Pharmacist, Mr B

A Pharmacy Company

A Report by the

Health and Disability Commissioner

(Case 04HDC11276)

Parties involved

Mr A	Consumer
Mrs A	Complainant
Mr B	Provider/ Pharmacist
Dr C	Orthopaedic Surgeon
Ms D	Pharmacy Technician
A Pharmacy Company	Employer

Complaint

On 24 June 2004, the Commissioner received a complaint from Mrs A about a pharmacy. The complaint was made on behalf of her husband, Mr A, to the Pharmaceutical Society of New Zealand, which forwarded the matter to this Office. The issue arising that the Commissioner investigated was summarised as follows:

- *Whether the pharmacy provided services of an appropriate standard on 19 June 2004 to Mr A. In particular, Hybloc 100mg was dispensed instead of tramadol 50mg.*

The investigation commenced on 22 September 2004.

Information reviewed

- Mrs A's letter of complaint to the Pharmaceutical Society of New Zealand, dated 22 June 2004.
- The pharmacy's Standard Operating Procedure for dispensing medication.
- Prescription written by Dr C.
- Information provided by:
  - Mrs A
  - Mr B
  - Ms D

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Information gathered during investigation

On Saturday 19 June 2004, Mrs A drove her husband, Mr A, home from a public hospital following a total hip replacement. Dr C, orthopaedic surgeon, had prescribed Mr A with tramadol for pain relief. The prescription, written by hand, was for 30 x 50mg tramadol. On the way home, Mrs A called into the pharmacy to have the medication dispensed.

The dispensing pharmacist on duty was Mr B. Mr B is listed as a director of the pharmacy company, which owns the pharmacy.

When Mrs A presented the prescription to Mr B, she recalled him remarking that the prescribed 50mg dose had not been available for a number of years. As an alternative, he suggested cutting in half 15 x 100mg of the same medication to correspond with Dr C's prescribed dose. Mrs A conveyed her surprise to Mr B that Dr C would prescribe medication in a dose that was no longer available. Nevertheless, she agreed with Mr B's suggestion, and purchased her husband's medication from him. Mrs A noted that the tablets Mr B dispensed differed in appearance from the tramadol capsules her husband had received in the public hospital, but thought that this was a different form of the same medication.

Dispensing
Mr B explained that he had misread Dr C's handwritten prescription, mistaking the word "tramadol" for "Trandate" (see Appendix 1). At the time Mrs A presented her husband's prescription, the pharmacy was especially busy as it was a Saturday. Mr B was the only pharmacist working in the dispensary, and there were other customers waiting for their medications to be dispensed. Mr B commented that he did not know why the medication had been prescribed, and observed that Dr C's writing was quite small. When he suggested contacting Dr C for clarification, Mrs A replied that it was likely he would have left the hospital for the day. Mr B stated:

> "I did not inform [Mrs A] that Tramadol was unavailable as I read the prescription as Trandate and informed her that Trandate was unavailable and tried to locate some stock in order to fill the prescription".

Mr B said that he sent his assistant, who was not technically trained, to the neighbouring pharmacy with a note asking to borrow 30 x 50mg Trandate tablets. As none were available at that pharmacy, Mr B resorted to using his own supply of 100mg Trandate tablets. He cut each of the 15 Trandate tablets in half to enable him to dispense the mediation in the dose prescribed by Dr C. However, Mrs A differed in her recollection, and informed me that Mr B dispensed 32 half tablets to her husband. At no time did Mr B ask Mrs A the purpose of Dr C's prescription.

Information sheet
Mr B explained that when a patient receives new medication, the computer automatically prints an information sheet about the medication. The sheet is comprehensive, covering matters such as a description of the medication, how the medication works, what to do

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before taking the medication, how to use it, directions on what to do while taking the medication, precautions, side effects, dose and safety advice (see Appendix 2). Mr B included a copy of the information pamphlet with the medication he dispensed to Mr A.

Mrs A said that the fact sheet outlining the drug's benefits and side effects was enclosed with the medication. However, she did not read it because her husband, who was in extreme pain, and their six-month-old baby, were waiting for her in the car. Mrs A recalled that her husband consumed a half tablet that evening and another that night.

On Sunday morning 20 June 2004, Mr A complained of a severe headache, dizziness, and hallucinations, and remained in pain. It was then that Mrs A read the information sheet provided by Mr B and realised that the medication dispensed was taken for hypertension. As the pharmacy was closed on a Sunday, Mrs A rang another pharmacy, where the pharmacist confirmed that Trandate, the medication named on the label of the bottle, was different from tramadol, and that the medications were used for treating different medical conditions.

Subsequent events
On 21 June, Mrs A went back to the pharmacy to report the error. As Mr B was out of town, she informed the attending staff member, Ms D, of the error. Ms D was working as a pharmacy technician in the dispensary when Mrs A returned with the incorrect medication. On learning of the mistake, Ms D retrieved the prescription from the dispensary. After viewing it, she commented that it was difficult to interpret the writing at first look. On further inspection, she realised that Mr B had dispensed Hybloc (Trandate). Ms D offered to dispense the correct medication, but Mrs A refused. Consequently, Ms D refunded the dispensing fee to Mrs A, who commented on the inconvenience she had experienced as a result of Mr B's error.

As Ms D was worried that Mr A may have taken a dose of Trandate, she immediately counted the number of half tablets in the bottle that Mrs A returned. She found 30 half tablets in the bottle and concluded that Mr A had not consumed any of the Trandate. Mrs A agreed that 30 half tablets were returned on 21 June 2004. However, she recalled that 32 half tablets had been dispensed on 19 June 2004, and that Mr A had consumed two half tablets that Saturday evening.

During the investigation, Mr B provided this Office with the bottle containing the Trandate tablets dispensed on 19 June 2004. There were 29 half tablets in the bottle, rather than the 30 recorded by Mr B in the following statement he provided to me:

> "Upon my return to work I was informed of the error. I was mortified that I had misread the doctor's writing and given incorrect medication. I was thankful that I had given [Mr A] a Med Info sheet and that he was able to identify that the medication was not the pain relief Tramadol that he was expecting.
>
> I wrote a letter of apology to [Mr A] and enclosed petrol vouchers for $30.00 to assist [Mrs A] with costs associated with her return to [the pharmacy] (enclosed). I did not

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contact [Mr A] by telephone as I did not have a contact number, although in hindsight I could have checked with telephone directory services.

[Mrs A] returned 30 x ½ tablets to the pharmacy on Monday 21 June, which suggests that [Mr A] in fact did not consume any of the medication and that the dispensing error may have been discovered when he went to take the first dose.

I am not denying that I made an error, just that there seems to be some conflicting information regarding the consumption of any medication and therefore the possible side effects that were alleged.

I did follow the standard Dispensing procedures of the pharmacy (a copy enclosed) and was the only pharmacist present at that time.

The dispensing error occurred due to the misreading of the doctor's handwriting. Reading the prescription as Trandate 50mg not Tramadol 50 mg, due to the small handwriting from a doctor I had not seen very often, if at all.

We have appropriate checking systems in place, the problem here was the doctor's writing and being unable to contact him.

I [Mr B] dispensed the prescription on the 21 of June 2004 and realised the consequences to [Mr A] and I am truly sorry for any undue pain caused to him.

To prevent errors with hard to read handwriting, the prescriptions are not to be dispensed until clarification can be sought from the prescriber.

If errors are made we try to contact the patient as soon as the error is known. Talk to the patient and assess the patient's needs, help them to resolve and minimise any danger to the patient. Advise them of their rights and record the details in an incident report."

Mr B has accepted full responsibility for dispensing the wrong medication. He acknowledged that in hindsight, irrespective of whether Dr C was available, he could have clarified Mr A's prescription with the nursing staff at the public hospital.

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Standard operating procedure

The pharmacy's *Standard Operating Procedure* applicable at the time stated:

"**Purpose:**

- To describe the procedure to follow to check a dispensed medication against the prescription.

Responsibility:

- The Pharmacist

3. Procedure:

- Prescriptions are to be checked only by pharmacists.
- Check the dispensed medicine against the prescription for:
- Label accuracy.
  - Name.
  - Date.
  - Medicine dose and form.
  - Instructions.
  - Contain the date of birth for a child under 13.
  - C&A labels.
- Contents accuracy
  - Correct medicine
  - Correct dose
  - Correct form and quantity

- Dispenser and checker to be identified on all prescriptions – stamp each prescription with the 'dispenser/checker' stamp and sign in the appropriate box.

- Checks are to be made at each step in dispensing, to help eliminate errors – (refer to PP1.01.10.1, The New Zealand Hospital Pharmacist Guidelines for minimising dispensing errors).

Created by: Mr B Date : 04/04

Approved by: Mr B Date : 04/04

Review date : 04/05."

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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

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."

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Opinion: Breach – Mr B

Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Mr A had the right to pharmacy services of an appropriate standard and 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 dispensing procedures.

On 19 June 2004, Mr B was the dispensing pharmacist who dispensed Mr A's medication. The prescription read 50mg tramadol. Mr B acknowledged that he had misread the handwriting on the prescription as 50mg Trandate. I accept that the pharmacy was busier than usual as it was a Saturday, and that Mr B had several customers to attend to, being the only pharmacist on duty.

Mr B's suspicions about the medication were aroused when he noted that the prescription was for Trandate 50mg, as Trandate 50mg tablets had not been available for a number of years. As the neighbouring pharmacy did not have any Trandate 50mg, Mr B used his own supply of 100mg Trandate, which he cut in half to correspond with the dose prescribed. He told Mrs A that he would check with Dr C before dispensing the medication, but did not do so when she stated that it was likely that Dr C had left the hospital for the day. Mr B has accepted full responsibility for the error, and acknowledged that irrespective of Dr C's availability, he could have clarified Mr A's prescription with the nursing staff at the hospital.

Mr B initialled the prescription after checking the medication name and Mr A's details, in accordance with the pharmacy's standard of practice. However, because Mr B was under the mistaken impression that the prescription was for Trandate, he incorrectly dispensed medication for treating hypertension. In my view, because there was doubt about the identity of the medication, as indicated by its unusual dosage, Mr B should have taken steps to clarify the purpose of the medication with either Mrs A, Dr C, or nursing staff at the public hospital.

Mr B's dispensing error constituted a breach of section 18(2) of the Medicines Act 1981, in that he supplied medicine otherwise than that pursuant to a prescription given by a medical practitioner.[1]

It is clear that Mr B did not correctly dispense tramadol as prescribed, in accordance with professional and ethical standards set by the Pharmaceutical Society of New Zealand. In these circumstances, Mr B breached Right 4(2) of the Code.

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

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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 from doing, or omitting to do, that which breached the Code.

Mr B is a director of the pharmacy, which is owned by the pharmacy company. On learning of his error, Mr B reviewed the procedures to determine whether the incident could have been avoided. Mr B simply misread the handwritten prescription, and has acknowledged that he should have enquired with the prescriber before dispensing the medication to Mr A.

I have reviewed the standards of practice operating at the pharmacy company at the time, and am satisfied that the pharmacy's standards comply with those set by the Pharmaceutical Society of New Zealand. I accept that the dispensing error in this case resulted from a human error by Mr B and was not due to 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.

Non-referral to Director of Proceedings

After learning about the dispensing error, Mr B apologised to Mr A 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 following his dispensing error.

In light of these circumstances, and taking into account Mrs A's express advice that she simply wanted the circumstances of the dispensing error to be investigated to prevent future recurrences, and that she did not want Mr B to be subjected to punitive measures, I have decided not to refer the matter to the Director of Proceedings for consideration of disciplinary proceedings.

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Follow-up actions

- A copy of my final report will be sent to the Pharmacy Council of New Zealand.
- A copy of my final report, with details identifying the parties removed, will sent to the Pharmaceutical Society of New Zealand Incorporated, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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- **Appendix 1**

Prescription Form

③

Circle one from each line

Y J A P O

1 2 3

Z (Circle if patient has High Use Health Card)

(Doctor's Name)

NZMC Reg. No.:

Name of Patient

MR MASTER MRS MISS MS (Circle one)

Date of Birth if patient under 13.

/ /

Pharmacy use only

Item Count

Does patient have Prescription Subsidy Card

Pharmacy Stamp

Rx	Period Quantity	Disp.	Dispensing Date of Repeat
Tramadol 50mg sig i BID prn m (30) 100 / ½ bd 15		1st 2nd 3rd	
Rx		1st 2nd 3rd	
Rx		1st 2nd 3rd	
Rx		1st 2nd 3rd	

Certified Extended Supply:

Substitution not permitted on this prescription unless specified in writing

WH28

Signature to Prescriber

Date

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Appendix 2

HYBLOC™ 100mg Tablets

labetalol hydrochloride

1. Medicine description

Available only on prescription.
This medicine contains **labetalol hydrochloride** *(a beta-blocker)* and is gluten-free.
It is an orange round, film coated tablet.
Distributor: Pacific Pharmaceuticals Ltd, Auckland.

2. How your medicine helps you

This medicine is used to treat hypertension (high blood pressure) . It works by reducing the work the heart has to do by reducing the force and speed of the heartbeat. It also relaxes and expands the blood vessels (lowers blood pressure), making it easier for the heart to pump blood around the body.

3. Before using your medicine

Important: Tell your doctor if you are *allergic* or *sensitive* to anything, including this medicine.
Do not use this medicine if you have: asthma, lung disorders or a history of breathing problems.
Other conditions including the following, may affect the use of this medicine. *Check with your doctor or pharmacist*: other heart problems, an adrenal gland tumour, diabetes, liver problems, kidney problems, are taking itraconazole, poor circulation, an overactive thyroid gland, unstable angina, playing drug-tested sports, a history of psoriasis, heart failure.
Other medicines including the following, may affect the use of this medicine. *Check with your pharmacist or doctor*: other antihypertensives, antiarrhythmics, calcium channel blockers, cimetidine, antidiabetic tablets, tricyclic antidepressants, clonidine, guanethidine, methyldopa.
SPECIAL PRECAUTIONS:

* **Food:** Take after food.
* **Alcohol:** Limit intake as alcohol may cause increased dizziness.
* **Driving/Operating machinery:** Avoid until you know how this medicine affects you. It may make you: dizzy, sleepy, affect your eyesight, or slow your reactions.
* **Pregnancy: Do not use this medicine** if you are pregnant or could become pregnant **until** you have discussed the *risks & benefits* during pregnancy with your pharmacist or doctor.
* **Breast feeding:** Breastfeeding is not recommended as this medicine passes into breast milk and it may affect your baby. Discuss with your pharmacist or doctor.
* **Older people:** May be more sensitive to this medicine.
* **Other:**
* This medicine may affect some laboratory tests.
* **Antacids:** if needed may be taken 1 hour before or 2 hours after this medicine.

4. How to use your medicine

Dose: Follow the instructions of your doctor/pharmacist and read the label carefully.
Safety: Keep all medicines out of children's reach and sight.

* Swallow the tablet/s **whole** with a full glass of water while sitting or standing *upright*. The coating makes swallowing easier.
* Always keep a supply of this medicine because it could be **dangerous** to stop using it **suddenly**. Your doctor will give you **special instructions** if you are stopping the medicine.

5. While using your medicine

* If you forget a dose, take it as soon as you remember but if it is almost time for the next dose, skip the missed dose. Take the next dose at the usual time. Do not double doses.
* Ask your pharmacist for advice on how to remember doses.
* You won't always be able to feel if this medicine is working. Even if you feel healthy, go back to your doctor for regular check-ups. **Do not stop taking the medicine.**
* **Store** this medicine in a cool, dry place. Protect from light.

SOME POSSIBLE SIDE EFFECTS: Although medicines have side-effects, most people do not experience any. If you have *any concerns or problems while using this medicine* contact your pharmacist or doctor for advice.

Side effect	Contact doctor/pharmacist
unusual skin rash; urinary problems	**straight away**
eye irritation; eyesight problems	for investigation promptly
dry eyes	if worrying or ongoing
tiredness; headache; dizziness	if severe or ongoing
muscle pain or weakness	for investigation promptly
nausea; vomiting	if severe or ongoing
sexual difficulty (men)	if worrying or unacceptable
yellowing of skin and eyes	for investigation promptly
stuffy nose	if worrying or ongoing
hair loss; increased sweating	if severe or unacceptable
swollen ankles or legs	for investigation promptly
sudden mood changes	for discussion promptly

To help decrease some side effects of this medicine: (1) Avoid standing up too quickly; (2) Drink plenty of fluid, especially in hot weather; (3) Dress warmly during cold weather.

URGENT: Get emergency medical help immediately...

* if you get any of the following: chest pain, shortness of breath, suddenly feeling weak/faint or having seizures or fits.
* if you suddenly get any of the following, wheezing, difficulty breathing, itchy skin, swelling of the arms, face, neck or tongue*(allergic reaction)*
* for overdose or accidental poisoning

6. Precautions and general information

* **Surgery/Anaesthetics:** Tell the surgeon, doctor, or dentist *in advance* that you are taking this medicine.
* It is essential that you take this medicine **exactly** as directed. **Do not stop taking it** without your doctor's permission.
* Ask your pharmacist for advice on how to remember doses.
* **For best results** take doses at same time/s each day.
* This medicine **may interact** with some medicines from pharmacies, supermarkets or healthfood shops causing problems. Check with pharmacist or doctor before using.
* **Lifestyle changes** to help control blood pressure, include diet changes, low salt intake, regular exercise, stopping smoking and maintaining ideal body weight.
* If you get pregnant while using this medicine tell your doctor.
* Keep all medicines out of children's reach and sight.
* If you have any concerns about this medicine or you would like more information ask your pharmacist.

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Before taking your medicine please read both sides of this leaflet and keep it for reference

Keep all medicines out of children's reach and sight

About this leaflet

- This leaflet does not contain all the information about this medicine. If you need more information, ask your pharmacist.
- Check with your pharmacist or doctor if you have been given this medicine for a reason not explained by this leaflet.
- This leaflet does not replace the advice of your doctor or pharmacist.

Have you checked?

Tell your doctor, pharmacist or dentist if you:

- are pregnant, planning a pregnancy or become pregnant while using this medicine
- are breast feeding
- have allergies or other medical conditions
- are using other medicines including any you buy
- are a smoker or have a high alcohol intake
- play a sport where you may be drug tested.

Other helpful hints

- Keep a record of your allergies, regular medicines and serious medical conditions.
- Ask your pharmacist for advice or special packaging to help you remember doses.
- Tell any other doctor, dentist or surgeon you visit that you are taking this medicine.
- Remember to collect any repeats for medicines **before** the repeat date on the medicine label.

Overdose or accidental poisoning – ACT QUICKLY

Call an ambulance.

Tell them what the person has taken and their age.

Side effects

- All medicines can have side effects but they usually are not serious. Possible side effects of this medicine are on the other side of this leaflet.
- If you have any concerns about taking this medicine or how it is affecting you, talk to your pharmacist or doctor.

Safety advice

- If your condition gets worse or changes contact your doctor or pharmacist.
- Do not give your medicine to other people or use it for any other condition unless directed by your doctor or pharmacist.
- Do not use expired medicines.
- Return all expired or unused medicines to your pharmacy for safe disposal.
- Carefully dispose of used medicine containers, out of the reach of children and pets.

Dose

- Your doctor, dentist or pharmacist has chosen the dose especially for your condition.
- Do not change the dose without checking first.
- If you have any concerns or do not understand the dose instructions, talk to your pharmacist.

Notes

www.medinfoleaflets.com

If you have any questions or would like more information, ask your pharmacist or doctor.

We welcome your comments about our leaflets, email us at: info@medinfo.co.nz

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medicine information for consumers

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