General Practitioner

Report on Opinion - Case 99HDC03994

Complaint

The consumer complained to the Ministry of Health about the service she received from a general practitioner. The Ministry of Health forwarded the complaint to the Commissioner on 23 March 1999. The complaint is that:

- *The consumer requested an oral contraceptive pill for her painful periods during a consultation in mid-March 1999 with a general practitioner, in which the general practitioner failed to assess the consumer fully before prescribing an OCP or informing her of the possible side effects of the OCP, in particular of possible blood clotting*.

Investigation Process

The complaint was received by the Health and Disability Commissioner on 25 March 1999 and an investigation commenced on 4 April 1999. Information was obtained from:

The consumer / complainant
The provider / general practitioner
The practice manager, medical centre
Senior Adviser (Medical), Medsafe, Ministry of Health

The consumer's medical records were obtained and reviewed by the Commissioner. The Commissioner sought advice from an independent general practitioner.

Background

Since 1996, the Ministry of Health advice to doctors regarding the third generation oral contraceptives has been to take a history, disclose risks and gain informed consent. This information has been stated publicly, in '*Prescriber Updates*' sent to doctors, in letters sent to doctors, and in patient information.

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Background *continued*

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), Ministry of Health, issued a publication entitled '*Oral Contraceptives and Blood Clots*' in February 1999 with an attached letter outlining the risks of third generation oral contraceptives and the link with blood clots. In the February 1999 covering letter to health providers in New Zealand, Medsafe requested that the publication be made available to women when being prescribed oral contraceptives and the leaflet be widely distributed to ensure easy access by women. The covering letter states, "*A copy is being sent to GPs, selected hospital doctors and specialists, midwives and Maori and Pacific health workers. Bulk copies are being sent to GP practices ...*".

Medsafe advised in its 1999 publication that a consumer should discuss the risks and symptoms with her doctor: "*You have a right to expect your doctor to explain the risks and symptoms to you in a way that you can understand*".

Blood clots in association with oral contraceptives are described as causing a blockage in the veins of the legs. The Medsafe publication advised that:

> "*Blood clots occur rarely with oral contraceptives, and deaths from blood clots are even more rare.*
>
> *The risk of a normal healthy woman developing a blood clot in one year is 1 in 30,000. The risk of blood clots is increased by pregnancy. Taking oral contraceptives containing oestrogens also increases the risk of blood clots, but not as much as being pregnant. The risk depends on the type of oral contraceptive.*"

Medsafe listed Marvelon as a combined oral contraceptive with low dose oestrogen and progestogen. It is described as a third generation oral contraceptive, containing the progestogens desogestrel or gestodene. (Marvelon actually contains desogestrel.) Medsafe advised that the risk of blood clots per year is 2 in 10,000 women, "*6 times the normal risk*" compared to non-use of any oral contraceptive pill, and twice the risk of second generation oral contraceptives.

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Information Gathered During Investigation

In mid-March 1999 the consumer went to a medical centre with a sore throat, headache and blocked nose. She consulted with a locum general practitioner (the provider).

The consumer advised the Commissioner that during the consultation she explained to the provider that she also wanted a contraceptive pill due to her painful periods. She advised that the provider asked her whether she had any serious illnesses in her family or whether she had any serious illnesses herself, but asked her no further questions. The consumer stated that she informed the provider there was nothing significant now or in her past but advised that she was currently taking Roaccutane (medication used for severe forms of acne). The consumer stated that the provider, "*then changed the type of contraceptive pill to be prescribed without further questioning*".

The provider advised the Commissioner that he suggested to the consumer that due to her skin problem, Marvelon would be a suitable contraceptive, "*because it has anti-androgenic properties which make it the oral contraceptive choice for women with acne*". The consumer advised that the provider described this pill as being "*a skin friendly oral contraceptive*". The consumer subsequently said that she did not know what Marvelon was before she had gone to the consultation.

The consumer said that she asked the provider whether the pill would be effective if she used it as a contraceptive while she was taking Roaccutane. The provider advised the Commissioner that he had been unsure as "*it is not a drug I am thoroughly familiar with*", so he had consulted the pharmaceutical reference book, 'New Ethicals Compendium'.

The consumer advised the Commissioner that the provider did not see anything specific in the reference book about interactions between Roaccutane and Marvelon. In his response to the Commissioner, the provider stated, "*so I was unable to give specific advice at this point*". The consumer advised the Commissioner that the provider then informed her she would be alright, but to use other contraceptive barriers "*just in case*".

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Information Gathered During Investigation *continued*

The provider advised the Commissioner that "*since pregnancy is very undesirable in women using Roaccutane, I suggested that barrier methods would provide an extra method of security in this situation, should the need arise*". The consumer said that she had left the medical centre feeling confused and unsure of "*what was 'O.K.' and what wasn't*".

The provider documented in the consumer's notes:

> "**[Mid-] *March 1999 at 15:53.* [provider's initials]**
> *Sore throat and blocked nose 2 days. Mild sinusitis. Chest normal.*
> *Temp 37.0*
> *Also wants to go on the pill. LMP* [last menstrual period] *19.2.99. Painful but regular periods over last few months. Takes roaccutane for acne. Good general health. No FH* [family history] *of serious illness.*
> ***Rx*** [prescription] *Amoxycillin 250 mg caps* [capsules]*; 1 tds* [three times daily] *– independent of food; 5 days*
> ***Rx** marvelon 30; 1 od* [once daily]*; 90*"

The Commissioner noted that there was no mention in the consumer's notes of blood pressure or weight being taken by the provider or any record of the information given to her about the oral contraceptive pill.

The consumer confirmed to the Commissioner that the provider did not take her weight or blood pressure or suggest that she get this done the next time she went to the doctor, and did not perform or ask her about a breast examination or cervical smear during the consultation. She additionally advised that the provider did not ask her whether she smoked or not.

The consumer stated that during the consultation, which was approximately 15 minutes long, the provider did not inform her of any of the risks of the contraceptive pill he had prescribed. She advised that he did not give her any pamphlets on this form of contraception or tell her where she could obtain further information. Further, the consumer stated that the provider had not told her how long she would be taking Marvelon for, or if there was a review date to see how she was progressing on Marvelon.

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Information Gathered During Investigation *continued*

The provider stated that he had not informed the consumer of an increased risk of blood clots in association with Marvelon as compared with other contraceptives because "*no such increased risk exists, or if it does exist, for practical purposes it is unmeasurably small*". The provider stated that as the manufacturers of Marvelon enclose a pamphlet on the side effects of this pill in the packaging, "*I usually don't read this list out when prescribing the drug*".

The practice manager of the medical centre advised the Commissioner that there is a sign at the front reception of the medical centre stating that information is available on the contraceptive pill in relation to blood clots. Additionally, she advised that the receptionists have the information fact sheet produced by the Ministry of Health on blood clots, and the practice nurses use a folder designed to help patients choose the most appropriate contraception.

The consumer advised that following the consultation her friend and flatmate told her that Marvelon, the contraceptive she had been prescribed, was one known to cause blood clots.

The consumer advised the Commissioner that since that consultation she no longer wanted to use this contraceptive pill, knowing the risks associated with using it.

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Report on Opinion - Case 99HDC03994, continued

Independent Advice to Commissioner

The Commissioner sought advice from an independent general practitioner who stated:

> "*I do not believe that* [the consumer] *was given enough information.* [The provider's] *view of using a third generation pill is not entirely in sync with the pamphlet that was handed out by the nurses. The pamphlet itself states that if a third generation oral contraceptive pill is used, the risk of thrombo-embolism* [blood clots] *is 2 per 10,000 as opposed to 1 per 10,000 if a second generation pill is used. Thus there is a difference in risk according to which pill is used and* [the consumer] *needed to be informed that this issue was present. I believe that* [the provider] *could well have then added to the conversation what his opinion about the whole situation was, but nevertheless* [the consumer] *needed to have the information that there was a body of opinion in the community which said that third generation oral contraceptive pills* ***possibly*** *carried a greater risk than second generation ones.*
>
> [The provider] *could simply have stated that there was a pamphlet inside the box going through all the more minor side effects and problems that the pill could have.* [The consumer] *... should have been informed of the current debate in the medical and scientific community about the relative risk of second and third generation contraceptive pills.*
>
> [The provider] *should have found out more information and if the New Ethicals did not provide him with enough information to be able to reassure* [the consumer] *about the contraceptive pill and Roaccutane, he should have rung a dermatologist and asked whether or not there was such an issue.*
>
> *I believe that taking a woman's weight* [and] *blood pressure ... is mandatory before prescribing oral contraceptives.*
>
> *Clearly the pamphlets that he has included as part of the collection held by the nurses could have been handed to* [the consumer] *at the time, but equally it might have been appropriate for these to be handed to her at the end of the consultation.*

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Independent Advice to Commissioner *continued*

Whether or not [the provider] *obtained enough information from* [the consumer] *regarding her personal and family history to identify risk factors for thrombo-embolism is somewhat moot. It is unclear to me whether this information was entirely obtained. What is meant from the statement issued from the Ministry of Health and published in the GP Weekly 25 February 1998 is simply that you need to ask the patient in some detail about her family history regarding thrombo-embolism, namely has any member of her family ever suffered a blood clot in their legs, or has any member of the family suffered a pulmonary embolism or clot in the lung. Also you need to ascertain from the patient concerned whether she has any risk factors herself, namely, smoking, obesity or past history of thrombo-embolism.*

It is unclear to me whether or not [the provider] *did indeed obtain a sufficient level of information ….*

[The provider] *has a clear duty to inform* [the consumer] *of the controversy about the third generation oral contraceptive pills and, as mentioned before, even the pamphlet issued through his own surgery states that there is a twofold increase in thrombo-embolism if the third generation oral contraceptive pill is used.*

Thus, in conclusion it does appear to me that [the provider] *did not entirely provide* [the consumer] *with care that complied with professional standards."*

General Practitioner

Report on Opinion - Case 99HDC03994, continued

Response to Provisional Opinion

The provider stated in response to the Commissioner's provisional opinion:

> "*I do not seem to have made it sufficiently clear that the consultation which took place* [in mid-March 1999] *was not for contraceptive needs. This is however clearly stated in the letter of complaint. I asked* [the consumer] *if she needed contraceptive protection and she replied that she did not. She specifically requested a pill for the relief of recent onset dysmenorrhea which had not responded to simple analgesics. Accordingly I prescribed what was intended to be a short term therapeutic trial of a drug which I considered suitable for this purpose, which also happened to be an oral contraceptive. If* [the consumer] *had asked me for contraceptive protection, the consultation would have proceeded along different lines, and I would have asked her to make a second appointment at a later date.*
>
> *As it happened she did attend another doctor at the same surgery a few months later for contraceptive needs. Your GP adviser outlines a number of observations ... which he/she feels are important when initiating long term contraception, but which were also omitted during the later consultation with the second doctor. Your GP adviser has not seen* [the consumer] *who is slim. Smoking is not a risk factor for venous thromboembolism. I agree that it is important to take a smoking history in older women who are being prescribed long term oral contraceptives, because of the risk of peripheral vascular disease and coronary artery disease. Neither of these considerations apply to* [the consumer] *who is 20 years old. Consequently I do not personally regard these as very serious omissions. ... I would however have recorded* [the consumer's] *blood pressure as a matter of course if I had been commencing her on long term oral contraceptive therapy. In this case I intended to check this on review at 3 months, if she had wanted to continue the treatment. In most cases of this kind short courses of therapy are all that is required, as usually the dysmenorrhea rights itself with time.*

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Report on Opinion - Case 99HDC03994, continued

Response to Provisional Opinion *continued*

[The consumer] *also asked me, in general terms, whether the pill prescribed would also provide contraceptive protection should the need arise in future, and I advised her on this to the best of my ability. Your independent GP suggests that I should have phoned a dermatologist to ask about possible interactions between Marvelon and Roaccutaine. I did in fact phone the Family Planning Clinic about this the following day to satisfy my own curiosity. The doctor on duty was unable to give any specific assurances, and concurred with my recommendation for barrier methods as an interim method in case of need. I have since consulted the specialist literature on this point, and find only anecdotal evidence that there is probably not a major problem. The literature also makes it very clear that Marvelon is a drug of choice in women with acne. It is also used in the treatment of acne. In retrospect I would not change the advice I gave to* [the consumer] *at the time. I think she needs to take particular care to avoid falling pregnant while she is taking Roaccutane. I was seeing* [the consumer] *for the first time, and was uncertain about her ability to comply with the need for daily pill taking. This consideration, and the known failure rate of oral contraceptives even when used carefully, prompted my recommendation for the use of barrier methods.*

It is difficult to deal fully with all these matters, and to anticipate all a patient's individual concerns, during a first brief consultation at a walk-in clinic. That is why continuity of care is important. [The consumer] *consulted me a month later about an unrelated problem, and this would have been a good opportunity for further explanations, but she didn't say anything about this.*

Your adviser also thinks that I should have provided [the consumer] *with information published by the Ministry of Health 25 February 1999* […]. *I am uncertain whether this pamphlet was available at the surgery in early March, I was working there only 1 day a week at the time. The pamphlet deals mainly with the risks of various oral contraceptives associated with long term use, and is not immediately relevant to the purpose of the consultation.*

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General Practitioner

Report on Opinion - Case 99HDC03994, continued

Response to Provisional Opinion *continued*

Your adviser states that 'a reasonable consumer would not ordinarily expect to be told about the absolute risks of a magnitude of 2 in 10,000'. He/she quotes a sixfold increase in a relative risk of blood clots for women using third generation oral contraceptives. This figure has been widely disputed, and in any case refers to women much older than [the consumer]*, who were most commonly obese, and had other risk factors which were not present in this case. As an expert on ... venous throboembolism ... I can inform you that* [the consumer's] *individual absolute risk of dying of a pulmonary embolism is probably less than 1 per million years of pill use, and is not much different from that of non pill users. The risks associated with 3 months of pill use in a fit and active 20 year old are immeasurably small.*

After talking with her flatmate, [the consumer] *was left with the impression that I had carelessly prescribed a very dangerous chemical. She understandably became quite angry about this, and I agree that an apology and a fuller explanation of the facts is required. I would be happy to provide this. I accept that it was unwise of me not to have discussed these matters in detail at the time. However since March last year there has been ongoing sensationalism in the media on this issue. Like most other practitioners, of necessity, I now routinely discuss these matters at some length in all patients requiring oral contraception, and this adds greatly to the consultation times. I no longer prescribe Marvelon, unless there are special reasons, as in this case.*"

General Practitioner

Report on Opinion - Case 99HDC03994, continued

Further Advice to Commissioner

The Commissioner sought further clarification from an independent general practitioner in relation to the additional points the provider raised in his response to the provisional opinion:

> "*With reference to the further letter from* [the provider] *concerning this consultation, there are a few points that need to be made.*
>
> *Firstly, I think that, irrespective of whether you are prescribing an oral contraceptive for dysmenorrhoea or for the purposes of contraception, the patient's blood pressure needs to be taken prior to starting the oral contraceptive. This is known as a baseline reading and is important because, if the subsequent level is known to be high, it needs to be compared to the blood pressure level prior to commencing the oral contraceptive. It could be argued that perhaps weight or breast examination is not essential but a blood pressure reading certainly is.*
>
> *Secondly, it should be pointed out that the debate that is currently before the media, and certainly was at the time of the consultation, regarding the difference between second and third generation pills, needed to be discussed and addressed with the complainant.*
>
> *As pointed out previously, the pamphlet that was given to* [the consumer] *from the Health Department did state that there was a doubling of the risk of venous thromboembolism between the use of a second or third generation pill. I admit that the risk is still very small but nevertheless this point needs to be discussed with the patient.*
>
> *Another point that needs to be made is that Marvelon is not the only oral contraceptive that is appropriate for use by people with acne. There is another pill called Diane 35 which is also very appropriate for this condition as it uses second generation hormones. So there is a choice and I feel, once again, it would have been appropriate for* [the consumer] *to have had some discussion about this.*

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General Practitioner

Report on Opinion - Case 99HDC03994, continued

Further Advice to Commissioner *continued*

I appreciate that [the provider] *was not in fact prescribing the pill for the contraceptive per se, but was prescribing it for dysmenorrhoea; nevertheless the risks are no different irrespective of the reason for prescribing it.*

I feel that overall [the consumer] *should have been fully informed about the debate regarding this issue. Whether the health professional feels that the risk is minimal or virtually non-existent, the consumer has a right to know of the debate taking place and that there are different opinions about it. Clearly* [the consumer] *feels that she was not adequately informed of these issues and did not have a chance to participate in any subsequent decision making.*"

General Practitioner

Report on Opinion - Case 99HDC03994, continued

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

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 – ...
(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; ...
2) 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.

RIGHT 7
Right to Make an Informed Choice and Give Informed Consent

1) 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.

General Practitioner

Report on Opinion - Case 99HDC03994, continued

Opinion: Breach General Practitioner

In my opinion the provider breached Right 4(1), Right 6(1)(b), Right 6(2) and Right 7(1) of the Code of Health and Disability Services Consumers' Rights.

Right 4(1)

The consumer was entitled to have medical services provided to her with reasonable care and skill. In my opinion, the services provided by the provider did not meet this standard.

History and tests
Before prescribing an oral contraceptive for the consumer, the provider had an obligation to ask her details of her family medical history, specifically regarding thrombo-embolism, and to clearly document these matters. Information provided to general practitioners by the Ministry of Health requires that a general practitioner obtain background medical information prior to the oral contraceptive being prescribed. The provider should also have checked the consumer's blood pressure. The fact that the provider intended to review the consumer's use of Marvelon after three months does not justify a failure to take her blood pressure.

Although I recognise that the provider was seeing a patient, who appeared to be a healthy young woman, for the first time during a brief consultation in a walk-in clinic, I do not accept that these facts justified his failure to undertake a standard history and blood pressure check. Nor is it relevant that the consumer's needs related to her dsymenorrhoea, rather than contraception. The fact remains that the medication the provider prescribed was an oral contraceptive with associated risks.

In my opinion, in omitting to take an adequate history and blood pressure, the provider failed to provide medical services with reasonable care and skill.

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General Practitioner

Report on Opinion - Case 99HDC03994, continued

Opinion: Breach General Practitioner *continued*

Roaccutane

I am advised that Roaccutane is a very powerful medication and that its use is contraindicated in women who are pregnant or who may become pregnant, given the near certainty of a major congenital abnormality in the event of a pregnancy. I am further advised that in practice virtually all women are started on an oral contraceptive before commencing Roaccutane and that continued use of Roaccutane is dependent on continuing use of the oral contraceptive.

The provider was unable to find sufficient definitive information regarding the interaction between Roaccutane and the oral contraceptive pill during his consultation with the consumer and simply advised her to use other barrier methods "just in case". I accept the advice of my medical advisor that the provider should have consulted a dermatologist if he was uncertain about potential drug interactions between Roaccutane and Marvelon. It is no answer that the provider consulted a Family Planning director, and the specialist literature, *after* he had prescribed Marvelon, although I accept that it was better than making no inquiry.

For these reasons, in my opinion the provider breached Right 4(1) of the Code.

Right 6(1)(b) and Right 6(2)

In my opinion, a reasonable consumer in the consumer's circumstances would expect to receive, or be directed to, general information about the side effects of the contraceptive pill, such as the risk of blood clots occurring when taking an oral contraceptive. She would also expect to receive specific information about the particular contraceptive pill that she was to be prescribed. Although the provider was aware there was written material concerning the risks associated with the oral contraceptive pill, and he himself was well versed in the issues surrounding the oral contraceptive pill, he did not use any of the written material available at the medical centre. Nor did the provider inform the consumer of the increased risk of blood clots from Marvelon.

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General Practitioner

Report on Opinion - Case 99HDC03994, continued

Opinion: Breach General Practitioner *continued*

The Ministry of Health (Medsafe) publication dated February 1999 clearly advises that a consumer should discuss the risks and her symptoms with her doctor and that the information needs to be given in a way that is understood. Additionally, the letter dated February 1999 from Medsafe, requests that its new publication titled '*Oral Contraceptives and Blood Clots*' be made available to women. It was widely distributed to health professionals throughout New Zealand, and followed up advice that had first been issued in 1996. The provider did not provide this information to the consumer.

In my opinion the consumer had the right to be provided with information about the benefits and side effects of oral contraceptive pills and the increase in relative risk of blood clots if a third generation contraceptive pill is used. It was not sufficient to rely on an information leaflet in the packet of pills. The provider needed to *discuss* the relevant issues with the consumer.

The fact that the provider intended to review the consumer's use of Marvelon after three months does not justify a failure to disclose and discuss the risk of blood clots. I am advised that there is no evidence that the risk of blood clots in oral contraceptives users increases with duration of use. Nor did the consumer's age (20 years) excuse the provider's nondisclosure. I am advised that the median age of New Zealand women who have died of a blood clot when taking an oral contraception pill is under 30 years.

I accept that a reasonable consumer would not ordinarily expect to be told about absolute risks of a magnitude of 2 in 10,000. However, in circumstances where there had been extensive publicity about the sixfold increase in risk of blood clots for women using third generation oral contraceptive pills, compared to non-use of every oral contraceptive pill, it is my opinion that fuller disclosure by the provider was required.

I am aware that there is continuing debate about the true extent of the risk of blood clots associated with the third generation oral contraceptive pills. However, in accordance with the Ministry of Health (Medsafe) advice, and in keeping with the reasonable expectations of consumers in such circumstances, health professionals in New Zealand are required to inform women about the debate and the heightened risk of blood clots.

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General Practitioner

Report on Opinion - Case 99HDC03994, continued

Opinion: Breach General Practitioner *continued*

In my opinion, by not fully informing the consumer of the side effects of Marvelon, the provider breached Right 6(1)(b) and Right 6(2) of the Code.

Right 7(1)

The consumer had not received sufficient information to enable her to make an informed choice and give informed consent to the provision of the contraceptive pill in general and of Marvelon in particular. Without this information she was unable to make an informed choice and give informed consent. In my opinion the provider breached Right 7(1) of the Code.

Opinion: No Breach Medical Centre

Right 6(1)(b), Right 6(2) and Right 7(1)

Vicarious liability

Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing which breached the Code.

In my opinion the medical centre did not breach the Code of Health and Disability Services Consumers' Rights. The Centre had a system in place whereby pamphlets about the oral contraceptive pill were readily available at the reception desk and accessible to patients. Additionally, the Centre's practice nurses had further pamphlets available. In my opinion, the medical centre had taken reasonably practicable steps to ensure that patients were adequately informed about oral contraceptives, and is not vicariously liable for the provider's breaches of the Code.

General Practitioner

Report on Opinion - Case 99HDC03994, continued

Actions

I recommend the provider takes the following actions:

- Apologises in writing to the consumer for his breach of the Code of Rights, and refunds the cost of her consultation and prescription ($25.00). This apology, together with a cheque for $25.00, is to be sent to the Commissioner's office and will be forwarded to the consumer.

- Reviews his practice in relation to prescribing oral contraceptives for patients.

Other Actions

A copy of this opinion will be sent to the Medical Council of New Zealand. A non-identifying copy of this opinion will be sent to the Ministry of Health, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Royal New Zealand College of General Practitioners.