Mr B – Pharmacist

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 04HDC04333)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer/complainant
Mr B	Provider/pharmacist
Dr D	House Surgeon

Complaint

On 15 March 2004 the Commissioner received a complaint from Mr A about a pharmacy. The following issues were identified for investigation:

The adequacy and appropriateness of services provided to Mr A on 9 March 2004 by the pharmacy, in particular:

- *whether the pharmacy staff incorrectly labelled paracetamol 500mg tablets as tramadol 50mg tablets*
- *whether the pharmacy staff incorrectly labelled tramadol 50mg tablets as paracetamol 500mg tablets.*

An investigation was commenced on 26 July 2004.

Information reviewed

- Complaint written by Mr A
- Information from Mr B

Information gathered during investigation

On 3 March 2004 Mr A was admitted to a public hospital with a small puncture wound to his left arm caused by a metal fragment. On 4 March Mr A underwent surgery to remove the fragment and repair his radial artery. He was discharged on 5 March 2004 with a course of oral antibiotics (Augmentin) and analgesia (paracetamol and tramadol) prescribed by Dr D. The prescription read as follows:

"Augmentin

Sig: 625 mg po tds

Mitte: 7 days

Paracetamol Tab 500mg

Sig: 1-2 tablets q4hly

Mitte: 50 tablets

Tramadol

Sig: 100mg po prn/tds

Mitte: 5 days."

On 9 March Mr A presented Dr D's prescription to sole pharmacist Mr B, at the pharmacy. When collecting the prescription Mr A advised Mr B that he did not require the Augmentin. Accordingly, Mr B took the Augmentin back and amended Mr A's receipt. Mr A stated:

> "When I got home [I] had the pills as per the labels, so I had my paracetamol (2 per 4 hours) at 2pm, 6pm and 9.30pm and tramadol at 10[pm] to help me sleep, but found that my feet and arms went numb and were still like that in the morning. [A]gain I had taken the paracetamol at 6am and midday but was feeling strange, I couldn't stand up for long, pains in my stomach, my head was not very clear and I couldn't eat food, I stopped the pain relief until that night and it was 10pm when I went to take some, it was then I found the labels were wrong.
>
> What makes me mad with this is that I was driving my kids to school when taking tramadol as paracetamol, I guess I'm lucky it wasn't blood pressure medication or heart medication as I might be dead. I think the only thing that the guy at the pharmacy had to do was to put labels on boxes and it's very clear on the photo[graph] that he couldn't do that."

Mr A informed me that after he stopped taking the tramadol capsules he slept until 2pm the next day. He did not report the error to the pharmacy but decided to make a complaint to the Health and Disability Commissioner.

Mr A provided the boxes of medication that Mr B dispensed for him on 9 March. The pharmacy labels of "TRAMADOL" (two capsules, three times daily if required) and "PARACETAMOL" (tablets to be taken one or two every four hours) were written as per Dr C's prescription. However, the box with the label 'TRAMADOL' contained foil-wrapped paracetamol tablets. The box labelled 'PARACETAMOL' contained foil-wrapped tramadol capsules. Therefore, while the pharmacy label and medication dispensed were correct, the labels on the boxes had been transposed.

Mr B admitted responsibility for the error. He stated:

> "I have been a pharmacist for 30 years and I am the sole pharmacist/proprietor of [the pharmacy] and do not have any other dispensary staff. I have one shop assistant and on checking the time this prescription dispensed found it was processed 1.26pm. As this is the lunch period, my staff may have been at lunch and I may well have been on my own. I cannot remember the exact situation nearly five months later.
>
> As sole dispenser it is my role to check prescriptions for corrections and legality, enter the information in the computer, dispense the medication, check it and then it hand it to the patient and counsel the patient."

Mr B recalled that Mr A was a former customer of his pharmacy some years previously and, as he was pleased to see him again, "there was probably some chit chat and catching up" which may have distracted him from his normal checking process. (Mr A denies that there was any distraction, and believes that Mr B may have confused him with his father, as he did not usually collect his own prescriptions). Mr B suggested that when Mr A cancelled the Augmentin prescription, this "could have led to a further distraction". The dispensing history document provided by Mr B confirms that Augmentin was cancelled. Mr B stated:

> "Although the labels were transposed, [Mr A] did not take more tramadol than the doctor had prescribed, as he only took three doses on the first day and two on the second before he discovered the error."

In his response, Mr A commented:

> "While I did take the correct dose of tramadol for any 24 hour period, I would like to point out that an entire 24 hour dose was taken within 6.5 hours [7.5 hours]. Add to that the two doses taken before midday the following day, and the effects of the drug were compounded as 10 tablets were taken within 24 hours not 6 … As one who doesn't regularly take pain relief I would not be used to these strong drugs and would have used them sparingly and only as necessary, hence me only taking what I thought was the one dose before retiring for the night."

Mr B commented that he was "mortified" that the error had occurred. He wrote:

> "I take much pride in the quality of services provided to my customers. I am extremely disappointed that such an error could occur. I can only assume that as we hadn't seen you for a long time some sociable chatter may have distracted me from my usual methodical dispensing and checking procedures. Also, as our records show it was lunch time, my wife was having lunch so her '2nd pair of eyes' wasn't available to spot any possible slip up.
>
> I would like to reassure you that the amount of tramadol taken was within the normal dose range for moderate to severe pain. Nausea and dizziness are very common side effects of tramadol at any dose. It was unfortunate that you experienced both."

Mr B explained that his wife is currently his shop assistant and sole staff. The only role that a shop assistant in his pharmacy has in relation to the dispensing process is to receive new

prescriptions, check names and addresses, and in the issue of finished prescriptions as described in the dispensing and checking protocol. Mr B stated that he has trained his staff to identify that the customer collecting the medicine is the correct person, and that the correct number of items are given on multiple item scripts, by checking against the receipt. Any possible inconsistency can be detected and corrected at this point. Mr B explained that on 9 March there was no specific documentation of the checking process required by the pharmacy standard operating procedures (SOPs):

> "At the time [Mr A's] script was dispensed separate dispensing and checking initialling on the prescription forms was not carried out. As there was only a sole pharmacist (myself or a locum) involved in the dispensing, the computer record, which indicates the pharmacist's name, was deemed sufficient. As you will see in the new protocol sent to you, I have added this extra step" (see Appendix).

Mr B provided a copy of the computer record that identified himself as the dispensing pharmacist for Mr A's prescription. Mr B also provided a copy of the prescription concerned and explained that a pharmacy stamp appears on the prescription as an identifier for claiming purposes only. Mr B stated that while prescriptions were not required to be initialled as checked at that time, the relevant SOPs required prescriptions to be checked.

Mr B explained that he was not able to provide a copy of the pharmacy SOPs in operation on 9 March 2004 because they had been overwritten on the computer file when he reviewed them, following this incident, and he did not keep a copy. Mr B provided a copy of the "Certificate of Pharmacy Quality Audit" dated 4 July 2002, which stated that the pharmacy services comply with Quality Standards for Pharmacy in New Zealand.

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 *Pharmacists Code of Ethics* Principle 2.6 states:

> "The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly."

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

> "The pharmacist maintains a disciplined dispensing procedure which ensures that the appropriate product is selected and dispensed correctly and efficiently."

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 that met professional and ethical standards. The standards that apply in this case were determined by the Pharmaceutical Society of New Zealand and state that all dispensed prescriptions must be finally checked to ensure accuracy. The checking pharmacist is solely responsible for such checking.

In this case, Mr B was the sole pharmacist and it was his responsibility to check the dispensed medication against the prescription. Mr B should have checked the label against the prescription to ensure it correctly stated the name, quantity and directions for use of the medication and the name of the patient. He should then have checked the box that the label was attached to, and its contents, against the prescription and against the label. In the case of Mr A's prescription, the labels were complete and accurate and paracetamol and tramadol were correctly selected from the pharmacy supply. However, the labels were inadvertently transposed between the two boxes. This error should have been noticed when the boxes containing the medications were checked against the label.

As a result of the error, Mr A took tramadol (thinking it was paracetamol) at 2pm, 6pm and 9.30pm as well as at 6am and midday the following day. Although Mr A did not take more than the maximum dosage prescribed of three times daily, tramadol was taken over three four-hour intervals during the afternoon and evening rather than being spread throughout the day. Mr A experienced numbness, stomach pain and an unclear head.

Mr B was not aware of the error until it was brought to his attention by my Office. Therefore, there are no contemporaneous incident reports or analysis of how the incident may have occurred. Mr B recalled "chatting" to Mr A when he came into the shop and speculated that this may have distracted him from his normal checking process. However, Mr A denies that this occurred. A further distraction may have occurred when Mr A

informed Mr B that he did not require the Augmentin, which interrupted the normal sequence of dispensing and checking.

It is not disputed that Mr B did not initial Mr A's prescription to record that it had been checked. However, Mr B advised that there was no requirement, under the applicable pharmacy standard operating procedures (SOPs), to initial prescriptions, and the computer record showing the name of the pharmacist was the only indication that any checking process had taken place. Mr B was not able to provide a copy of the relevant SOPs, which have since been amended to include the requirement to initial prescriptions as checked.

According to professional standards, the checking pharmacist is responsible for checking the dispensed medication. Mr B may have properly checked the accuracy of the label against the prescription, and the dosage of the medication, although without the requirement of initialling the prescription it is not possible to ascertain what, if any, checking actually occurred.

Mr B did not detect that the labels had been transposed and that the medication in the boxes was therefore incorrect. The possibility of distraction during the dispensing process highlights the need for vigilance when checking. While a shop assistant may usefully check the identity of the customer and that dispensed items correspond with the pharmacy receipt, this does not in any way detract from the responsibility of the checking pharmacist.

Mr B failed to comply with the Pharmacist's *Code of Ethics* and the Quality Standards, which required him to ensure the medication was dispensed correctly. Accordingly, in failing to comply with these legal and professional standards, Mr B breached Right 4(2) of the Code.

Opinion: No breach – The Pharmacy

Vicarious liability
Mr B, the sole pharmacist/proprietor of the pharmacy, breached Right 4(2) of the Code. Section 72 of the Health and Disability Commissioner Act 1994 provides for the vicarious liability of an employing authority for the actions of an employee, agent or member.

Mr B was unfortunately not able to provide a copy of the applicable standard operating procedures, as he stated they have since been replaced and he did not keep a previous copy. He confirmed that it was a requirement under the relevant standard operating procedures in place to check dispensing, but there was no requirement at the time to verify the checking process by initialling prescriptions as checked.

It appears that the error in this case resulted from an individual omission by Mr B, apparently due to him being distracted from his checking. There is no evidence to suggest that the pharmacy systems were not appropriate. I note that the pharmacy was audited on 4 July 2002 and received a certificate to record that the standards of practice operating at the

pharmacy at the time were in accordance with the standards set by the Pharmaceutical Society of New Zealand. The standard operating procedures have since been amended to include the initialling of prescriptions when checked, which is a useful safeguard and documents checking.

Actions taken

- Mr B has reviewed the pharmacy standard operating procedures and his dispensing practice. He has also provided a letter of apology which has been forwarded to Mr A.

Follow-up actions

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

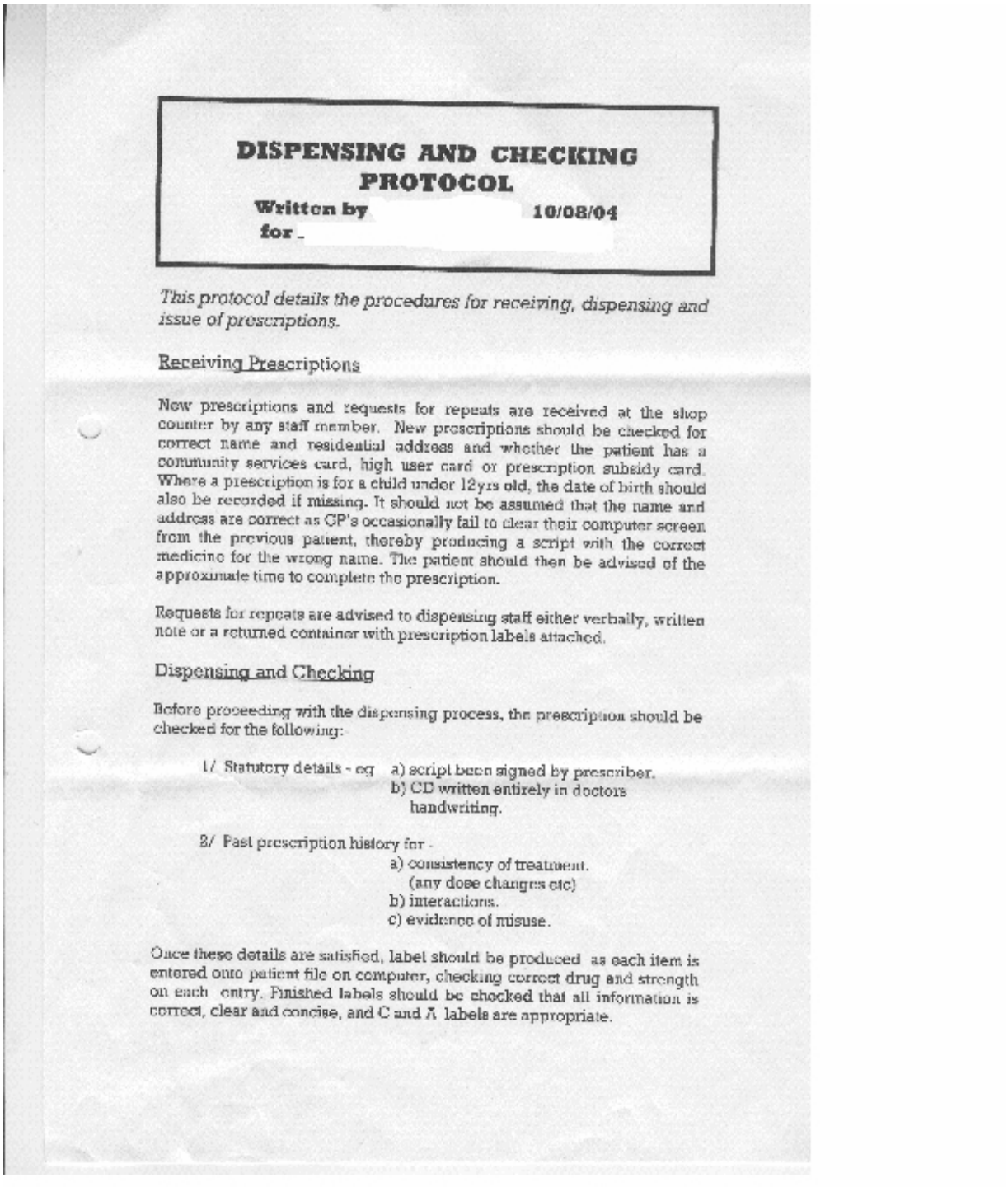
Non-referral to Director of Proceedings

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.

Relevant factors in this case are that it was a one-off mistake; the pharmacist has been in practice for many (30) years without (to his knowledge) any dispensing errors; adequate standard operating procedures appear to have been in place; the pharmacist's prompt admission of the responsibility and offer of an apology; and the steps taken to improve the pharmacy's standard operating procedures.

In these circumstances, I have decided that the public interest does not require that Mr B be referred to the Director of Proceedings.

APPENDIX A



DISPENSING AND CHECKING PROTOCOL

Written by **10/08/04**
for _

This protocol details the procedures for receiving, dispensing and issue of prescriptions.

Receiving Prescriptions

New prescriptions and requests for repeats are received at the shop counter by any staff member. New prescriptions should be checked for correct name and residential address and whether the patient has a community services card, high user card or prescription subsidy card. Where a prescription is for a child under 12yrs old, the date of birth should also be recorded if missing. It should not be assumed that the name and address are correct as GP's occasionally fail to clear their computer screen from the previous patient, thereby producing a script with the correct medicine for the wrong name. The patient should then be advised of the approximate time to complete the prescription.

Requests for repeats are advised to dispensing staff either verbally, written note or a returned container with prescription labels attached.

Dispensing and Checking

Before proceeding with the dispensing process, the prescription should be checked for the following:

1/ Statutory details - eg a) script been signed by prescriber.
b) CD written entirely in doctors handwriting.

2/ Past prescription history for -
a) consistency of treatment. (any dose changes etc)
b) interactions.
c) evidence of misuse.

Once these details are satisfied, label should be produced as each item is entered onto patient file on computer, checking correct drug and strength on each entry. Finished labels should be checked that all information is correct, clear and concise, and C and A labels are appropriate.

Each item is then counted, measured or compounded as the case may be and put in a suitable container. Where pharmacist is sole dispenser and checker each container should be labelled immediately. If script is being dispensed by intern or dispensing assistant, the container should be placed with stock bottle, with label left to be affixed by pharmacist, at final check. Each medicine's expiry date should also be checked before counting or measuring. Each form should then be initialled by the dispenser and checker.

Issue of Prescription

Once prescription is complete, the medicine can be issued to patient.
Depending on nature of advice required, the prescriptions can be issued by an appropriate staff member. If advice is of a simple nature (eg no more repeats left - see doctor for new script) the medicine may be issued by any staff member. When advice is more complex nature, the script should be issued by the pharmacist.
If patient or caregiver is not present when script completed, the medicine should be wrapped and labelled with patient name and address and any charges that apply. Where advice is required , a note to refer to the pharmacist before handing out should be attached to the package. Except where scripts are too bulky, they are placed on ledge between shop and dispensary for collection. Bulky prescriptions (eg special foods) are to be remain in the dispensary.
At the point of issue the receiving person should be correctly identified as the proper person to collect that medicine, by establishing name and address of patient for whom the medicine is prescribed.

This protocol is due for review August 2005