired outcome, and that he was experienced in performing the procedure.

69. Dr C advised HDC that he believed that it was not necessary to give Mrs A information about the dermal filler because Mrs A had total trust in him. The trust a patient reposes in their doctor does not diminish a doctor's duty under the Code, but rather the doctor must still provide full and accurate disclosure of the information a reasonable consumer, in the particular consumer's circumstances, would wish to receive.

70. Dr C failed to provide Mrs A with information a reasonable consumer, in her circumstances, would expect to receive. He did not provide adequate information about risks, benefits, side effects, or that the dermal filler was not approved for use in New Zealand. This was a breach of Right 6(1) of the Code. As Mrs A did not receive sufficient information, she was not in a position to make an informed choice and give informed consent. Accordingly, I find Dr C also breached Right 7(1) of the Code.

Follow-up care

71. Mrs A advised that within two weeks of the procedure she was suffering swelling and inflammation. She contacted Dr C, who unsuccessfully attempted to treat her.

72. Dr Cattin identified three aspects of Dr C's follow up care that were concerning. The first was Dr C's management of Mrs A's adverse outcome to the procedure. In Dr Cattin's view, it would have been prudent to refer Mrs A to a plastic surgeon for

[16] See MedSafe *Regulatory issues: Unapproved use of medicines* <www.medsafe.org.nz>.

advice and a possible biopsy when the symptoms were first reported. She stated that early referral to a plastic surgeon was mandatory to manage adverse outcomes.

73. The second was Dr C's lack of logic and clinical rationale in his follow up care, as he had prescribed Mrs A with various medication without any clear rationale supporting his clinical decisions. The third was the lack of documentation.

74. Dr Cattin concluded that in light of the inadequacies identified, the follow-up care was inappropriate and inadequate.

75. I agree with Dr Cattin's advice and find that Dr C's failure to refer Mrs A to a plastic surgeon when she first reported the side effects, coupled with his lack of logical and clinical rationale to his follow up care, breached Right 4(1) of the Code.

Documentation

76. HDC made several requests for Dr C to provide all relevant clinical records of the care and treatment he provided to Mrs A. The notes Dr C provided only relate to the procedure and not the follow-up care. Therefore, there is no evidence that notes of the follow-up care, including additional treatment prescribed, were kept.

77. Failure to maintain an adequate clinical record is, in itself, a breach of professional standards. The MCNZ Guideline *The maintenance and retention of patient records (*August 2008) provides that the clinical record should note the relevant clinical findings, decisions made, information given to patients, and any drugs or other treatment prescribed. Furthermore, this Office has frequently emphasised the importance of record keeping.[17]

78. Accordingly, I find that Dr C did not keep adequate records of his follow up care of Mrs A and therefore breached Right 4(2) of the Code.

Recommendations

79. I recommended in my provisional opinion that Dr C provide Mrs A with a written apology. Dr C provided the apology and it was forwarded to Mrs A.

80. I also recommend that Dr C:

- review health practitioners' obligations under the Medicines Act 1981;
- review the Medical Council of New Zealand's Guidelines *Good prescribing practice* and *Statement on complementary and alternative medicine*;
- review the MedSafe information sheet *Regulatory issues: Unapproved use of medicines;* and

[17] See Opinions 10HDC00610 and 10HDC00509 (available from ww.hdc.org.nz).

- report back to my Office by **30 July 2012** on his learning and reflections of the above reviews.

Follow-up actions

- Dr C will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

- An anonymised copy of the final report, but advising of Dr C's name, will be sent to the Medical Council of New Zealand with a recommendation that it undertake a competency review of Dr C.

- A copy of the final report with details identifying the parties removed, except the expert who advised on this case, will be sent to the New Zealand College of Appearance Medicine and the relevant district health boards, and they will be advised of Dr C's name.

- A copy of the final report with details identifying the parties removed, except the expert who advised on this case, will be sent to Medsafe and the Director-General of Health.

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

Addendum

The Director of Proceedings decided to issue proceedings, which are pending.

Appendix A: Independent expert advice – cosmetic physician

The following independent expert advice was provided by cosmetic physician, Dr Teresa Cattin:

> "Thank you for the documentation regarding the complaint by [Mrs A] against [Dr C] (Ref 10/00986) which I have now reviewed.
>
> Background:
> In considering the standard of care provided by [Dr C], I have assessed his care against the New Zealand College of Appearance Medicine (NZCAM) Standards and Protocols for doctors performing category 2 (i.e. nonsurgical) cosmetic procedures. The NZCAM Standards and Protocols are evidence based guidelines developed to ensure best practice in the delivery of cosmetic procedures and have been reviewed and endorsed by the Royal New Zealand College of General Practitioners and the New Zealand Medical Council. As such they can be used as a standard against which doctors performing cosmetic procedures can be measured.
>
> The New Zealand College of Appearance Medicine includes the majority of general practitioners performing cosmetic procedures with 33 Fellows. Fellowship is achieved by attaining the Diploma in Appearance Medicine. Competency is assessed annually through clinical audit and completion of continuing medical education requirements in appearance medicine.
>
> 1. *NZCAM membership*
> The claim by [Dr C] (item 9 of his October 30th 2011 response to HDC) that he was an associate member of NZCAM at the time (July 2009) he treated [Mrs A] is incorrect. [Dr C] had been an "Affiliate" member of NZCAM from April 2008 to March 2009, but his membership had lapsed at the time of treatment. A late subscription for affiliate membership was received from [Dr C] [in October 2009], 3 months after he treated [Mrs A]. This membership lapsed March 2010 and has not been renewed. The Affiliate membership category is being abolished as it does not confer any assurance of competence and is not consistent with the new NZMC requirements for doctors performing cosmetic procedures.
>
> 2. *Was [Dr C's] decision to use the product the dermal filler for "midface volumisation" reasonable?*
> There are over 100 different dermal fillers available worldwide, the majority of these are untested, unapproved and many pose a potentially serious health risk to the patient. A doctor performing injectable cosmetic procedures must select the products carefully after reviewing robust clinical evidence, peer-reviewed journals and discussion with more experienced colleagues. In particular the choice of product must be independent of "data" provided by the manufacturer or supplier.

NZCAM only endorses products which have undergone rigorous clinical trials and have been approved by either FDA, TGA or Medsafe. If a member wishes to trial a new product they are required to submit the clinical data and relevant peer-reviewed articles to the Executive, and if that is deemed adequate, it is then discussed by all members. If a significant number of senior members do not support its use, the product is not endorsed.

We regard this approach as mandatory to ensure patient safety in view of the large number of unregistered cosmetic injectable products available.

[Dr C's] decision to use the dermal filler was not reasonable. It does not appear that he sought any rigorous evidence regarding its safety or efficacy before treating patients. NZCAM would regard this with severe disapproval.

3. *Was the consultation process, including provision of necessary information, prior to the procedure appropriate ?*
The information [Dr C] provided to the patient prior to the procedure related to another product (i.e. [an approved filler]), not the product he injected the patient with. This would be regarded with severe disapproval by NZCAM as it is intentionally misleading the patient. It is neither reasonable nor safe to assume that one filler will have the same safety and efficacy profile as another even if the products appear to be approximately similar.

   Clearly [the dermal filler] is not similar to [the approved filler], while both contain calcium hydroxyapetite the pathologist reported the presence of other material, possibly polymethylmethacrylate. As the information provided to the patient did not relate to [the dermal filler], the consultation process was not appropriate or acceptable.

   The consenting procedure is below that expected of a doctor providing cosmetic procedures. Furthermore [Dr C] failed to inform the patient that her details would be supplied to Medsafe as the product was unapproved:

   6.6.5 Patient 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. The keeping of the database enables Med safe to contact the prescriber if a problem subsequently arises with the medicine which may require follow-up with the patient.

   (Ref: NZCAM Protocol: Informed Consent)

4. *Should the risk of granuloma have been discussed?*
The patient must be informed of all common side-effects plus any severe, rare side-effects. Granuloma formation as shown in this case, is well documented in

the literature and is known to have an increased risk with particulate fillers, of which [the dermal filler] is one. If there is a risk of granuloma formation for any particular product it should be known by the practitioner and specifically discussed with the patient as part of the consent process.

5. *Can any conclusions about [Dr C's] technique of injection be drawn from [Mrs A] complications?*
No conclusions can be drawn about [Dr C's] technique. This product should never have been injected as a dermal filler and I believe the granulomas would have formed regardless of the injection technique used. It is clearly not safe to inject as a dermal filler.

I note in the biopsy result and comment from [the plastic surgeon]f that product was seen in the dermis which admittedly is not the correct placement for a volumising filler, which may be why [the plastic surgeon] commented that the injections had been too superficial, but I believe the main problem was the product itself.

6. *Was [Dr C's] follow-up care appropriate?*
[Dr C's] follow up care was not appropriate or adequate.
I have the following concerns regarding the follow-up care:

(a). Management of adverse events.

Two weeks after treatment, [Dr C] was advised that there was redness at the treated areas, which he diagnosed without seeing the patient, as 'inflammation or infection'.

It would have been prudent at this point to refer to a specialist, usually a plastic surgeon, for advice and a biopsy if appropriate. There are known cases of infection following deep filler injections developing into severe facial cellulitis needing aggressive intravenous antibiotic treatment.

In the event of a potentially catastrophic adverse event, early referral to a plastic surgeon for biopsy and management is mandatory. [Mrs A] did not see a plastic surgeon until referred by [her GP] in March 2010. The lesions were eventually identified as necrotizing granulomas from biopsy specimens taken on 30/08/10 by [the plastic surgeon]

(b).There does not seem to be any logical approach or rationale to the management of this adverse event with various drugs being tried, including Allopurinol, intra-lesional Kenacort, laser, oral prednisone, doxycycline and other unspecified antibiotics.

(c) The consultation notes for visits and the record and content of phone calls occurring after the treatment date have not been provided by [Dr C] but from the documents supplied to me it appears that the follow up care was below the

standard that is expected. It is also of concern that [Mrs A] has suffered financially as a result of the treatment provided by [Dr C].

Further comments:

With regard to the NZMC Statement on Cosmetic Procedures (October 2011), category 2 cosmetic procedures (which includes dermal fillers) may be performed by a doctor registered in a vocational scope of practice whose competence has been accredited by the Royal New Zealand College of General Practitioners (via NZCAM) and who has the necessary training expertise and experience. Adequate training is considered to be either the NZCAM Diploma in Appearance Medicine or training provided by the New Zealand Dermatological Society or Royal Australian College of Surgeons.

If a doctor performing cosmetic procedures is not vocationally registered and/or has not undergone accredited training they may work under the collegial supervision of a vocationally trained doctor whose training has been accredited.

Furthermore, if a doctor is performing cosmetic procedures, they must participate in clinical audit and reporting on a number of clinical indicators (section 29, NZMC Statement on Cosmetic Procedures, 2011). This should contribute towards the mandatory requirements for continuing medical education and recertification.

[Dr C] has not achieved the NZCAM Diploma in Appearance Medicine or undergone a competency assessment. [Dr C] is not participating in the NZCAM continuing medical education and recertification programme nor is he working under the supervision of an accredited Fellow of NZCAM."