Pharmacist, Mr B

A Pharmacy Company

A Report by the

Health and Disability Commissioner

(Case 04HDC11354)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Mr B	Provider/Pharmacist
Dr C	General Practitioner
Ms D	Dispensing pharmacist
Ms E	Dispensing technician
A Pharmacy	Provider/Pharmacy
A Pharmacy Company	Employer

Complaint

On 2 July 2004, the Commissioner received a complaint from Mrs A about a pharmacy. The following issues were identified for investigation:

Whether the pharmacy provided services of an appropriate standard to Mrs A. In particular:

- *There was a shortage of Betaloc tablets dispensed to Mrs A in November 2003 (47.5mg per day instead of 95mg)*
- *Another medication instead of Duride 60mg was dispensed to Mrs A on 25 June 2004.*

The investigation commenced on 21 September 2004.

Information reviewed

- Mrs A's letter of complaint dated 29 June 2004
- The pharmacy's Standard Operating Procedures for dispensing medication
- The pharmacy's dosepack charts for Mrs A
- Prescriptions written by Dr C
- Information provided by:
  - Mrs A
  - Mr B

Information gathered during investigation

Background
Mrs A lives in a town and has been dealing with her local pharmacy for approximately 17 years. The pharmacy was previously owned and operated by another pharmacist before Mr B became its manager and charge pharmacist. In addition to these roles, Mr B became the sole director and shareholder of the pharmacy company (which owns the pharmacy) from mid September 2004.

Heart attack in October 2003
In October 2003, Mrs A suffered a heart attack and was admitted to a public hospital for treatment. Following her discharge, Mrs A consulted her general practitioner Dr C, for advice on managing her heart condition. She was prescribed several medications including Betaloc (for controlling her high blood pressure), and Duride (for preventing angina).

At first, Mrs A was prescribed 47.5mg of Betaloc daily, but the dose was subsequently increased to 95mg daily. To assist her in managing her medication, the Betaloc and Duride tablets were initially dispensed in blister packs, but were later dispensed in bottles.

Dispensing error in November 2003
On 11 November 2003, Mrs A collected a repeat prescription of Betaloc, and noticed that she was short of one Betaloc tablet per day (47.5mg instead of 95mg per day). The error has been acknowledged by Mr B, then the charge pharmacist and manager of the pharmacy, although he himself did not dispense the Betaloc. The dispensing pharmacist on duty was Ms D, and the dispensing technician was Ms E. Both Ms D and Ms E were no longer employed at the pharmacy when the investigation commenced. Mr B recalled:

> "While I was the charge pharmacist at the time of this event the standard operating procedure provided for the pharmacist doing the final check of any blister packed medicine to assume responsibility for the accuracy of that pack."

Mr B explained that dispensing medication into blister packs involves a "completely different dispensing style from non-blister packed medications". The name of the prescribed medication is first entered into the computer system which is programmed to generate repeat copies of prescriptions, and to print the medication name on the foil backing of the blister pack. After selecting the required medication from the dispensary storage shelves, the medication is packed by the pharmacist/pharmacy technician into blister packs.

As there are more steps involved in dispensing medication into blister packs, the pharmacy has designated a separate area in the dispensary to minimise interruptions to staff. This practice was in place in November 2003.

Due to the passing of time and as Mr B himself did not dispense the Betaloc, he cannot recall in detail the incident of 11 November 2003. He is also unable to recall if he was on

duty in the pharmacy that day. Nevertheless, he investigated Mrs A's complaint and concluded:

> "The dispensing pharmacist seems to have followed the pharmacy dispensing procedure except for the final check which failed to recognise that only one Betaloc CR 47.5mg was in each blister pack and not two 47.5mg tables to provide the daily dose of 95mg prescribed."

Mr B explained that there was an acute nationwide shortage of Betaloc 95mg tablets in October-November 2003 due to the pharmaceutical manufacturer reducing its supply worldwide. To supplement the shortage, it was common for pharmacies in the same locality to borrow medication from one another. As Mrs A's dosepack chart of 11 November 2003 contained a line stating "Betaloc 47.5 (unichem)", Mr B surmised that the dispensing pharmacist had only dispensed half of Mrs A's daily prescribed dose (47.5mg instead of 95mg per day) under the mistaken assumption that she had obtained the other half of her Betaloc prescription from another pharmacy in close vicinity.

Dosepack chart

The pharmacy's computer system is programmed to generate a dosepack chart for each customer they dispense medication to. In addition to the patient's details and the prescribing doctor's name, the dosepack chart lists all prescribed medications dispensed on a particular date, along with their respective instructions and a brief description of each medication's dose, use and features. Mr B explained that the dosepack chart enables the pharmacy to retain a record of all the medication dispensed to date, since original prescriptions older than five months are routinely forwarded to Health Benefits for checking and payment of subsidies.

Dispensing error in June 2004

Mrs A also complained about another dispensing error when she presented a repeat prescription of Duride 60mg tablets to the pharmacy on 25 June 2004. Both the trainee pharmacy technician and Mr B were involved in dispensing her medication that day, with Mr B as the only pharmacist on duty. Mrs A recalled that by then, the Duride was no longer being dispensed in a blister pack but in a bottle. However, Mr B differed in his recollection, and informed me that he was still dispensing Mrs A's medication in a blister pack.

When Mrs A opened the packaged medication at home, she discovered that the tablets were round, small and white, which differed from the oval, medium sized and dull yellow coloured Duride 60mg tablets she was familiar with. She suspected that the wrong medication had been dispensed and contacted Mr B immediately. Based on the information she relayed, Mr B concluded that the wrong medication had been dispensed and acknowledged the error during the telephone discussion.

On 29 June 2004, Mrs A returned the wrongly dispensed medication to the pharmacy. Mr B noted that Coronex (another prescription medication for treating angina) had been dispensed instead of Duride. He also noted that as Mrs A had not consumed any of the

Coronex tablets, she was not at risk of any adverse effects. Mr B corrected the error by dispensing the prescribed Duride 60mg tablets.

Mr B explained that both Duride and Coronex are isosorbides (drugs prescribed to treat angina by relaxing the smooth muscle of the arteries and veins). Although Mr B had keyed "Duride 60mg" into the pharmacy's computer system based on Dr C's prescription, Duride's generic name, *isosorbide mononitrate* was printed on the foil backing of the blister pack. The error occurred because Coronex has a similar generic name of *isosorbide dinitrate,* and the confusion between both names resulted in Mr B selecting the wrong medication from the storage shelves. As all prescribed medications in the dispensary were stored alphabetically by their brand name rather than their generic name, Coronex and Duride were not stored in close proximity to each other. Hence, despite the respective positions where they were stored and the apparent physical differences between Duride and Coronex, Mr B explained that he was unaware that he had selected the wrong medication when he placed the Coronex tablets into the blister pack. Furthermore, as the generic name on the foil backing appeared to match the brand name stated on Dr C's prescription, Mr B did not detect the dispensing error during the final check he conducted as part of the pharmacy's dispensing procedures. Mr B stated:

> "I followed the pharmacy's dispensing procedure except that my final checking failed to disclose that the wrong brand of isosorbide had been included in the blister pack."

Incorrect labels

Mrs A also complained of one occasion where the pharmacy staff mixed up the labels on her and husband's medication. She stated:

> "I also recall an incident when there was a mix up with my husband's tablets. Recently upon picking up prescriptions for both my husband and myself I noticed that my name was on his tablets and vice versa, upon pointing this out to them, it was corrected.
>
> What really worries me is the amount of people who trust that their medication is being dispensed correctly and never check before taking it, especially the elderly."

Mr B informed me that he had no recollection of this incident, and that the pharmacy did not have any incident reports about the mix-up. In the pharmacy dispensing records Mr B provided, the only common dates when medication was dispensed to both Mr and Mrs A were 20 January and 29 June 2004. Mrs A considered that the mix-up may have occurred on 20 January 2004, but was unable to provide any further information. Accordingly, this aspect of Mrs A's complaint was not further investigated.

Preventative measures taken

Since being informed of the dispensing errors, Mr B informed me that he has implemented several measures to prevent future dispensing errors. Dispensing staff are now required to check that the features and markings of the medication they select from the storage shelves

are consistent with the description of the medication stated on the Toniq[1] Dispensing Chart. Along with ensuring that the medication name printed on the dispensing label matches that stated on the prescription, Mr B has introduced additional checks into the dispensing procedure. This involves the pharmacist checking that the medication name stated on the blister pack foil backing is consistent with the medication stated on the prescription. Mr B has highlighted the generic name of each drug, and attached a cautionary note for the dispensing pharmacist to check that the correct medication is being dispensed. Where possible, he ensures that a minimum of two staff are involved in the dispensing, to facilitate double checking and team support. However, this can at times be difficult since the pharmacy employs three dispensary staff, of whom Mr B is the only registered pharmacist. Other measures adopted to enhance accuracy in dispensing have included issuing periodic reminders to staff not to dispense in haste, and to follow all steps listed in the dispensing procedures.

Mr B informed me that Mrs A's complaint has provided a valuable learning experience for him and his pharmacy technicians, as it highlights the importance of high accuracy when dispensing. This is imperative given that the pharmacy provides a large dispensary service for private patients and several rest homes in the area.

Review of dispensing procedures

Mr B's responsibilities as a charge pharmacist include reviewing the pharmacy's dispensing procedures annually. The procedures were reviewed by Mr B on 10 September 2003 before the dispensing errors occurred on 11 November 2003 and 25 June 2004. In addition, he provided a copy of the Quality Audit (Medsafe audit) carried out by the Pharmaceutical Society of New Zealand on 11 September 2001 which certified that the pharmacy's services were compliant with the Quality Standards for Pharmacy in New Zealand. Mr B informed me that since then, the pharmacy has not had a further quality audit.

Apology

Mrs A informed me that she was not happy with Mr B's manner when she returned to the pharmacy on 29 June 2004. She believed that he should have extended an apology then. However, Mr B explained that Mrs A appeared upset, and requested for all her and her husband's medication records as she intended to obtain all future prescribed medications from another pharmacy. Given the circumstances, Mr B considered that there was no opportunity to apologise.

Subsequently, on 23 October 2004, Mr B sent a written apology to Mrs A. In his letter, Mr B acknowledged the inconvenience caused to Mrs A, and accepted full responsibility for both dispensing errors. Mrs A has advised that she is satisfied with Mr B's letter of apology.

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[1] Toniq is a Christchurch based company that writes and supplies pharmacy software products to approximately two-thirds of pharmacies in New Zealand.

Standing Operating Procedure

The pharmacy had a standard operating procedure in place when the dispensing errors occurred. The procedures are reviewed annually, and a review took place on 11 September 2003, two months before the first dispensing error. Mr B supplied a copy of the standard operating procedure at the time, which stated:

"Dispensing

Subject: Dispensing a Prescription

1. **Purpose:** To ensure all prescriptions are dispensed in an orderly and correct manner.

2. **Responsibility of:** Pharmacist, Pharmacy Technician

3. **Procedure:**
   - Receive prescription
   - Check all customer details are correct
   - Check all prescription details are correct
   - Stamp prescription with date stamp and dispensed/checked stamp
   - Annotate prescription with patient code, supply quantity, special authorities, specialist recommendation if necessary
   - Enter details in computer
   - Check for interactions/adverse reactions
   - Produce label
   - Dispense the correct quantity of medicine
   - Attach correct label and any cautionary advisory labels
   - Pharmacist to make final check against prescription

NOTE: 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.

Created by: [Mr B] Date: 10/09/03

Approved by: [Mr B] Date: 11/09/03

Review date: 10/09/04."

Policy

Mr B also supplied a copy of the pharmacy's dispensing policy at the time, which stated:

> **"Dispensing**
>
> Policy No. 1 Issue Date: 15/08/01
>
> **Aim:** The pharmacy aims for 100% accuracy when dispensing prescriptions
>
> **Intent:** Only appropriately trained staff (Pharmacists, Pharmacy Technicians) will be involved in dispensing prescriptions.
> Prescriptions will be dispensed in an orderly fashion.
> A Pharmacist will be responsible for the final check of every prescription.
>
> Pharmacist or Manager Signature:
>
> Review Date: 15/08/02."

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's Code of Ethics (2001), 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 the suitability of the patient within the limitations of available information, and dispense it correctly."

The Quality Standards for Pharmacy in New Zealand Standard 6.2 states:

> "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 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), Mrs A had the right to pharmacy services that met professional and ethical standards. The standards that apply in this case are determined by the Pharmaceutical Society of New Zealand (the Society).[2] Standard 6 of the Society's Quality Standards places a duty on the pharmacist to maintain a disciplined dispensing procedure, and Principle 2.2.6 of the Code of Ethics 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 dispensing procedures.

When Mrs A collected a repeat prescription for Betaloc on 11 November 2003, Ms D was the dispensing pharmacist and was assisted by a dispensing technician, Ms E. I accept that as Mr B himself did not dispense the Betaloc, he cannot recall the incident in detail. I have noted his explanation that there was a nationwide shortage of Betaloc in October-November 2003. I also accept that while Mr B has investigated the circumstances resulting in the dispensing error, he could not be definitive about what occurred, since Ms D and Ms E were no longer employed by the pharmacy when the investigation commenced. Mr B can only surmise that it was likely Ms D dispensed half of the prescribed amount of Betaloc under the mistaken assumption that Mrs A had obtained the other half of what she required from another pharmacy. Nevertheless, as Mr B was the manager and charge pharmacist of the pharmacy at the time of the incident, he was ultimately responsible for ensuring that the prescribed Betaloc was dispensed correctly to Mrs A.

A further dispensing error occurred on 25 June 2004 when Coronex was dispensed instead of Duride 60mg. Mr B has acknowledged that he made a "human error" in selecting the wrong medication for angina. I accept his explanation that he had entered the correct

[2] The Society ceased to exist on 18 September 2004. As the dispensing errors occurred before 18 September 2004, the standards prescribed by the Society are applicable.

brand name "Duride" into his computer system, since its corresponding generic name, *isosorbide mononitrate*, was printed on the foil backing of the blister pack. However, the similarity in generic names between *isosorbide mononitrate* and *isosorbide dinitrate* resulted in Mr B confusing Duride for Coronex. Hence despite their apparent physical differences, Mr B did not detect the dispensing error when he conducted a final check as part of the pharmacy's dispensing procedures.

Both dispensing errors of 11 November 2003 and 25 June 2004 constituted a breach of section 18(2) of the Medicines Act 1981, in that Mr B supplied medicine otherwise than pursuant to a prescription given by a medical practitioner.[3]

It is clear that Mrs A received only half of her prescribed amount of Betaloc, and that Mr B did not correctly dispense the Duride as prescribed, in accordance with professional and ethical standards set by the Society. In these circumstances, Mr B breached Right 4(2) of the Code.

Opinion: No breach – The Pharmacy Company

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's breach of the Code.

At the time both dispensing errors occurred, Mr B was the charge pharmacist and manager of the pharmacy, but held no interest in the owning company. When the investigation commenced on 21 September 2004, he was also the sole director and shareholder of the pharmacy company, in addition to being the charge pharmacist. On learning of the dispensing errors, Mr B investigated the circumstances to ascertain the cause of the errors and instigated additional checks as part of the pharmacy's dispensing procedures. I am aware that Mr B reviews the pharmacy's dispensing procedures annually, and that a review took place on 10 September 2003. Prior to the dispensing errors occurring, the Pharmaceutical Society of New Zealand had audited and certified on 11 September 2001 that the pharmacy's services were compliant with the Quality Standards for Pharmacy in New Zealand.

I have reviewed the dispensing operating procedures in place at the time both dispensing errors occurred, and am satisfied that the pharmacy's standards comply with those set by

[3] See *Re PR* (Decision of the Disciplinary Committee of the Pharmaceutical Society of New Zealand, 8 May 2002).

the Pharmaceutical Society of New Zealand. I accept that it was likely the first dispensing error resulted from a mistaken assumption that half of the required amount of Betaloc had been dispensed by another pharmacy, and that the second error resulted from a human error by Mr B. Both incidents were not due to a systems failure. Accordingly, in my opinion, the pharmacy company is not vicariously liable for Mr B's breach of Right 4(2) of the Code.

Non-referral to Director of Proceedings

Mr B has apologised in writing to Mrs A. I commend Mr B on his prompt and unreserved admission of responsibility.

Mr B has reviewed his practice and the pharmacy's dispensing policies following both dispensing errors.

In light of these circumstances, and taking into account Mrs A's express advice that she simply wanted the circumstances of the dispensing errors to be investigated to prevent future recurrences, and that she is satisfied with Mr B's apology, I have decided that there is no public interest in further proceedings, and have not referred this matter to the Director of Proceedings.

Follow-up actions

- A copy of this report will be sent to the Pharmacy Council 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.