Pharmacist, Mr B

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 04HDC10307)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mr B	Provider / Pharmacist
A Pharmacy	Employer
Dr C	Ophthalmologist

Complaint

On 17 June 2004 the Commissioner received a complaint from Ms A about the services provided to her by Mr B at a pharmacy. The following issue was identified for investigation:

- *Whether Mr B of the pharmacy provided services of an appropriate standard to Ms A on 25 March 2004 by dispensing 20 mg prednisone tablets instead of the prescribed 5 mg prednisone tablets.*

An investigation was commenced on 21 September 2004.

Information reviewed

- Ms A's prescription of 25 March 2004 from Dr C

- Information provided by:
  – Ms A
  – Mr B
  – Dr C

Information gathered during investigation

Background
Ms A, age 42, lives in a town and regularly consults Dr C, an ophthalmologist, about her ocular sarcoidosis (chronic inflammation of the eye). On 25 March 2004, Dr C started Ms A on prednisone to prevent development of cystoid macular oedema (inflammation of the retina). However, he did not intend to prescribe Ms A prednisone on a long-term basis. He prescribed 30mg of prednisone to be taken on a daily basis for the first two weeks, followed by a reduced dosage of 20mg daily for the next two weeks. Ms A had previously received steroid injections for her eye inflammation, but had found that these were no longer effective.

On 25 March, Ms A presented the prescription for prednisone to a pharmacy in the town. Mr B was the only pharmacist on duty at that time. As prednisone tablets come in 1mg, 5mg and 20mg strengths, the prescription required Mr B to dispense a total of 140 prednisone 5mg tablets so that Ms A could take six tablets daily for the first two weeks, followed by four tablets daily for the remaining two weeks. The correct number of tablets was dispensed, but, whilst dispensing the prednisone, Mr B mistakenly selected the 20mg tablets instead of the 5mg tablets.

Side effects experienced

After returning from the pharmacy at approximately 11am, Ms A mistakenly took six prednisone 20mg tablets thinking that she was consuming a total of 30mg prednisone per Dr C's prescription. Ms A informed me that that evening, within 10 hours of starting her medication, her eyesight became "miraculously clear" and she began experiencing feelings of euphoria. Ms A continued taking six prednisone 20mg tablets daily between 26–29 March 2004, during which she experienced severe side effects, including indigestion, tight knees, paranoia, depression, irritability, buzzing teeth, increased blood pressure, fatigue, hallucination and insomnia. Ms A informed me that initially, she did not give too much thought to the side effects she was experiencing as Dr C had alerted her to the likelihood of experiencing some side effects such as dyspepsia (indigestion), slight feelings of euphoria, fluid retention and weight gain. However, after five days, Ms A stopped taking the prednisone as she felt that her side effects were considerably more severe than Dr C had advised.

On 30 March 2004, Ms A informed Dr C of the severe side effects she had been experiencing since starting the medication, and enquired about the possibility of reducing the prednisone dosage to four tablets from 1 April 2004. Dr C was agreeable to her suggestion to reduce her intake of prednisone. As he was under the impression that Ms A had been taking 30mg of prednisone daily between 25–29 March 2004, he recommended that she reduce the dosage to 5mg (one tablet) daily. Dr C also commented that it was odd for Ms A to be reacting so adversely to the prednisone as he had prescribed what he considered to be a relatively low dosage.

From 1 April 2004, Ms A reduced her prednisone dosage to one tablet each morning, mistakenly thinking that she was consuming 5mg of prednisone daily, while in fact she was consuming 20mg. Subsequently, Ms A had follow-up appointments with Dr C on 7 April and 11 May 2004, when she obtained further prescriptions of prednisone. The prescription of 11 May stated that Ms A was to take prednisone in a gradually reducing dosage every fortnight, starting with 4mg daily for the first two weeks and finishing with 1mg daily in the seventh and eighth week.

On 13 May 2004, Ms A obtained a further prescription of prednisone from the pharmacy but did not take her medication until approximately 2pm that day. After taking 4mg of prednisone (four 1mg tablets), Ms A noticed that her vision was distorted while working on the computer. According to Ms A, "everything was fuzzy" except for straight lines on a page. When Ms A resumed her previous dosage of one prednisone tablet (20mg) on 14 May, she noticed that her vision became clear again. Thinking that she had been alternating

between 5mg and 4mg doses of prednisone, Ms A informed Dr C of her reactions, and queried how a 1mg dose could make such a significant difference. She also reported to Dr C a similar incident in the previous week, when she had doubled her consumption of prednisone after forgetting to take it the previous day, and had experienced a change from distorted to clear vision.

On 17 May, Ms A reduced her prednisone dosage to 4mg, and reported to Dr C that she was experiencing mild visual distortion in her right eye. Ms A continued taking prednisone at the reduced dose of 4mg for several days, and informed Dr C on 20 May that her vision had become clearer in both eyes.

After reducing her prednisone dosage to 3mg on 31 May 2004, Ms A experienced distorted vision in her right eye. She struggled to read what was on the computer, and could not identify the number plate of the car in front while driving. In contrast to 13 May (when she had also experienced visual distortion), Ms A reported to Dr C that her vision had worsened, citing for example that straight lines now appeared "dented", she was unable to read the digits on the wall clock, and she could not distinguish between the clock and the wall it hung on. Ms A asked Dr C about the feasibility of increasing her prednisone dosage to 10mg daily. As he was agreeable, Ms A took two prednisone tablets daily between 1–13 June, thinking that she was consuming 10mg when in fact she was consuming a total of 40mg (two 20mg tablets).

Confirmation of the dispensing error

On 14 June, Ms A reduced her prednisone consumption to what she thought was 9mg when she had in fact consumed 24mg (one 20mg tablet and four 1mg tablets). While talking to her mother in mid-June, Ms A discovered that her mother was also taking prednisone, and that the medication dispensed to her mother looked exactly like hers. When Ms A informed her mother of this, her mother enquired whether she had also been prescribed prednisone 20mg. Since Ms A was aware that she had lowered the dosage she was consuming following her discussions with Dr C, her mother's question, coupled with the severe side effects she had been experiencing, alerted her to the possibility that the wrong prednisone dosage had been dispensed.

To allay her suspicion, Ms A advised me that she subsequently viewed her own prednisone tablets under a magnifying glass and saw inscribed on the tablets "20mg" instead of "5mg." On 16 June Ms A informed Dr C of the dispensing error and sought his advice on the prednisone dosage she should take for the next 2½ months. In addition, she took the bottle of prednisone tablets that were dispensed on 25 March to another pharmacy, and the pharmacist verified that it contained prednisone 20mg tablets despite the label stating the dosage as 5mg. Ms A then reported the dispensing error to the Pharmaceutical Society of New Zealand.

Mr B advised me that he first became aware of the dispensing error on 17 June 2004, when he received a copy of Ms A's complaint to the Pharmaceutical Society of New Zealand. Mr B explained that the error occurred when he selected the wrong prednisone dosage from the cabinet shelf, as both white plastic containers of prednisone 5mg and 20mg were stored

beside each other. Since both prednisone containers were essentially the same, they were distinguished exteriorly by their individual coloured bands, with prednisone 5mg having a purple band and prednisone 20mg an orange band. In addition, the tablets differed in colour depending on the dosage, with prednisone 5mg being white and prednisone 20mg pink. The dosages of 5mg and 20mg were also inscribed on the respective tablets. Notwithstanding the similarities between both the 5mg and 20mg prednisone containers, Mr B explained that it was more systematic for a pharmacy to store all its medicines within the same group in close proximity on the cabinet shelves.

Mr B informed me that Ms A's prednisone tablets were dispensed into a brown plastic bottle on 25 March, and that the colour of the bottle clouded the colour of the prednisone tablets once they were inside the bottle. Mr B also informed me that being the only pharmacist on duty at the time Ms A presented her prescription, it was likely that he could have been interrupted by phone calls and other customers walking into the pharmacy. Nevertheless, Mr B has acknowledged that he was solely responsible for the dispensing error made.

Mr B advised me that a final check of Ms A's prescription was conducted before handing the medication to her. The final check entailed ensuring that the medication dispensed corresponded with the medication stated on the prescription. Despite carrying out the final check, Mr B admitted that he failed to notice that the brown bottle contained a higher strength of prednisone, since the label printed corresponded with the dosage stated on Dr C's prescription.

Subsequent events

On the day he was notified of the dispensing error, Mr B sent a written apology to Ms A. I have been advised by Ms A that she is satisfied with Mr B's apology and his explanation of the dispensing error made. Mr B also contacted Dr C to apologise to him for the error.

Mr B advised me that he has now instigated an additional checking measure in his dispensing procedures. The check involves leaving the container from which the medication was dispensed on the dispensing bench until the customer has collected his/her medication. At the point of collection, the pharmacist on duty will carry out a further check to ensure that the medication being dispensed corresponds with both the prescription and the medication in the container that has been left on the dispensing bench. Mr B informed me that the container is only returned to the storage shelf after the customer has collected his/her medication. Prior to the dispensing error, the container was returned to the storage shelf as soon as the required amount of medication had been dispensed. In his apology letter to Ms A, Mr B also informed her of the additional checking measure he has since implemented to prevent future dispensing errors. I have been advised by Ms A that she is satisfied with the measures taken in this respect by Mr B.

Dispensary Operating Procedures

The pharmacy had a dispensary operating procedure in place when the dispensing error occurred. Mr B reviews the procedure annually, and a review took place on 30 August 2003. The pharmacy's Dispensary Operating Procedures as reviewed on 30 August 2003 are set out below. In addition, Mr B advised me that the Pharmaceutical Society of New Zealand conducted an audit at the pharmacy on 1 May 2003, and certified that the pharmacy's services were compliant with the Quality Standards for Pharmacy in New Zealand.

"6.2 DISPENSING – [A PHARMACY]

> The Pharmacist in charge of the dispensing operations of [a pharmacy] maintains a methodical and disciplined approach to procedures which ensure the accuracy of all dispensing operations, whether by him/herself or the Dispensary Technincian under supervision.

DATE OR [sic] WRITING: 16th FEBRUARY, 2000

WRITTEN BY: [MR B]

PERSON RESPONSIBLE: Pharmacist on duty

SIGNATURE OF AUTHOR

REVIEW DATE: 30 August 03

All dispensary operations meet the practice advice issued by the PSNZ in the Pharmacy Practice Handbook

When a prescription is received by a staff member from a patient the Pharmacist or Dispensary Technician shall:

* Receive the Rx [prescription] from the staff member or patient.
* Ascertain
  - Verify the legality of all prescription data
  - Check patient details
  - Advise patient of waiting time and stock availability
  - Enter script into computer and generate label

- Select stock – check against prescription
- Dispense as required
- Attach label to container
- Check, initial and prepare for issue to patient
- Hand out prescription to patient at Dispensary after checking address etc to verify the correct patient is receiving the prescription
- Counsel the patient as required at the dispensary so that such counselling is private and accompany patient to point of sale to receive payment when appropriate.

* Rx processed by Pharmacist or Technician and medication history checked to ensure consistency of treatment and any evidence of misuse or non-compliance e.g. not collecting all eligible repeats at the appropriate time.

– hold Rx in collection area if patient is not in pharmacy

* Annotate Rx and put in box with completed scripts

* If Rx cannot be filled completely, patient is advised and informed when balance will be available.

Process Rx as normal and write 'owing' amount on Rx, then file in box for scripts awaiting completion.

Practitioners [sic] Supply Orders"

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.

Other relevant standards

The Pharmaceutical Society of New Zealand Pharmacy Practice Handbook 2003 states:

> "Principle 2: Beneficence 2.6
>
> The pharmacist who is responsible for dispensing of the prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly."
>
> Standard 6 Services: Principle 6.2
>
> "A pharmacist maintains a disciplined dispensing procedure which ensures that the appropriate product is selected and dispensed correctly and efficiently."

The Medicines Act 1981, section 18 states:

> "(2) No person may sell by retail any prescription medicine otherwise other than under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber."

Opinion: Breach – Mr B

Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Ms A had the right to have pharmacy services provided that met professional and ethical standards. The standards that apply in this case are determined by the Pharmaceutical Society of New Zealand (the Society). Standard 6 of the Society's Practice guidelines places a duty on the pharmacist to maintain a disciplined dispensing procedure, and Principle 2.2.6 holds the dispensing pharmacist responsible for ensuring that the appropriate product is selected, and dispensed correctly. These requirements have been incorporated into the pharmacy's dispensary operating procedures.

On 25 March 2004, Mr B was the dispensing pharmacist who received and processed Ms A's prescription. As the prescription stated "prednisone 30mg daily 2 weeks" and "prednisone 20mg daily 2 weeks", Mr B was aware that it required him to dispense 140 tablets of 5mg strength. However, he acknowledged that in the process of dispensing, he had selected the wrong strength of prednisone from the cabinet shelf, as the containers of both 5mg and 20mg prednisone were stored beside each other. I accept that being the only pharmacist on duty at the time Ms A presented her prescription, the circumstances necessitated Mr B's attending to phone calls or to other customers in the midst of dispensing the prednisone medication. As a result, Mr B could have been distracted whilst dispensing. Furthermore, as the containers of both 5mg and 20mg prednisone were

essentially the same in appearance except for their respective coloured bands, the selection error was not immediately apparent. Nevertheless, as the 5mg and 20mg prednisone tablets differ in colour and have the dosage inscribed on each tablet, there were factors present to alert Mr B to the fact that he had selected the wrong dosage before the tablets were dispensed into the brown plastic bottle. As a result of selecting the wrong strength, Ms A consumed prednisone at four times above the dosage prescribed by Dr C, and reacted severely to the medication between 25-29 March 2004.

Mr B made two errors while dispensing Ms A's medication. The first error occurred when he selected prednisone 20mg instead of prednisone 5mg from the cabinet shelf. The second error was made when Mr B checked the label on the brown plastic bottle against Dr C's prescription as part of the final checking procedures but failed to detect the dispensing error.

It is clear that Mr B did not correctly dispense the prednisone from the prescription in accordance with the professional and ethical standards set by the Pharmaceutical Society of New Zealand, and therefore breached Right 4(2) of the Code.

Opinion: No breach – The Pharmacy

Vicarious liability
In addition to any direct liability for a breach of the Code, employers may be vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for any breach of the Code by an employee. 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 that breached the Code.

Mr B is the managing director of the pharmacy. A year before the dispensing error occurred, the Pharmaceutical Society of New Zealand audited the pharmacy and certified that its services were compliant with the Quality Standards for Pharmacy in New Zealand. I am aware that Mr B reviews his dispensing procedures annually, and that a review took place on 30 August 2003. Furthermore, on learning about the dispensing error, Mr B instigated an additional check in his dispensing procedures. I have reviewed the pharmacy's dispensary operating procedures that were in place at the time of the dispensing error, and I am satisfied that the pharmacy's procedures comply with the standards set by the Pharmaceutical Society of New Zealand. I am satisfied that the dispensing error in this case resulted from a selection error by Mr B, and was not a systems failure. Accordingly, in my opinion, the pharmacy is not vicariously liable for Mr B's breach of Right 4(2) of the Code.

Actions taken

Mr B apologised in writing to Ms A within the same day of learning about his dispensing error. He also contacted Dr C to explain the error made and to apologise to him. I commend Mr B on his prompt and unreserved admission of responsibility.

Mr B has instigated a further check into his dispensing procedure and reviews the pharmacy's dispensing procedures annually.

Follow-up actions

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

Non-referral to Director of Proceedings

When a pharmacist breaches the Code of Health and Disability Services Consumers' Rights by making a dispensing error, a referral to the Director of Proceedings may be indicated.

In light of the circumstances, and taking into account Ms A's express advice that she simply wanted the wrong dispensing to be investigated, and that she is satisfied with the actions taken by Mr B following discovery of the error, I have decided not to refer this matter to the Director of Proceedings for consideration of disciplinary proceedings.

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