24 June 2025

HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Informed consent not obtained during Ayurvedic medicine consultation for man's abdominal pain

Decision 21HDC01615

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1. On 15 July 2021 HDC received a complaint from Mr A (aged 60 years at the time of the events) about the care provided to him by Dr B,[1] an Ayurvedic practitioner[2] at a health clinic.

Background

2. Mr A said that he had an appointment with 'senior practitioner [Dr B]' at the health clinic in July 2021 regarding abdominal pain that had started after he had had a kidney removed some years previously. Mr A told HDC that at the start of the appointment he told Dr B about the pain and was then told about the herbal-based supplements that could help with the pain.

3. At his consultation with Dr B, Mr A was required to sign a disclaimer form setting out the terms of the customer relationship and the conditions of treatment. The form states:

> 'While all care is taken with the quality and appropriateness of the herbal medications and therapies, as herbs and Ayurvedic treatments are still under research process very rarely, there may be adverse reactions. I accept full responsibility for any adverse reactions I may have, and will inform the practitioner of them and withdraw the treatment with immediate effect as I am aware Ayurvedic medicines are manufactured in India.'

4. The form signed by Mr A also states, 'I have been explained about no refund policy at any given circumstances (sic)' and 'the cost and procedures are well explained to me (sic)'. Mr A told HDC that he did not understand the treatment adequately prior to making payment and proceeding.

5. Dr B said that the form was given to Mr A at the beginning of the consultation, and he was given sufficient time to read it before signing it, with consultation costs and the herbal-based supplements and other remedies explained to him. Dr B said that she doesn't promise to cure patients. The agreement form stated that '[Dr B] does not make any medical diagnosis and does not claim to "cure" any specific disease'.

6. Dr B said that Mr A had a one-hour consultation with her, during which they discussed diet and lifestyle changes, as well as herbal-based supplements that were available and their associated risk factors. She said that they discussed the 'Ayurvedic point of view'. She provided information about herbal supplements and Mr A decided to try them. Dr B said: '[W]hatever verbal information and medical history [Mr A] provided we take that along with

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[1] Dr B gained her qualification in Ayurvedic Medicine and Surgery overseas.
[2] A holistic health model from India.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

lab test reports to try and assist him for his well-being.' Dr B said that 'herbal preparation prescription is made after individual consultation' and each bottle advises to 'contact your [general practitioner (GP)] if you notice any side effects'. No clinical notes or written records of Mr A's appointment with Dr B were provided.

7. Mr A said that Dr B did not tell him what the supplements were called, what they contained, or the risks or possible adverse side-effects. Mr A said that upon checking the bottles when he got home, he found that there was no name of the supplement or information about the ingredients on the bottles. The only information on the bottles was instructions that the supplements should be taken once after breakfast and dinner, and the following statement:

> 'This herbal formula is only intended for [the] use of [Dr B's] specific patients. Ayurvedic herbs are not a replacement to your prescribed medicines. If any herbal supplement is not suitable to you, please consult your GP and withdraw the use of these supplements.'

8. Dr B stated:

> '[M]ost herbal supplements we purchase locally in NZ and dispense them to individual clients after individual consultation. Patients are given herbal supplements for only one month or 90 days' supply and we do monthly or 90 days follow ups … Most Herbs have no expiry dates.'

9. A few days after the appointment, Mr A contacted Dr B and informed her that he had booked an appointment with his GP.. He asked Dr B for the ingredients list for the herbal supplements he had purchased so that he could discuss them with his GP. After further communication between Dr B and Mr A, Dr B emailed the ingredients list as requested. Dr B told HDC that from what Mr A said, she was under the impression that he had not consumed the herbal supplements. Mr A told HDC that he had 'taken the pills for a few days and felt some dizziness'.

10. Dr B told HDC that she imports herbs or ready-made herbal supplements from India, and she does not manufacture them. She said that most of these herbs and remedies lack research on adverse effects, and therefore she always includes disclaimers on the bottles to ensure that patients are aware of this. Dr B said that the health clinic communicates information effectively, gives full attention and care, and provides respectful treatment to every patient.

Response to provisional opinion

Dr B

11. Dr B was given an opportunity to comment on the provisional opinion. She advised that she had no further comments except to offer her sincere apologies. Dr B said that this experience is an opportunity for her to improve the quality of her dedicated service further and to take additional precautions to prevent such situations from happening in the future.

Mr A

12. Mr A was given an opportunity to comment on the provisional opinion. He advised that he agreed with the substance of the report.

Opinion: Dr B — breach

13. Dr B had a one-hour appointment with Mr A in which she prescribed herbal supplements for pain. Having considered the lack of information on the consent form and supplement bottles regarding ingredients and potential side-effects, and Mr A's statement that he was not informed of these things verbally, I am not satisfied that sufficient information was provided by Dr B. In addition, no safety-netting advice was provided to Mr A other than to contact his GP and discontinue use if the medication was 'not suitable'. I do not consider this to be useful safety-netting advice as Mr A had no information on the ingredients of the supplements or the possible side-effects he could experience. I acknowledge that as part of the consultation, Mr A was required to sign a consent form accepting that there may be adverse side-effects and taking responsibility for any he might experience. However, I consider that without displaying the ingredients of the supplements on the bottles, insufficient information was provided when Mr A was required to agree to the terms and provide informed consent.

14. Right 6(2)[3] of the Code of Health and Disability Services Consumers' Rights (the Code) stipulates that before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer in those circumstances could expect. I consider that a list of the ingredients of the supplements is information that a reasonable consumer could expect, and for that reason Dr B failed to provide Mr A with the information that he needed to make informed choices about his treatment. Accordingly, I find that Dr B breached Right 6(2) of the Code. It follows that Mr A did not give informed consent, and he was unable to take responsibility for any adverse side-effects due to the lack of information provided to him by Dr B. As such, I find that Dr B also breached Right 7(1)[4] of the Code.

Opinion: Health Clinic — educational comment

15. Dr B did not provide HDC with any clinical or written records of her consultation with Mr A but said that at the health clinic they communicate information effectively, give full attention, and care, and provide respectful treatment to every patient. However, without documentation from the appointment, it is unclear exactly what information was communicated to Mr A. I encourage the clinic to reflect on these events, and the importance of implementing a system of effective record-keeping.

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[3] Right 6(2) states: 'Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.'

[4] Right 7(1) states: 'Services may be provided to a consumer only if that 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.'

Changes made

16. Dr B said that she now makes an extra effort to emphasise and explain the terms and service promised to customers.

Recommendations and follow-up actions

17. As Dr B no longer has a clinic in New Zealand, recommendations have been limited to the following:

- I recommend that Dr B provide a written apology to Mr A for the criticisms in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.
- I recommend that Dr B complete the HDC online modules for further learning (https://www.hdc.org.nz/education/online-learning/). Evidence of completion of the online modules is to be provided to HDC within three months of the date of this report.

18. A copy of this report with details identifying the parties removed will be sent to Medsafe requesting consideration of the development of a policy that requires sufficient labelling of herbal supplements.

19. A copy of this report with details identifying the parties removed will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner