A Pharmacy

A Pharmacist

A Report by the

Health and Disability Commissioner

(Case 01/10717)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer
Mr B	Provider – Pharmacist, a pharmacy
Dr C	General Practitioner
Ms D	Pharmacist, a pharmacy
Ms E	Medicines Control Advisor

Independent expert advice was obtained from Ms Rosemary Langham, pharmacist.

Complaint

On 26 September 2001 the Commissioner received a complaint from Mr A about a pharmacy. The complaint is that:

- *On 17 August 2001 a pharmacist at a pharmacy did not provide services of an appropriate standard to Mr A when thye dispensed Accupril (antihypertensive) 5mg tablets instead of Accupril 10mg tablets as prescribed by Mr A' general practitioner.*

- *In late 1999 or early 2000 a pharmacist at the Pharmacy did not provide services of an appropriate standard to Mr A when they dispensed the wrong dosage of atenolol.*

The complaint was initially received by the Pharmaceutical Society of New Zealand and forwarded to the Commissioner.

An investigation was commenced on 19 November 2001.

Information reviewed

- Response from Mr B and computer printout of medicines dispensed to Mr A.

- Letter from Ms E, Medicines Control Advisor, relating to audit of the pharmacy.

- Pharmaceutical Society of New Zealand Code of Ethics and Professional Standards.

Information gathered during investigation

Dispensing error, Accupril
On 21 September 2001 Mr A visited his general practitioner, Dr C, for a regular check-up, as he had been taking antihypertensive medication for several years. Dr C took Mr A's blood pressure and found that it was not adequately controlled by his current dose of antihypertensive medication, Accupril. Dr C proposed increasing the dose from 10mg to 20mg, but was advised by Mr A that he was currently taking only 5mg. Dr C was sure he had prescribed 10mg at Mr A's previous visit on 17 August 2001, so rang Mr B, a pharmacist at a pharmacy, to check. Mr B advised that 10mg had been dispensed. Dr C then gave Mr A a prescription for 20mg, which he had dispensed at the pharmacy.

On his return home Mr A checked the tablets he had been taking and found that the manufacturer's label on the box, the individual foil-wrapped tablets, and the tablets themselves were labelled 5mg. The pharmacy label, however, had "Accupril 10mg" printed on it, along with the dispensing instruction, "Take ONE TABLET daily." Mr A rang Dr C's practice nurse as he was concerned that he had been taking only half the dose prescribed, and was unsure of the dose he should be taking. The practice nurse advised him to return for a further consultation. Mr A then phoned the pharmacy and left a voice mail message asking for someone to telephone him.

In response to the complaint, Mr B stated that Ms D, a part-time pharmacist, received the telephone message on 23 September but did not see Mr B until 26 September 2001, when she passed on the message to him. Mr B rang Mr A and agreed that a prescribing error had been made. Mr B advised that he was the dispensing chemist and that when Mr A had presented him with a prescription for Accupril 10mg, he had produced a dispensing label for Accupril 10mg but picked up a pack of Accupril 5mg. He sincerely apologised to Mr A both verbally and in writing, refunded the prescription costs and offered reimbursement for costs incurred in returning to the doctor.

Mr A provided the package and label in support of the dispensing error.

Dispensing error, atenolol
Mr A stated that he had decided to go ahead with the complaint as the pharmacy had previously made a dispensing error. Although he could not recall the details clearly, Mr A stated that the previous error had involved a repeat prescription. The incident occurred in either 1999 or early 2000 and involved the antihypertensive drug atenolol. Mr A found that the repeat prescription of atenolol dispensed was different from the tablet he had been taking. He complained to Mr B and received a verbal apology. Mr B stated that he was the dispensing chemist on this occasion also but that the event had occurred in 2001 and the earliest record he has of dispensing prescriptions for Mr A is May 2001.

Dr C stated that he was not aware of any adverse effects that Mr A may have suffered as a result of the dispensing errors.

Dispensing of medication
Mr B advised that he accepted full responsibility for the error of dispensing 5mg instead of 10mg of Accupril on 17 August 2001 and the error of dispensing a repeat dose of atenolol that was different from that prescribed and dispensed previously.

Mr B advised that in the case of the error in dispensing Accupril he "produced a label for Accupril 10mg but picked a pack of Accupril 5mg, [and] this was given to Mr A". Additionally, both Accupril and atenolol have been included in Pharmac's "sole supply" system. "Sole supply" means that Pharmac fund a particular brand of a drug in a particular strength or form. This system has been introduced over the last few years, along with other changes in the dispensing process initiated by the Ministry of Health. Mr B stated that unfamiliarity with different packs and medicines may have contributed to the error. Additionally, Mr B stated that he works for much of the time as a sole pharmacist, is subject to frequent interruption and has recently endured a threat to kill him, attempted break-ins and intimidation from homebake manufacturers.

Policy and procedures
The Ministry of Health's Medsafe section advised me that the pharmacy underwent a Pharmacy Quality Audit, which includes audit of the dispensing process, on 26 January 2000. As a result of the audit the dispensing and checking standard operating procedure was amended and subsequently found to meet audit requirements.

Mr B provided a copy of the pharmacy Standard Operation Procedure for Dispensing and Checking, issued on 1 May 2000 and in force at the time of the errors in dispensing Mr A's medication. A copy of this document is included in the "Relevant standards" section of the opinion.

Mr B stated that since the dispensing error the pharmacy has changed its procedure. The new Dispensing and Checking Procedure issued on 7 December 2001 includes a further checking step as follows:

> "If only one pharmacist is on duty the work is set aside and then re-visited a short time later for a re-check by that Pharmacist. Counselling to take place (if required) left back of Pharmacy."

Additionally, the revised procedure includes the requirement that staff be instructed to minimise interruptions and distractions to pharmacists while they are dispensing.

Response to provisional opinion
I received responses from both Mr B and his lawyers, noting that Mr B is a pharmacist with 30 years' experience and that the "errors occurred in an environment and at a time when Mr B was experiencing a high level of stress at work". Mr B's lawyers submitted that he has taken "full responsibility" and "action steps to address his errors".

Independent advice to Commissioner

Independent expert advice was obtained from Ms Rosemary Langham, pharmacist.

"As requested I have reviewed the following documents

A	Letter of complaint from [Mr A] to Pharmaceutical Society 23/9/01
B	Letter from [Mr B] MPS to Health and Disability Commissioner 12/12/01 Letter from [Mr B] MPD to [Mr A] 28/11/01 Phone call from [Ms F] (investigation officer) to [Mr B] 12/12/01
B1	Copy of prescription and prescription details report
C	SOP for dispensing and checking 7/12/01
D	Revised SOP for dispensing and checking 7/12/01
E	Photocopy of incorrectly dispensed Accupril box (both sides)
F	Letter from [Mr A] to Pharmaceutical Society 28/9/01 Phone call from [Ms F] (investigation officer) to Mr A 15/11/01 Letter from [Mr A] to Health and Disability Commissioner 4/12/01

In response to your specific requests

- **Do you consider the revised SOP dated 7/12/01 is sufficient to ensure safe dispensing and checking**

The extra check that has been inserted in the SOP should ensure that dispensing errors like this one do not occur again. In the original and revised SOP in the second paragraph 'Pharmacist check prescription' should have ensured that the error didn't occur in the first instance.

However I feel there may be some benefit in also including in the SOP a more detailed process for dispensing so that each step, and the checking processes involved in each step, are clearly identified no matter who is doing the actual dispensing as opposed to final checking.

Eg Select medicine-check medicine strength and quantity against prescription
Attach label-check against prescription etc.

- **Other Issues**

Unfortunately dispensing errors occur in most pharmacies at some time. The fact that [Mr A] has had two errors made in the dispensing of his medication is indeed most unfortunate.

Notwithstanding the fact that errors have occurred, I think [Mr B] has acknowledged his errors and has done his best to rectify the situation."

Relevant standards

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

> "PART 2 CODE OF ETHICS AND PROFESSIONAL STANDARDS
> 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 the following steps:
>
> 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 for label accuracy – name, date, medicine strength and form, instructions, C & A labels and content accuracy – correct medicine, dose, form and quantity …"

The following standard operating procedure for dispensing and checking medications was in place at the pharmacy at the time of the dispensing error involving Mr A:

> **"Standard Operating Procedure**
>
> | | |
> |---|---|
> | Pharmacy Name: | The pharmacy |
> | Subject: | Dispensing and Checking Procedure |
> | Page: | 1 |
> | Document: | A |
> | Issue Date: | 1.5.2000 |
> | Supersedes: | N/A NEW DOCUMENT Old S.O.P. |

Purpose:

To provide guidelines for safe and efficient dispensing and checking procedures that meet the quality standards for Pharmacy in New Zealand (PSNZ 1996).
Procedure:

1. All members of staff receive prescriptions. Details of Name, Addresses Codes, Cards, Chem numbers, etc. checked. Cards sighted. If repeats, determine via questions and stamp details, check stock, inform patient when prescriptions will be ready. If appropriate, requirement for safety cap (See Section 6 Schedule) is discussed and noted.

   Dispensing staff enter details into Dispensing System. Medicine dispensed and labels attached – 3 part. Pharmacist checks Prescriptions initial Prescriptions, Medicines bagged and Med Info sheets attached.

   Prescriptions forms held on bench, prior to being checked and completion of annotation, any comments that need to be made to patient, ie owed medicine information etc. noted by 'See RN', 'See [Ms D]' – on outside of bag and above staff alerted when medicines handed out. Counselling to take place (if required) left back of Pharmacy.

   On handing out prescription, patient asked for their name and address – to confirm correct patient.

   When repeats dispensed, if done by Alex, Alex places 2nd or 3rd part label on pad and annotates script log at later date all other scripts assumed to have been done by Richard.

   Created by: [Mr B] Date: 1.5.2000"

The standard operating procedure for dispensing and checking medications at the pharmacy was amended as follows as a result of the dispensing error involving Mr A:

"… If two or more pharmacists are on duty when the prescription is completed work is checked by the other pharmacist.

If only one pharmacist is on duty the work is set aside and then re-visited a short time later for a re-check by that Pharmacist. Counselling to take place (if required) left back of Pharmacy.

On handing out prescription, patient asked for their name and address – to confirm correct patient.

Staff have been instructed, that where possible, interruptions/distractions to those who are dispensing are minimised – without compromising professional service levels. …"

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 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.

Opinion: Breach – Mr B

Right 4(1)
It is accepted by the parties that instead of dispensing Accupril 10mg tablets, as prescribed by Dr C, Mr B dispensed Accupril 5mg tablets. On an earlier occasion he dispensed an incorrect repeat dose of atenolol.

The importance of the checking process when dispensing prescription medicines cannot be overstated. The Pharmaceutical Society of New Zealand's *Code of Ethics* and *Pharmacy Practice Handbook* emphasise the responsibility of dispensing pharmacists to maintain a disciplined procedure in order to ensure that the "appropriate product is selected and dispensed correctly and efficiently".

It is acknowledged that Mr B stated that he was under pressure at the time of the dispensing error. Further, my independent expert noted that Mr B acknowledged his errors and did his best to rectify the situation. I accept that Mr B did act appropriately in acknowledging his errors, apologising and reimbursing Mr A. However, in *Catchpole* (6 September 2001) the Disciplinary Committee of the Pharmaceutical Society decided that dispensing errors constitute professional misconduct and in such circumstances disciplinary action is warranted.

Mr B failed to take reasonable care and skill when checking and dispensing the prescriptions to Mr A. In my opinion Mr B breached Right 4(1) of the Code.

Opinion: No Breach – The Pharmacy

Vicarious liability
Under section 72(2) of the Health and Disability Commissioner Act 1994, employers are vicariously liable 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 supplied me with a written policy dated 1 May 2000 regarding the dispensing and checking of medication at the pharmacy. This policy complied with the standards of the Pharmaceutical Society of New Zealand. Accordingly, the pharmacy had taken reasonable steps to prevent the medication error that occurred, and is not vicariously liable for Mr B's breaches of the Code.

Action

I recommend that Mr B take the following action:

- Amend the pharmacy Standard Operating Procedures as suggested by my expert advisor.

I note that Mr B has already apologised to Mr A both verbally and in writing.

Further 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 further action should be taken.

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

- A copy of this opinion, with identifying features removed, will be sent to Medsafe, Ministry of Health.

Other comment

I note that in response to my provisional opinion, Mr B made the constructive suggestion that all pharmacy bags containing prescription medicines be stamped with words such as "please check your prescription – if you have any concerns please telephone the pharmacy at …". I endorse this sensible proposal.

Addendum

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