A Pharmacist

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 00/03977)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
A Pharmacy	Pharmacy
Mr B	Pharmacist
Mrs C	Pharmacist
Ms D	Pharmacist

Mrs C died during the course of my investigation.

Complaint

On 13 April 2000 the Commissioner received a complaint from Ms A regarding services provided to her by The Pharmacy, Mr B, pharmacist, and Mrs C, pharmacist. The complaint is that:

- *On 19 January 2000 Mr B dispensed Diflucan 200mg tablets to Ms A instead of danazol, as prescribed by Ms A's specialist.*

- *When Ms A was provided with the medication on 19 January 2000 she was not given any information about the prescribed medication.*

- *On 19 February 2000 Mrs C at the pharmacy informed Ms A in a public area of the pharmacy and in a loud manner that she had been provided with the incorrect medication. This meant that all of the other customers could hear what was being said.*

- *Mrs C did not facilitate an environment that enabled effective communication with Ms A, as she was also informed of the error in front of her son and no assistance was provided when he became distressed.*

- *When Ms A was informed of the dispensing error she was not given any information regarding the medication that had been provided. She was also not given the medication that had been prescribed.*

- *Although Mrs C informed Ms A that her general practitioner and the surgeon would be contacted to discuss the possible effects of the incorrectly dispensed medication upon Ms A and her scheduled surgery at a public hospital these people were never contacted.*

An investigation was commenced on 17 April 2000.

Information reviewed

- Complaint letter from Ms A
- Response from Mr B and the Pharmacy and attached documentation
- Response from Mrs C
- Notes from an interview with Mrs C and Mr B and site visit
- Information from Ms D
- Information and medical records from Dr E, general practitioner
- Medical records from a public hospital
- Information from Dr F, surgeon

The Commissioner obtained independent expert advice from Mr Alan Fraser, pharmacist, and Dr David Cook, obstetrician and gynaecologist.

Information gathered during investigation

Background
On 14 January 2000, Ms A visited her general practitioner, Dr E, with heavy vaginal bleeding. Dr E referred Ms A to Dr G, a senior gynaecological registrar at a public hospital, on 16 January 2000.

On 19 January 2000, Ms A consulted Dr G. Dr G counselled Ms A on her options and she decided to have an endometrial ablation (removal of the mucous membrane lining the uterus, used as an alternative to hysterectomy or hormone therapy). Dr F was to perform this operation on 24 February. Dr G prescribed a five week course of danazol. Danazol is an endometrial thinning agent. Its side effects include acne, oedema, weight gain, and flushing and sweating. Dr G stressed to Ms A that, despite any side effects, it was vital that she took the full five-week course of the medication. This was to ensure that her uterus had shrunk sufficiently for the ablation procedure to be performed.

19 January 2000 – prescription first dispensed
On the same day, Ms A went to a pharmacy. Mr B and Mr H, both of whom are pharmacists, jointly owned the pharmacy in early 2000. Mr B continues to work at the pharmacy but is no longer a part owner. The pharmacy is a large pharmacy in a very busy area. It dispenses approximately 250 prescriptions a day and is open seven days a week.

Ms A handed over the prescription written on Dr G's prescription paper. It prescribed danazol 200mg for five weeks for Ms A, one tablet to be taken three times a day. The prescription was dispensed and checked by Mr B. Mr B stated that he checked the prescription before dispensing the medication to Ms A. Mr B stated that although he checked that the prescription was correctly labelled "danazol", he mistakenly gave Ms A

four weeks' supply of Diflucan 200mg with one repeat for a further week's supply. Mr B was at a loss as to how he made the error but accepts that the error was made and takes full responsibility for it. He was the sole pharmacist on duty on this day. (A copy of the Pharmacy's Prescription Handling and Checking Protocol is attached as Appendix One.) Mr B told Ms A that a repeat would be necessary because the pharmacy did not have a full supply of danazol in stock. On the packaging "Danocrine" (the trade name for danazol) is in bold type and "danazol" is in smaller type.

Diflucan is an anti-fungal agent prescribed by specialists and comes in 200mg capsules. It can be prescribed in courses, lasting eight weeks or for longer periods to prevent infection. It is used to treat cryptococcal meningitis and cryptococcal infections at other sites with a dose of 400mg daily. The most common side effects are nausea, abdominal pain, diarrhoea and flatulence.

Ms A was given the prescription with no other literature or advice to tell her of the side effects of the medication. Mr B stated that there is usually no information given to the customer other than the instructions on the packet or bottle for prescription medicines of Diflucan and danazol. In response to my provisional opinion, the lawyer representing Mr B and the pharmacy submitted that when a patient has been seen by a specialist it is reasonable to presume that the specialist has fully informed him or her of the risks, benefits and side effects of the medication. It was further noted that danazol can be prescribed for a number of symptoms and conditions and can only be prescribed by a specialist. Mr B was aware that danazol was prescribed to treat gynaecological symptoms but had no further details. If he offered any further information he risked contradicting the specialist and confusing the patient. It was acknowledged that a pharmacist has a greater obligation to provide information when medicine is provided to a person who has not seen a medical professional, such as in the case of pharmacy only medicines.

Ms A felt sick when taking the tablets and confirmed with another pharmacy that this was a side effect of the medication. This second pharmacy was shown the medication she was taking but Ms A did not tell the pharmacy what she was taking it for. Ms A did not approach her general practitioner or a public hospital about the side effects she was experiencing.

19 February 2000 – dispensing error discovered

On Saturday, 19 February 2000, Ms A returned to the pharmacy to pick up her repeat prescription at lunchtime. She was with her 10-year-old son and, as the pharmacy was busy, they dropped off the prescription and left the store to return later.

Ms D, pharmacist, began her shift at the pharmacy at midday and went to the dispensary area. She picked up an empty Diflucan box and noticed it had a label on it stating it was danazol. She realised there had been a dispensing error and discussed this with Mrs C, pharmacist. Mrs C checked on the computer and found that danazol had been entered,

but was unable to check whether it was the correct medication, as the original prescription had been sent to another area for processing.

Ms A stated that when she and her son returned 10 minutes later there were about seven people in the pharmacy waiting for prescriptions. Mrs C told her that it was likely that she had been given the wrong medication in January. Mrs C said she was not initially aware that Ms A had her son with her, but became aware of his presence during the conversation. Ms A said the conversation occurred close to the front counter and the pharmacy was very busy at the time with a number of people close by. Ms A stated that her son became distressed, asking her if she was going to die. Ms A stated that all the explanation was done in a very public and loud manner and the other customers in the pharmacy could not avoid hearing the conversation. Mrs C said that she spoke in a low tone when she was telling Ms A about the error. Ms D confirmed this.

Mrs C initially spoke to Ms A by the front counter next to the dispensary. Ms D said that there were a number of customers in the shop. There are seats for customers to use while waiting for their prescriptions, placed 12 to 15 feet from the dispensing counter.

Ms A said that she was distressed and concerned about what impact the prescribing error would have on her surgery, which was scheduled for five days later. When Ms A said that she was a participant in a trial being run by the gynaecological department at a public hospital, Mrs C moved the discussion into the manager's office. The manager's office is a small office with a door separate from the dispensing area, serving counter and retail area. Mrs C could not remember whether Ms A's son accompanied his mother into the office. Ms A told Mrs C that the medication was intended to shrink her womb prior to an operation but that she was still bleeding and had diarrhoea.

Mrs C explained to Ms A that Diflucan was an anti-fungal agent and that diarrhoea was a possible side effect of the drug. Mrs C consulted *New Ethicals* (a pharmaceutical prescription guidebook), where GI (gastrointestinal) disturbances are listed as side effects of Diflucan, and explained this to Ms A. Mrs C stated she explained to Ms A that she was not prepared to give her any further medication without consulting an appropriate person, preferably Dr F, to explain the mistake and seek advice on further action. Mrs C also stated that she told Ms A that, being a Saturday afternoon, there might be some difficulty in contacting an appropriate authority at a public hospital. Mrs C then took Ms A's telephone number and assured Ms A she would be contacted as soon as she was able to obtain direction on the course of action to be taken. Mrs C said that she apologised again for the situation, and that she would do everything possible to resolve the situation. Ms A then left the pharmacy.

Ms A said that she and her son were taken to one side, after some discussion, and told that the pharmacist would contact her GP, Dr E, and Dr F. Ms A stated that she left the pharmacy with no medication, no information about the medication she had been on, and no information about the side effects she may have suffered.

Mrs C stated that she and Ms D briefly discussed the situation after Ms A left, and Mrs C then telephoned the hospital. Mrs C asked to speak to Dr F, but was informed that he was unavailable. Mrs C was put through to Ms I, duty nurse, at the public hospital. Mrs C explained the situation to Ms I, who advised Mrs C to find a doctor from the Department and get instructions on the course of action to take. Mrs C thought it was unnecessary to contact Ms A at this stage, as she hoped to hear from the hospital in a very short time.

Mrs C then telephoned Mr B at home, and explained the incident and the subsequent action taken, and gave him Ms A's telephone number. Mr B telephoned Ms A at her home and apologised for what had occurred. He explained to Ms A that she was given anti-fungal tablets instead of the danazol and that Mrs C had contacted the hospital. Mr B advised Ms A that he was waiting for instructions from Dr F about what to do. Mr B told Ms A that if the specialist considered that Ms A should commence the course of danazol immediately, then the pharmacy would deliver the medication directly to her. He also stated that the pharmacy would review its dispensing protocols and procedures to ensure that such a dispensing error did not occur again.

Mrs C finished work at 4.00pm. Before she left she told Ms D what she had done and that she was expecting a return call from the hospital.

Dr J, a registrar at the public hospital, telephoned the Pharmacy and spoke to Ms D. Ms D explained that a dispensing error had occurred and Ms A had received Diflucan instead of danazol. Ms D then asked what course of action the pharmacy should take. Dr J said that he would need to discuss Ms A's treatment with her specialist, Dr F and not to give her any medication until further instructions had been received. Dr J said he would call back on Monday as he would not be able to contact Dr F until then.

Ms D then called Mr B and Mrs C to tell them what Dr J said. As Ms D works in the pharmacy on Saturdays only, she also left a note for Mr B. Mr B stated that he then called Ms A to inform her that Dr J had said to take no medication until he had spoken with Dr F and this would not occur until Monday. Ms A denied receiving this call.

Monday, 21 February 2000
On Monday morning, after hearing nothing from the hospital, Mr B called the public hospital to talk to Dr F. Mr B was put through to Dr J and was told he had spoken to Dr F but that they had not yet made a decision. Mr B stated that he specifically asked if Ms A should start taking danazol, and was told that the decision was still to be made. Mr B asked Dr J if he should ring Ms A to explain what was happening and was told that the doctors would be in touch with Ms A when a decision was made.

Ms A telephoned her GP, Dr E, for advice on the Monday morning. Dr E knew nothing about what had happened over the weekend.

Dr E confirmed that Ms A contacted her on the Monday after Ms A discovered she had been given an anti-fungal medication instead of danazol. Dr E expressed her shock that such a mistake had taken place. Dr E reassured Ms A that the medication was unlikely to have caused her harm and suggested that she contact the hospital on Ms A's behalf, to check whether the mistake would compromise her upcoming surgery. Dr E stated that Ms A was upset about the mistake and was also frustrated because she had gone to enormous trouble to arrange her work commitments to have surgery on 24 February.

Dr E cannot recall whether she talked to the Pharmacy; she may have done but did not make a note of it and cannot remember. Mr B said that Dr E called him and they discussed the dispensing error. He relayed what he had been told by Dr J and asked whether he should contact Ms A. Dr E said she would contact the hospital and follow up with Ms A. Mr B said that he asked to be kept informed but heard nothing further from the hospital or Dr E.

Dr E contacted Dr G at the public hospital, and explained that a pharmacist had made an error and that Ms A had not received the prescribed course of danazol. Dr E stated that Dr G was reassuring and said that the surgery would not necessarily be cancelled and that he would see Ms A and perhaps perform an ultrasound to check the endometrial thickness.

Subsequent events
After discussing the matter with Dr E, Dr G arranged for an urgent appointment with Ms A and ordered an ultrasound scan. Ms A had an ultrasound scan on 22 February 2000. In a letter to Ms A's general practitioner, Dr G stated:

> "Unfortunately [Ms A] did not receive the appropriate endometrial thinning agent pre-operatively. She states this was due to a prescription error. However, at the time of surgery her endometrium had recently been shed with menstruation and transvaginal scanning revealed an adequately thinned endometrium, so we proceeded to surgery."

On 24 February 2000, Ms A had an ablation performed at a public hospital by Dr F.

After-effects of surgery
Ms A stated that after the ablation and her discharge from hospital she experienced a lot of pain and was subsequently readmitted to hospital. She questioned whether the pain she had suffered was a result of the dispensing error.

Mr B said that the Diflucan should essentially have been eliminated from Ms A's body by the time she had surgery, and considered it is unlikely that the pain experienced by Ms A would have been caused by anti-fungal medication she stopped taking five days before the operation. Dr F said that the Diflucan would not have affected Ms A, and that pain is a normal side effect of an ablation. Some people feel different levels of pain than others.

My independent obstetrician and gynaecological advisor, confirmed that pain is a normal side effect of an ablation and that danazol would only have assisted in treating Ms A's heavy periods.

Review of dispensing procedures
Mr B stated that he discussed the incident in full with his partner, Mr H, and with Mrs C and Ms D and they agreed how important it was that the checking procedure was followed correctly. The dispensing procedure was reviewed and it was emphasised that the pharmacist who carries out the final checking of the prescription should not be the one who dispenses it.

Mr B provided copies of the pharmacy's previous dispensing procedure and of the comprehensive new dispensing procedure (attached as Appendix Two). The checking procedure has been intensified with the aim of ensuring two different people check the prescription before it is given to the patient. Since the incident, staffing levels have been increased to relieve the pharmacists' workload and decrease distractions, and there are now at least two qualified pharmacists present in the pharmacy during the week.

Mr B stated that the pharmacy's new policy is to protect patient privacy by taking the patient completely away from the pharmacy floor area to a separate office on every occasion where there is a query or problem with a prescription.

Pharmacy policies and procedures in regard to privacy and communication with customers
The Pharmacy did not have a written policy in place to guide staff on communicating sensitive information and on issues of physical privacy. In response to my provisional opinion, the lawyer for the pharmacy submitted that a pharmacy can comply with Rights 1(2) and 4(2) without having a written policy. The response also noted that no legal, professional, ethical or other standards require the formulation of a written policy.

Mr B stated that the owners of the pharmacy have always instructed pharmacists and other staff to deal with matters in a sensitive way and to have regard to the privacy of consumers. Privacy issues were discussed with staff and incorporated into day-to-day operations. One of the bullet points in the job description for pharmacist/manager positions was that the pharmacist/manager provides "accurate, appropriate advice in a sensitive and caring manner on health care, drug use and products available".

In an audit conducted in 2001 Medsafe asked the pharmacy whether clients received appropriate advice in a private and confidential manner and were assured by the pharmacy that clients did receive advice in a private and confidential manner.

Mrs C stated that she realises it was a very stressful situation for both parties and apologised unreservedly for any distress she may have caused either Ms A or her son, and

for the fact that Ms A found Mrs C's handling of the situation unsatisfactory. Mrs C stated that at all times she attempted to put the welfare of Ms A first.

Mr B also apologised to Ms A at the time of the incident and in a letter to the Commissioner.

Independent advice to Commissioner

The following expert advice was received from Mr Alan Fraser, an independent pharmacist:

"What information should be given to a consumer when dispensing Diflucan or Danazol?
No information is usually given to the patient other than the instructions on the packet or bottle. The doctor usually informs the patient of any side effects.

A pharmacist would not breach any standards by not giving out any information concerning either Danazol or Diflucan.

What should a pharmacist do when a dispensing error is discovered?
The pharmacist should involve the patient (without unduly alarming them) by making a frank and honest admission of the mistake and informing the patient that the pharmacist would contact the prescriber of the medication (in this case the specialist) to discuss how to proceed. A repeat should not be dispensed until the pharmacist had discussed the issue with the specialist and received instructions from him/her."

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 1
Right to be Treated with Respect

…
2) Every consumer has the right to have his or her privacy respected.

RIGHT 4
Right to Services of an Appropriate Standard

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

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; …

Other Relevant Standards

The following standards from the "Pharmacy Practice Handbook" (Pharmaceutical Society of New Zealand, 1999) are applicable to this complaint:

"***PART 2 – CODE OF ETHICS AND PROFESSIONAL STANDARDS***
CODE OF ETHICS
Rule 2 Pharmaceutical services

2.6 A pharmacist must take responsibility for providing the consumer (or consumer's agent) with information on:

- directions for safe and effective use of the medication;
- the expected outcome(s) of the drug therapy;
- what to do if side effects occur;
- storage requirements of the medications;
- disposal of unused medicine(s) and medical products.

Rule 4 Pharmacy environment

4.3 A pharmacist must ensure that an area in the pharmacy is set available for private and confidential counselling to take place.

2.2 QUALITY STANDARDS FOR PHARMACY IN NEW ZEALAND
Standard 6 Pharmaceutical Services

6.2. Dispensing
The pharmacist maintains a disciplined dispensing procedure, which ensures that the appropriate product is selected and dispensed correctly and efficiently.

PART 4 – PRACTICE ADVICE

4.1 PRESCRIPTION AND DISPENSING SERVICES

4.1.1 Dispensing
…
Guidelines to Support the Definition of Dispensing

Dispensing involves following steps:
…
- **Selecting the correct medication:**
  - The pharmacist is responsible for the final check of the prescription to ensure it is the correct medicine, dosage, form and strength."

Opinion: Breach – Mr B

Right 4(1) and Right 4(2)

Dispensing
In my opinion Mr B breached Right 4(1) and Right 4(2) of the Code of Health and Disability Services Consumers' Rights.

Mr B dispensed 200mg Diflucan capsules to Ms A instead of the prescribed 200mg danazol capsules. Although Mr B stated that he checked that the prescription was correctly labelled "danazol", he obviously failed to check that the contents were correct.

The Pharmaceutical Society of New Zealand and the pharmacy's internal dispensing standards emphasise the importance of checking the medication dispensed against the

prescription to ensure it is the correct medicine, dosage, and strength. Clearly, this did not occur.

In my opinion, Mr B did not dispense Ms A's prescription with reasonable care and skill and in a manner that complied with professional and other relevant standards, when he dispensed 200mg Diflucan, instead of the prescribed 200mg danazol, and breached Right 4(1) and Right 4(2) of the Code.

I acknowledge that Mr B and the pharmacy apologised to Ms A when the error was discovered and contacted one of the medical professionals involved in Ms A's care to advise them of the error. Mr B and the pharmacy have also taken steps to prevent such an error occurring again by revising the dispensing policy and employing more staff.

I take this opportunity to emphasise the need for pharmacists to be vigilant when dispensing medication, and to carefully check the prescription and the product dispensed to ensure that it is correct.

Right 6(1)(b)

Information about side effects
Ms A said that she did not receive any information about danazol when she picked up her prescription from the pharmacy on 19 January 2000. Mr B said that no information was usually given to the consumer other than whatever information was provided by the manufacturer of the product. He said that the pharmacist is entitled to presume that the medicine, as well as its side effects, would have been discussed with the patient prior to prescription. The obligation to provide detailed information about side effects should fall on the prescriber. My independent advisor said that the doctor who prescribed the drug usually provided information on side effects, and that "usually" a pharmacist would give the consumer no information about prescription medicine, other than the instructions on the packet or bottle.

Right 6(1) of the Code of Health and Disability Services Consumers' Rights affirms a consumer's right to receive the information that a reasonable consumer in that consumer's circumstances would expect to receive, including information about risks, side effects and benefits. This is a consumer-centred standard, based on a consumer's reasonable expectations, rather than the accepted practice amongst providers.

I accept that the prescribing doctor is best placed to discuss in detail the risks, side effects and benefits of proposed medication; however, this does not absolve the pharmacist of responsibility for informing consumers of common side effects and giving instructions about how to take their medication. Although the purpose for which medication is prescribed can differ, the most common side effects remain the same. The information sheet provided by the manufacturer is not sufficient to discharge the pharmacist's obligations. The pharmacist still has a responsibility to comply with the Code and

provide relevant information and advice to customers when dispensing prescriptions and pharmacy only medicines. I note that counselling customers about medication use and providing professional advice is recognised as a professional responsibility of a registered pharmacist in Rule 2.6 of the Code of Ethics. I further note that the new dispensing procedure for the pharmacy recognises that a pharmacist should provide counselling to a customer in appropriate circumstances.

In my opinion, by failing to provide Ms A with any information about the side effects of her prescribed medication, danazol, Mr B breached Right 6(1)(b) of the Code.

Opinion: Breach – The Pharmacy

Right 1(2)

Communication of sensitive information
In February 2000 the Pharmacy had no written policy or procedure to guide staff about the most appropriate environment for communicating sensitive information to consumers. The Pharmacy does not dispute this but suggests that a pharmacy can comply with the obligations set out in Right 1(2) without a written policy being in place. The Pharmacy advised me that the manager's office was the designated private area, away from the shop floor, where sensitive information could be discussed with consumers. It also said that staff were instructed to deal with matters in a sensitive way and to have regard to the privacy of consumers and that this was incorporated into day-to-day operations. The Pharmacy also referred to the job description for pharmacists, which states that pharmacists must provide advice in a sensitive and caring manner.

Pharmacy staff need guidance about how to handle disclosure of sensitive information, such as an explanation that a dispensing error has occurred. I am satisfied that the steps taken by a Pharmacy to provide guidance to staff were sufficient to ensure that staff complied with their obligations under the Code. Staff need more specific instructions than being asked to discuss matters sensitively. They need to know that physical privacy is as important as information privacy; when a matter should be discussed in privacy; and that the manager's office was available for private discussions. The basis for instructions to staff should be a written policy on which verbal directions and reminders can be based.

In my opinion by failing to have an appropriate policy in place the Pharmacy and its owners, pharmacists Mr B and Mr H, breached Right 1(2) of the Code.

Opinion: No breach – The Pharmacy

Right 4(1)

Failure to provide replacement prescribed medication
Ms A stated that when she was told she had been dispensed the incorrect medication she was not given the one week quantity of danazol that was still to be dispensed. I accept that Mrs C told Ms A that it was not wise to start taking the medication without receiving advice from the medical practitioner who prescribed it and that Mr B echoed this advice when he called Ms A. Dr J confirmed that the medication should not be started until he had spoken with Dr F. In my opinion this action was reasonable in the circumstances, as the prescribed medication was part of a clinical trial and was prescribed specifically for use prior to surgery that was to take place within five days. Accordingly the Pharmacy did not breach Right 4(1) of the Code in relation to this matter.

Right 4(5)

Follow-up with surgeon and general practitioner
Where, as occurred in this case, it is discovered that a dispensing error has occurred, resulting in a consumer taking the wrong medication for a four week period, it is imperative that the medical practitioner who prescribed the medication be contacted to ensure appropriate follow-up care. Right 4(5) of the Code requires health care providers to co-operate to ensure quality and continuity of care for consumers. Ms A was concerned that no contact was made with her surgeon and general practitioner by the pharmacy.

After discovering the dispensing error and discussing it with Ms A, Mrs C immediately attempted to contact Dr F at the public hospital. When she was unable to contact Dr F she discussed the issues with a nurse, who said she would get a doctor to call her back. Ms D received the call and passed on the pharmacy's concerns to Dr J. Dr J telephoned the pharmacy and said he would talk to Dr F and get back to the pharmacy on the following Monday. When the pharmacy had not been contacted on the Monday, Mr B contacted Dr J, who said that a decision had not yet been made and that the hospital would discuss the issues with Ms A. Later that day Mr B also discussed the issues with Dr E after receiving a call from her. Dr E said she would follow up with Ms A.

Although the pharmacy staff did not attempt to contact the prescriber of the medication, Dr G, attempts were made to contact Dr F, as Mrs C had been informed by Ms A that Dr F was managing her care and was to undertake the surgery planned for later that week. I accept that this was the appropriate action to take in the circumstances.

I note that pharmacy staff did not contact Dr E, Ms A's general practitioner, on Monday 21 February. In my opinion, it would have been wise to do so, in the interests of ensuring

quality and continuity of care for Ms A. However, I accept that the first priority was to contact Dr F.

It would also have been prudent for pharmacy staff to contact Ms A on Monday 21 February and reassure her that her surgeon was aware of the error and would follow up with her shortly. I accept that Mr B was told by the hospital and Dr E that they would contact Ms A to discuss the impact of the medication error with her, but consider that the pharmacy staff should have passed this information on to Ms A.

Taking account of all the circumstances, I am satisfied that the pharmacy acted reasonably in attempting to contact Ms A's surgeon, and did not breach Right 4(5) of the Code.

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. However, under section 72(5) an employing authority has a defence if it shows that it took such steps as were reasonably practicable to prevent an employee from breaching the Code.

Mr B breached Rights 4(1), 4(2) and 6(1)(b) of the Code. The Pharmacy had a dispensing procedure and policy in place that required a series of checks to be made to ensure that a prescribed medicine is dispensed correctly, and that a consumer is given appropriate information when receiving medication. I accept that the pharmacy had taken reasonable actions in the circumstances to prevent a dispensing error from occurring. Accordingly, in my opinion the Pharmacy is not vicariously liable for Mr B's breaches of the Code.

Opinion: No further action – Mrs C

Mrs C died during the course of this investigation. In these circumstances I have decided, in the exercise of the discretion under section 37(2) of the Health and Disability Commissioner Act 1994, to take no further action in relation to the complaint against her.

Actions

- I recommend that the Pharmacy provide a copy of its new dispensing procedure to the Pharmaceutical Society of New Zealand for approval.

Further actions

- A copy of this opinion will be sent to the Pharmaceutical Society of New Zealand and the Privacy Commissioner.

- A copy of this opinion, with identifying features removed, will be sent to the New Zealand College of Pharmacists, and placed on the Commissioner's website, www.hdc.org.nz, for educational purposes.

- I will refer this matter to the Director of Proceedings in accordance with section 45(f) of the Health and Disability Act 1994 for the purpose of deciding whether any further action should be taken.

Addendum

The Director of Proceedings considered this matter and decided not to issue proceedings before the Pharmaceutical Society Disciplinary Committee or the Human Rights Review Tribunal.

Appendix One

[the] PHARMACY

Standard Operating Procedure

Prescription Handling and Checking

Receive Script: From customer/fax/phone

Check:

- Correct name and address of pt
- Correct pt classification (eg. A1, A3, J, Y, P, etc)
  - if necessary view CS/High use/Exemption card
  - age if child
- Script signed and dated by Prescriber
- Script legible quick assessment of script, est. time

Process Script: using "Lots Windows"

- Stamp with today's date
- Choose correct patient/enter patient into computer
  - Check for irregularities eg. Current meds interaction, repeats owing
- Enter Prescriber
- If script is phoned/faxed select "phoned status"
- Check approp then enter - dose (Maximum)
  - quantity
  - instructions
  - duration (any limits?)
- Enter chem #/change $ if appropriate
- Enter repeats as necessary (NB, not if certified exempt med, check schedule)
- Check label is displayed by computer
  Pt, prescriber, drug, quantity, dose, repeats, CAL labels etc.
- Print (attach certified phone script to faxed copy)

Fill Script: Select med from shelf, check name, strength, Quantity

against:
- script
- label

- Check stock levels and expiry (reorder?)
- Count/pour and place in appropriate container, CRC if required?)
- Attach label to container & unique ID tag to script and any CAL labels required

- If insufficient stock attach "owe" sticker to container and script
- Enter drugs owing in computer
- If compounding use correct manufacturing sheet and document accordingly (get checked)

Check Again:

Label instructions and script are consistent:
- med
- Strength
- Quantity

- Correct stock has been used
- Repeats are included as necessary
- CAL labels are on label/or attach appropriate CAL labels
- Return stock to shelf/fridge. Date if necessary

Annotate and Check

Quantity and form of med dispensed is clearly stated

- Item count to be claimed and appropriate charge (eg. $15, $3 or NSS) in top right hand corner or BFF if blow fee
- Repeats are stated on script
- Sign "dispensed by" box
- Place for checking in tray (including stock container) – interns, externs, technicians only
- Checked and signed by pharmacist, script into tray/owing pile
- Medications and receipt placed on shelf alphabetically according to patient surname

Give to Customer

Check name and address to ensure correct Pt

- Run through medication purpose & how/when to take it (label and CAL's) & duration
- Run through possible side effects/interactions where approp.
- Run through storage e.g. Fridge, out of reach of children
- Get patient to repeat back instructions as they understand to check understanding
- Any questions? Collect Fee.

Appendix Two
[The] Pharmacy
New Dispensing Procedure

1. Purpose

1.1 The pharmacist maintains a disciplined dispensing procedure that ensures that the appropriate product is selected and dispensed correctly and efficiently.

2. Procedure

2.1 When receiving the prescription or order from the patient or the patient's agent, the pharmacist shall

Check correctness of prescription – The prescription must

- Be legibly and indelibly printed (in the doctor's handwriting, or printed).
- Be personally signed by the prescriber and dated.
- Contain the name and address of the prescriber.
- Have the title, surname, initial and address of the client.
- Contain the date of birth for a child under 13.
- Include the name of the medicine, the form and the strength.
- Give the dose to be given or taken, or directions for use.

2.2 - Check the period or quantity of supply. If the prescription is to be dispensed on more than one occasion, check the interval between dispensings.

2.3 - Check that the quantity does not exceed 3 months, except for oral contraceptives (6 months' supply).

Note that prescriptions are only allowed to be dispensed in monthly lots. The quantity given per month must be annotated. If the prescription is to be dispensed state (because of fulfilment of exemption criteria) this must also be annotated.

2.4 - Check that for a dental prescription, that the quantity is for no more than 5 days plus 5 days to a maximum of 10 days' supply, or 3 months' supply for sodium fluoride.

2.5 - Check that for a midwife's prescription that the maximum supply is 3 months, and is only for antenatal, intrapartum and postnatal care.

2.5.1 Check client details

- Check that the details on the prescription are correct (name, address, age (if necessary).
- Check whether the client is the holder of a community services high user's or prescription subsidy card.
- In some cases the prescription may be a Practitioner's Supply Order (PSO) or Bulk Supply Order (BSO). Information on PSO's is provided in the front of the New Ethical Catalogue and further information on PSO's and BSO's is contained in the general rules section of the Pharmaceutical Schedule.

2.6 Record prescription details
- Key in relevant data into the dispensary computer.
- Select a product which best serves the interest of the patient (i.e. maintains continuity of treatment and bioavailability).
- Make sure that any dispensing information is current and up to date.
- Prescription records must be maintained for a minimum of three years. Controlled drug forms need to be kept for four years.

2.7 Generate label
- Make the language and lettering on the label simple and clear.
- Don't overwrite corrections on the label.
- Keep the label background plain.
- The printer ribbon must be changed at such intervals so that the label is able to be read easily.
- Labels are prepared in accordance with the recommendations of the Pharmaceutical Society Council, and should ensure that the intentions of the prescriber are properly represented. Each label should contain.
  - Client name (title, surname, and initial).
  - Date.
  - Name or description of contents.
  - Quantity dispensed.
  - Directions for use – dose and frequency of dose, method and frequency of use.
  - Reference number (this should also be on the prescription).
  - Name and address of pharmacy.
  - Prescriber's name and reference.

  Double check labels against the original prescription for any mistakes before attaching them to the container.

2.8 Select correct medicine
- Check that the right medicine and brand is used.
- Check the expiry date.
- Check the strength, form and quantity of the medicine against the prescription.

2.10 Count and pour medicine and label container
- Count and pour only one item at a time if there are several items. Take items off the shelf one at a time. Count and label the first item before selecting the next item.
- Follow policies and procedures on compounding. See policy and procedure 96 SOP DC 1301.
- Use a suitable container for the medicine, and affix the label so that directions are clear, and if using an original container, no important information on the label is obscured.
- Attach any Cautionary and Advisory (C & A) labels if required.
- For further information, refer to the Pharmaceutical Society of NZ Dispensing Guide.

2.11 Check the dispensing procedure
This MUST be done by another pharmacist
- If a calculation is involved, this is rechecked and if possible checked by another pharmacist.
- Check the dispensed medicine against the prescription for,
- label accuracy – name, date, medicine dose and form, instructions, C & A labels.
- contents accuracy – correct medicine, dose, form, quantity.
- The dispenser and checker must be able to be identified at all times. Each item must be initialled appropriately to reflect this.
- If the full supply of the medication is unable to be given, follow procedure 96 SOP DC 0801 for medicine owes.

2.12 Hand out prescription
- Annotate prescription in accordance with contract requirements, initial prescription and assemble prescription items, with receipt on shelf. Check against prescription and store in alphabetical order on the shelf to await collection.
- On return of the client (or client's agent), check the items against the receipt and hand them over to the client, making sure first that the right person is receiving the right prescription.

2.13 Counsel the client (if appropriate)
- Pharmacy takes responsibility for providing its customers with sufficient information so that he/she derives the maximum therapeutic benefit and encounters the minimum untoward side effects from their medication. The Pharmacy Guild statement is used as a guide on patient counselling.
- Make sure the client knows and understands the answers to these questions.
- Why is the medicine being prescribed for me?
- How do I take it?
- When do I take it?
- How long do I take it for?
- How do I know if I have a side effect and what should I do?
- What special precautions should I take?
- Are there any food or other medicines I should avoid?
- Should I avoid alcoholic drinks?
- How will I know if the medicine is working?
- When should I call the doctor?
- How should I store the medicine?
- Do I have a repeat prescription to collect?
- If so, how and when should I collect it?

2.14 Dispense repeat prescription
- Recall patient name and details including prescription number from computer & generate label.
- Generate CRC

- Count & compound as required.
- Check, initial prescription and prepare for issue to patient.

2.15 Miscellaneous

- If preparing an extemporaneous mixture, all ingredient details will be recorded in the manner set out in the NZ Code of Good Manufacturing Practice Part 3. An appropriate expiry date will be determined.
- When a prescription is dispensed by the pharmacy technician or pharmacy student under training, the above steps will be followed. In addition the pharmacist will monitor the progress and check the dispensed products against the prescription, and take responsibility for any counselling.