Pharmacist, Mr B

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 03HDC13660)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A (dec)	Consumer
Mr B	Provider / Pharmacist
Dr C	General Practitioner
Mrs D	Consumer's daughter

Complaint

On 10 September 2003 the Commissioner received a complaint from the late Mr A's daughter about services provided to him by Mr B at Mr B's pharmacy. The issue arising from the complaint that the Commissioner investigated is as follows:

- *The circumstances surrounding Mr B's dispensing of Mr A's warfarin at the pharmacy on 26 August 2003.*

An investigation was commenced on 15 October 2003.

Information reviewed

- Medical records from Dr C and the regional hospital
- Response from Mr B
- Response from the pharmacy
- Mr A's prescription for warfarin and blister pack of medications

Information gathered during investigation

Mr A was an 81-year-old gentleman admitted to a regional hospital on 19 July 2003 with right lower lobe pneumonia. Mr A had a number of other medical problems, including ischaemic heart disease, congestive cardiac failure and atrial fibrillation (irregular heart rate), which were controlled by medication. Mr A was discharged on 26 August with prescriptions for the following:

"Atonastatin 20mg nocte (at night)
famotidine 20mg nocte
warfarin 3mg
Atrovent 500mcg neb QID (nebules four times daily)
salbutamol 1.25mg neb TID (three times daily)

Diltiazem LA 180mg mane (morning)
frusemide 40mg mane
bromhexine 8mg TID
carvedilol 12.5mg BD (twice daily)
losartan 12.5mg mane
prednisone 24mg mane"

Mr A was discharged into the care of his daughter, Mrs D. On the way home from the hospital, Mr A and Mrs D took the prescriptions for his medication to the pharmacy for dispensing. Mr B was the pharmacist on duty. The medication was dispensed in "blister packs" (all medication to be taken at a particular time is dispensed into individual compartments).

Mrs D advised me that on 27 August 2003, before her father took his morning medications, he noticed his medication had changed. Instead of one warfarin tablet he had three 3mg tablets (totalling 9mg) to take. Mr A commented that he had never had more than 5mg warfarin before. Mrs D said that if the warfarin had been prescribed by Dr C, she would simply have telephoned him to check the dosage, but it has been her experience that ringing the hospital was "absolutely hopeless" because she was never able to locate the doctor who wrote the original prescription. Mrs D advised her father that the doctor must know what he is doing and Mr A took the medication.

Mr A continued to take 9mg warfarin daily until Mrs D noted that scratches on his feet were bleeding, and he was bleeding from other skin areas. Mrs D telephoned Dr C on Monday 1 September, six days after leaving hospital.

Dr C had been Mr A's general practitioner for many years. The hospital sent the discharge summary to Dr C, who was to see Mr A the week after he left hospital. Dr C advised me that, before Mr A went into hospital, he had been taking warfarin for a number of months and been stabilised on 3mg or 5mg warfarin a day, depending on the INR (a blood test to determine the clotting time). The discharge summary indicated that Mr A was to have 3mg warfarin a day until Dr C saw him the following week.

Dr C saw Mr A on Monday 1 September. Mr A said that he was on 9mg of warfarin a day. Dr C telephoned the hospital to check the dose and, on learning that the discharge dose was 3mg a day, Dr C discontinued the warfarin and ordered an INR test. The INR was greater than 10 (usual therapeutic range 2.0-3.0), and Dr C arranged Mr A's admission to hospital. Mr A was admitted on 2 September and treated with intravenous vitamin K to reverse the anti-clotting effect. On admission his notes record "INR 22 on admission! ?over warfarinised". Mr A began coughing up blood-stained sputum, "secondary to pulm haemorrhage" (bleeding into the lungs) on 4 September. By 5 September his INR was 2.4.

Dispensing error

Mrs D returned to the pharmacy, where she spoke to Mr B. Mr B confirmed that he was the dispensing pharmacist and, on checking his computer, realised how he had incorrectly dispensed Mr A's warfarin. Mr B explained the error in the following manner:

> "I was the dispensing pharmacist and accept I made an error in dispensing [Mr A's] prescriptions on 26th August 2003. He should have received one 3mg warfarin tablet instead of three.
>
> [Mr A] came in with his daughter. They presented the prescriptions and also carvedilol and losarten tablets supplied by the hospital, to be put into foil packs. I checked the prescription against his previous medication and checked that all was OK. I noted that he previously was on 3mg and 1mg of Warfarin.
>
> The error occurred when I was entering the prescription details into the computer. The figure three must have been in my brain and I entered the incorrect data. I dispensed from the foil and must have missed the error when checking against the prescription. The foil was prepared in between doing other prescriptions, but as I recall I did not put myself under pressure and my mind was not on other things. In fact as I recall I was giving full attention and diligence. I do not feel that the error was due to a fault in our procedure but unfortunately a human error on my part. It was not a case of flippant disregard or rushing but an unexplained blind spot.
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> …
>
> I was made aware of the error about a week later when … his daughter [Mrs D] came into the pharmacy. … [Mrs D] questioned what was actually written on the prescription. It was then I realised the error and admitted that it was my fault. I was quite stunned by the revelation and remember noting that I seemed more upset than she. I was probably in a state of shock as I can't recall actually discussing complaint procedures."

Mr B immediately apologised for the error and telephoned Mrs D on a number of occasions to see how her father was. He also provided a written apology and a sympathy card on the death of her father.

Subsequent events

In the days following Mr A's admission to hospital his clotting factors returned to normal. However, his previous medical problems resurfaced, in particular the pneumonia. Mr A's pneumonia and heart failure did not respond to treatment, and he developed MRSA (methicillin-resistant *Staphylococcus aureus*). Mr A died on 17 September 2003.

Quality Assurance Policies

The pharmacy had a number of quality assurance policies in place. The policies follow the Pharmacy Practice Handbook 2003 published by the Pharmaceutical Society of New Zealand. The pharmacy's Standard Operating Procedure for dispensing medication is set out below:

"**1. Purpose**

1.1 The pharmacist maintains a disciplined dispensing procedure that ensures that the appropriate produce 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.

…

2.7 Record prescription details

- Key in relevant data into the dispensary computer.
- Select a product which best serves the interest of the patient (ie, 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.

2.8 General label

- Make the language and lettering on the label simple and clear.
- Don't overwrite corrections on the label.
- Keep the label background plain.
- 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.

2.9 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.

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2.11 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.
- 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.

2.12 Check the dispensing procedure

This must be done by a 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 his.
- If the full supply of the medication is unable to be given, follow procedure for medicine owes."

Code of Health and Disability Services Consumers' Rights

The following provision 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 the suitability of 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 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 Mr 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). 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 the appropriate

product is selected and dispensed correctly. These requirements have been imported into the pharmacy's dispensing policies.

On 26 August 2003 Mr B was the dispensing pharmacist who made up the blister packs containing Mr A's medications. The prescription read 3mg warfarin a day. Mr B acknowledged that he noted the prescription for 3mg and that he was not stressed at the time or distracted by other customers. He simply made a human error. The figure three must have "remained in his head" when he entered the information into the computer.

The computer printed 3mg warfarin three tablets daily onto the foil that backs the blister pack. Mr B checked the foil but did not detect the error. He dispensed the medication from the foil into the blister pack, adding three 3mg tablets as indicated on the foil label. As a consequence Mr A took 9mg warfarin daily for six days (a total of 54mg instead of the prescribed dose of 18mg). He suffered bleeding into his skin and lungs.

Mr B made three errors while dispensing Mr A's warfarin. The initial error occurred when he entered the wrong number of warfarin tablets into the computer; he failed to detect the error when he checked the printed computer label against the prescription; and he placed the number of tablets into the blister compartment as indicated on the printed label instead of the number on the original prescription, contrary to the pharmacy's dispensing policy (see para 2.8).

In these circumstances the dispensing error probably 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.[1]

I note that the Society has given two warnings to the profession about the level of dispensing errors involving warfarin, published in *Pharmacy Interactions*, which is sent to all registered pharmacists. The warnings are very clear. The first warning in the June 1999 issue of *Interactions*, under the heading *Warfarin Dispensing Errors*, contained a clear warning to the profession to be vigilant when dispensing warfarin. The second warning in the October 1999 issue of *Interactions*, under the heading *Dispensing Errors Still Cause Concern*, brought the profession's attention to the high number of complaints received by the Health and Disability Commissioner about incorrect dispensing of warfarin. I am concerned that despite these warnings Mr B did not appear to take any special precaution when dispensing warfarin to Mr A.

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

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

Opinion: No breach – The Pharmacy

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

Mr B is a director of the pharmacy. Both Mr B and the other director share in the management and operation of the pharmacy. On learning of this error both took time to review the incident and examine their procedures to determine whether the incident could have been avoided. I have reviewed the standards of practice operating at the pharmacy at the time and am satisfied that the pharmacy's standards 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 human error by Mr B and 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 to Mr A before his death and to Mr A's family in writing, expressing regret and remorse for his actions. I commend Mr B on his prompt and unreserved admission of responsibility.

Mr B has reviewed his practice and the pharmacy's dispensing policies in light of his dispensing error.

In these circumstances, and taking account of the express wishes of Mr A's family that they simply wanted the circumstances of the wrong dispensing to be investigated, I have decided not to refer this matter to the Director of Proceedings for consideration of disciplinary proceedings.

Further 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 sent to the Pharmaceutical Society and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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