The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM

Complaint

The Commissioner received a complaint regarding the services provided to Mrs A by a pharmacy. The complaint is that:

- *On 9 March 2000 Mrs A was prescribed prednisone 5mg. Mrs A took her prescription to the pharmacy where she was dispensed 20mg tablets rather than the 5mg tablets prescribed.*

Investigation Process

The complaint was received on 14 April 2000 and an investigation was commenced on 11 May 2000. On 31 May 2000 the investigation was extended to include Ms B, technician, and Mr C, pharmacist. Information was obtained from:

Mrs A	Consumer / Complainant
Ms B	Technician, the pharmacy / Provider
Mr C	Pharmacist, the pharmacy / Provider
Dr D	General Practitioner
Ms E	Pharmacist, the pharmacy
Ms F	Manager, the pharmacy

Mrs A's relevant medical records from her general practitioner were reviewed by the Commissioner.

The Commissioner obtained information from an independent pharmacy advisor.

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Information Gathered During Investigation

On 9 March 2000 Mrs A consulted her general practitioner, Dr D, because she was suffering from arthritis, sleeplessness, lack of appetite and periods of irrational behaviour. Dr D prescribed prednisone 5mg (a corticosteroid) and instructed Mrs A to take four tablets with food each morning. The prescription form completed by Dr D stated:

> "*Px* [prescription] *prednisone 5mg*
> *sig 20mg 4 daily ntte* [to be taken in the morning] *50 stat.*"

Mrs A took the prescription to the pharmacy where she was dispensed a bottle of pills. The label on this bottle stated:

> "*Do not stop taking this medicine.*
> *50 Prednisone tablets 5mg (APO)*
> *Take 4 tablets with food each morning as directed.*"

This prescription was stamped with the pharmacy stamp, the "*dispensed by*" box was signed by Ms B, technician, and the "*dispensed and checked by*" box was completed by Mr C, pharmacist.

Mrs A stated to the Commissioner that over the following 12 days she continued to feel unwell, felt her liver was enlarged, felt her sweat was burning her skin and suffered mouth ulcers. The potential side effects of a cortisone preparation, such as prednisone, include stomach ulcers and bleeding, nervous and hormone disturbances, muscle and bone damage and eye changes.

At 10.51am on the morning of 20 March 2000 Mrs A rang the pharmacy and spoke to Ms E, pharmacist. Mrs A asked what prednisone 5mg tablets look like and, after a discussion with Ms E about the colour and form of the prednisone tablets, decided that her bottle contained 20mg tablets. Ms E advised that she would check the records and phone Mrs A back.

Continued on next page

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Information Gathered During Investigation ***continued***

In a joint letter to the Commissioner, Ms F, manager of the pharmacy, Ms E and Mr C explained what occurred after Ms E spoke to Mrs A as follows. Ms E consulted other pharmacy staff and checked the pharmacy's computer records. The computer records indicated that prednisone 5mg had been dispensed on 9 March 2000. A staff member rang Health Benefits Limited and obtained a copy of the prescription, as written by Dr D, and looked up the side effects of prednisone in a medical reference text. After reviewing this information Ms E rang Mrs A back and stated that it appeared the pharmacy had dispensed the wrong tablets and Ms E apologised to Mrs A and attempted to comfort and reassure her. During the phone conversation Ms E advised Mrs A of the side effects of prednisone and stated that a high dose of prednisone was unlikely to cause mouth ulcers or to have damaging effects on the liver. The letter stated that Ms E informed Mrs A she would call Dr D and then she would phone Mrs A back after speaking to the general practitioner.

The letter further stated that Ms E rang Dr D and informed him that Mrs A had been taking 80mg of prednisone daily, rather than 20mg, and that Dr D had thanked her for informing him and that they discussed the effects of a high dose of prednisone.

According to the letter, Ms E rang Mrs A back and stated she had informed Dr D and that Mrs A would need to talk to her doctor about reducing the level of prednisone she was on.

Later on the same day Mrs A contacted Dr D. Dr D's notes indicate that he consulted another practitioner and developed a plan for slowly reducing the level of prednisone Mrs A was taking.

On 22 March 2000 Mrs A consulted Dr D. Dr D's notes stated that he examined her and established that there was evidence of oedema (excessive accumulation of fluid in the body tissues) but no other evidence of congestive heart failure and her chest was clear. Mrs A stated to the Commissioner that Dr D referred her to the Rheumatology Unit at a public hospital for monitoring as an inpatient while the level of prednisone was reduced.

Continued on next page

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Information Gathered During Investigation *continued*

Mrs A stated to the Commissioner that she took two days off work to rest and returned to work before being admitted to the Rheumatology Unit at the hospital on 27 March 2000.

Mrs A also advised the Commissioner that during her admission to hospital she developed cardiac problems. These settled and Mrs A was discharged on 31 March 2000, returning to work on 4 April 2000.

Mrs A provided the Commissioner with the bottle containing the remaining prednisone tablets. Following a description of the tablets, an independent pharmacist confirmed that the tablets were likely to be 20mg prednisone tablets.

According to my advisor, 5mg prednisone tablets are coloured white and, until recently, supplies of 20mg prednisone tablets were coloured pink to allow for ease of identification and checking. Both tablets are now white. A recent article written by the Pharmacy Defence Association and printed in the November 2000 issue of the Pharmaceutical Society of New Zealand newsletter, 'Interactions', stated:

> "*Too many times 20mg tablets are dispensed instead of 5mg. Previously 20mg tablets were pink and thus an error was picked up when counting the tablets. The bottles are different sizes, so please ensure you read the label correctly.*"

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4
Right to Services of an Appropriate Standard

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

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Professional Standards

The Pharmaceutical Society of New Zealand's 'Code of Ethics', (December 1996) states:

Rule 2.12
"*A Pharmacist must dispense the specific medicine prescribed …*"

The Pharmaceutical Society of New Zealand's 'Handbook of Pharmacy Practice' (August 1999) states:

"**PRESCRIPTION AND DISPENSING SERVICES**

4.1.1 Dispensing
…
- *Selecting the correct medicine:*
  - *Check the selected medicine against the prescription to ensure it is the correct medicine, dosage form and strength.*

  …
- *Checking the dispensing procedure:*
  - *The pharmacist is responsible for the final check of the prescription.*
  - *Check the label accuracy – name, date, medicine strength and form, instructions, C & A labels and contents accuracy – correct medicine, dose, form and quantity.*"

The 'Standard Operating Procedure' of the pharmacy states:

"SUBJECT: Dispensing a prescription

"**2. PROCEDURE:**
a) Receive prescription (all staff)
b) Check all customer details are correct (all staff)
c) Check all prescription details are correct
d) Enter details in computer
e) Check stocks of the medicine prescribed
f) Check for interactions/adverse reactions
g) Produce label
h) Dispense the correct quantity of medicine

Continued on next page

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Professional Standards *continued*

i) Attach the correct label (and technician initial)

j) Pharmacist to make final check against prescription and initial script.

At each stage the dispenser should mentally check that the details are correct, that the label instructions are clear, and that the correct medicine is selected."

Opinion: Breach Ms B

In my opinion, Ms B breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights. Mrs A brought in a script for 5mg prednisone tablets and was given a bottle of 20mg prednisone tablets.

Ms B, the dispensing technician, is recorded as having dispensed the prednisone tablets. However, rather than dispensing the 5mg prednisone tablets as prescribed, Ms B dispensed 20mg tablets to Mrs A. I note that 20mg prednisone tablets were previously provided in a pink colour to differentiate them from white 5mg prednisone tablets and that both forms of tablet are now coloured white. I accept that this may have contributed to the wrong dosage being dispensed to Mrs A. However, the pharmacy procedure for dispensing medication sets out the responsibilities of the dispensing technician, which includes dispensing the correct quantity of medicine. Ms B did not meet her obligations when she dispensed 20mg prednisone tablets rather than 5mg prednisone tablets to the consumer. In my opinion, by failing to meet this standard, Ms B breached Right 4(2) of the Code.

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Opinion: Breach Mr C

In my opinion, Mr C breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights. Mr C signed Mrs A's prescription to indicate that he checked the dispensed medication against the prescription. In my opinion Mr C failed to check adequately that the tablets dispensed were 5mg in strength, as prescribed. Accordingly, Mr C breached Rule 4.1.1 in the Pharmaceutical Society of New Zealand's 'Handbook of Pharmacy Practice' which states that the dispenser must check the selected medicine against the prescription to ensure that it is the correct medicine, dosage, form and strength. Rule 2.12 of the Pharmaceutical Society's Code of Ethics requires pharmacists to dispense the specific medicine prescribed. In addition, the pharmacy procedure states that the pharmacist is responsible for the final check of the dispensed medication against the prescription and initial script.

By failing to follow this procedure and adhere to the Society's standards, Mr C breached Right 4(2) of the Code.

Opinion: No Breach The Pharmacy

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 things that breach the Code.

I am satisfied that the pharmacy had a policy and procedure in place to ensure that medicines are dispensed in compliance with legislative and professional requirements and that the incorrectly dispensed medication was a product of human error. Accordingly, I am of the view that the pharmacy is not vicariously liable for Ms B's and Mr C's breaches of the Code.

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Actions

I recommend that Ms B:

- Apologise in writing to Mrs A for her breach of Right 4(2) of the Code. This apology is to be sent to the Commissioner within one month and will be forwarded to Mrs A.

- Review her practice in relation to the dispensing of medicines to ensure that it complies with relevant pharmacy standards.

I recommend that Mr C:

- Apologise in writing to Mrs A for his breach of Right 4(2) of the Code. The apology is to be sent to the Commissioner within one month and will be forwarded to Mrs A.

- Review his practice in relation to checking the dispensing of medicines, to ensure that it complies with relevant pharmacy standards.

I recommend that the pharmacy:

- Review the dispensing procedures in place at the pharmacy to safeguard against further errors and to ensure that in future medicines are checked correctly. The pharmacy is to confirm to the Commissioner that this has been done within one month.

Response to Provisional Opinion

In response to the Commissioner's provisional opinion, the pharmacy, Mr C and Ms B submitted written apologies for forwarding to Mrs A.

The pharmacy confirmed that it has revised its Standard Operating Procedure for dispensing prescriptions so that a selected medicine is always checked against the prescription by a pharmacist to ensure that the correct medicine, dosage, form and strength has been dispensed.

The Pharmacy / Ms B / Mr C

Opinion – Case 00HDC04055/AM, continued

Other Actions

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

- I will forward the apologies from Mr C, Ms B and the pharmacy to Mrs A.

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

- A copy of this opinion will be sent to Medsafe, Ministry of Health, with a recommendation that the availability in New Zealand of tablets of similar size and colour for different doses of the same prescription medicine, in particular prednisone, be reviewed.