Pharmacist, Mr B

A Pharmacy

(A Pharmacy Company)

A Report by the

Health and Disability Commissioner

(Case 04HDC11716)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Mr A	Complainant/Consumer's husband
Mr B	Provider/pharmacist
Dr C	General practitioner
Dr D	General practitioner
Dr E	General practitioner
Mrs F	Pharmacy technician
Mr G	Pharmacist
A Pharmacy	Pharmacy
A Pharmacy Company	Owner of pharmacy

Complaint

On 12 July 2004 the Commissioner received a complaint from Mr A about services provided by Mr B at a pharmacy. The following issue was identified for investigation:

- *Whether Mr B provided services of an appropriate standard to Mrs A on 14 July 2004. In particular, whether Mr B dispensed erythromycin and paracetamol to Mrs A in bottles that were incorrectly labelled.*

An investigation was commenced on 12 November 2004.

Information reviewed

Information provided by:

- Mrs A
- Mr A
- Mr B
- Dr E, general practitioner

Information gathered during investigation

On 13 June 2004 Mrs A consulted general practitioner Dr D about her swollen tonsils which were causing considerable pain and difficulty in swallowing. Dr D advised Mrs A to rinse her throat with tea tree oil and eat raw garlic for relief. He also prescribed codeine 30mg tablets four times daily. Mrs A commenced the codeine tablets that evening and took them "for a little while", until she was unable to swallow.

Mrs A's symptoms deteriorated and on 14 June she consulted general practitioner Dr C. Mrs A stated that Dr C was "horrified" by the state of her throat. Mr A stated that Dr C diagnosed an "extremely severe case of Quinsy" and that Dr C considered admitting her to hospital. The relevant medical records state:

> "VERY sore left throat, saw doctor yesterday → pain relief only
> On examination, erosive tonsillitis with oedema of uvula + distortion of left throat (almost qualifies as quinsy!)
> Barely able to swallow – 1 glass of water today.
> Temperature = 37.2"

Dr C prescribed liquid suspensions of erythromycin 400mg/5ml, mitte (amount) 210ml (erythromycin is used as an alternative to penicillin in patients, such as Mrs A, who are allergic to penicillin) and paracetamol 250mg/5ml, mitte 300ml (for pain relief) to treat Mrs A's condition. The dosages prescribed were 10ml three times a day, and 10–20ml once every four hours, respectively.

Mr A presented Mrs A's prescription to the pharmacy later that day. The liquid suspensions were correctly prepared by pharmacy technician Mrs F. However, pharmacist Mr B transposed the labels for paracetamol and erythromycin, and as a result the medications were incorrectly labelled. The bottle marked "paracetamol" contained liquid erythromycin. The bottle marked "erythromycin" contained liquid paracetamol. Mr B explained:

> "[Mrs F] prepared both liquid preparations at the 'liquids bench' at the same time. The original bottles were left on the liquids bench so I could see what bottles were used. The prepared medicines were then brought to the dispensing bench and the labels were inadvertently transposed on the wrong medicine."

Mr A commented that the bottles containing the medication were identical and only differed slightly in size. Accordingly, there was nothing to alert them to the fact that the bottles were incorrectly labelled. On the evening of 14 June, Mrs A commenced taking her medication (together with the codeine tablets prescribed by Dr D) according to the label instructions. Mr A stated "there was minimal improvement and she [Mrs A] was in extreme pain".

Mrs A took the medicine until 16 June (when she consulted Dr C again). Mrs A estimated that in the period 14–16 June she had taken 120ml of erythromycin solution per day, when

she thought she was taking 120ml of paracetamol solution per day. Mr B has correctly observed that, if this was the amount taken from the 210ml bottle of erythromycin, it would have lasted only 1.75 days. Mrs A's prescription allowed for between 40 to 80ml of paracetamol solution per day. Therefore, it appears that Mrs A took a smaller dosage of erythromycin than she has calculated over the first few days, and, because the dosage allowed for variable amounts, it is not possible to calculate precisely how much she took. However, it appears that Mrs A took 10–50ml more erythromycin than she had intended (when the prescribed daily dosage was 30ml).

In addition, Mrs A took 30ml of paracetamol per day when she had intended to take the 30ml of erythromycin. Therefore, Mrs A took less paracetamol than had been prescribed (40–80ml).

Mrs A stated that on 16 June Dr C considered admitting her to hospital due to her significant dehydration as a result of being unable to swallow. Mrs A stated that Dr C instructed her to increase the dosage of (liquid) paracetamol to assist with pain relief and to continue taking the erythromycin, as prescribed. Dr C also advised Mrs A to use paracetamol tablets, instead of the liquid form, when she regained her ability to swallow tablets, as well as continuing with erythromycin (and codeine). The medical records state:

> "Follow up check: able to swallow (liquids)
> Temperature: 36.9
> throat: still quite asymmetric much less red + pussy.
>
> PLAN AND TREATMENT
>
> continue Erythromycin for 10 to 14 days
> continue pain relief."

Mrs A increased the liquid dosage of (what she thought was) paracetamol as instructed (she does not have an accurate record of what increased level she took). She estimated she was able to commence taking paracetamol in a tablet form after "three or four days". Mr A stated:

> "As soon as [Mrs A] could swallow slightly she stopped taking [what she thought was] the liquid paracetamol and only took the tablets. She continued on with [what she thought was] the liquid erythromycin."

In reality, Mrs A had ceased taking erythromycin and was taking two lots of paracetamol (liquid and oral). She stated:

> "By my calculations at this stage I was taking 120mg per day of Codeine, plus 6000mg per day of Paracetamol tablets, plus 1500mgs per day of liquid Paracetamol and absolutely no antibiotic."

Mr A stated that Mrs A's condition did not improve, and that she appeared very tired. Mr and Mrs A then obtained a repeat erythromycin prescription at a "different" pharmacy on 20 June. (Mrs A stated that she started using medicine from this bottle on 21 June.) Mrs A explained that at this point they realised that a dispensing error had been made by the pharmacy on 14 June. Mr A stated:

> "… we realised the new bottle of Erythromycin looked, smelt and tasted different to the original one. In fact it looked, smelt and tasted identical to the bottle originally labelled Paracetamol."

On 24 June Mr A visited general practitioner Dr E (who is Mrs A's regular general practitioner) for a personal consultation and mentioned his concerns about Mrs A's medicine. Dr E advised Mr A to discuss the matter with the pharmacy. Later that afternoon, Mr and Mrs A returned to the pharmacy and spoke to pharmacist Mr G, who agreed that the bottles were mislabelled. Mr G recorded the details of their discussion on a customer complaint record, as follows:

> "What is the problem or complaint?
>
> Patient had received Paracetamol 250mg/5ml and Erythromycin 400mg/5ml (both in 300ml bottle) but the labels were placed on the wrong bottle. Patient had been taking the bottle labelled with the antibiotic but in fact she had been taking the Paracetamol. She hadn't gotten any better so she called the doctor.
>
> Doctor had recommended them to double the dose of antibiotic, which meant she took double the dose of the Paracetamol. She went back to the doctor and they found that the labels were wrong. Pharmacist ([Mr G]) checked and saw and smelt that the wrong medication was labelled. Customer or patient feel that one of the products should have been placed in the fridge but hadn't. They also thought that she was not getting the proper pain relief and treatment for the infection. Contacted ([Mr G]) the patient later on to ask what they wanted done and explain the progress of the complaint.
> Pharmacist on duty and dispensed: [Mr B]
> Technician – [Mrs F]."

There is no further entry on the Chemist customer complaint record to indicate the progress of the complaint, although the form has further headings such as "Action required" and "Date complaint resolved".

Mrs A explained that Mr B telephoned her on 25 June. Mrs A recalled "all he said was that he had rung up to apologise". Mrs A informed him that she appreciated the call, but that she considered the dispensing error to be a very serious event.

Mr B confirmed that he had telephoned Mrs A to apologise. He stated:

> "I then phoned [Mrs A] on Friday 25th June to apologise and did so repeatedly, from memory four times. I talked to [Mrs A] for over ten minutes and was sympathetic to her comments. She was very obliging and was very grateful of my concern for her well-being. At no stage did she make any suggestion of taking the matter further and I took it that she had accepted my apologies and that was the end of the matter."

Mr A subsequently advised this Office that they were not interested in receiving a letter of apology, due to the seriousness of the error. Mr A has commented that, in his view, the checking of liquid suspensions requires a different procedure as there may be no identifying features for checking purposes. He stated:

> "I myself have observed the quality procedures in place at [the pharmacy] for some time now as I am a regular customer. They have good procedures where in general someone assembles the prescription and someone else checks it before it is given to the customer. This works well where there are tablets etc in clearly identified packs etc. I cannot see how it can work properly where you have two liquid medicines in the same coloured containers especially if the dispensing chemist has put the wrong label on the bottle. All the checker does in this case, is verify the labels match the doctor's prescription."

Mr B has reviewed pharmacy practice for the dispensing of liquids. He stated:

> "Since this incident I have reviewed the pharmacy protocols and there is a potential for error when more than two liquids are prescribed at one time.
>
> The procedure has now been changed if a prescription has more than two liquid forms on it. They are to be prepared one at a time with the technician bringing the original bottle over to the dispensing bench along with the prepared bottle. Each item is prepared and labelled before doing the next liquid product.
>
> …
>
> In conclusion I accept that I have made a labelling error. I have apologised profusely to the patient. I am quite frankly unhappy with my performance and accuracy. Standard operating procedures have been changed to hopefully eradicate the risk of this type of error occurring again."

Standard Operating Procedures

There are no separate Standard Operating Procedures (SOPs) for the dispensing of liquid suspensions at the pharmacy. The pharmacy SOP 18 "Dispensing Medications" (dated December 2000) outlines the steps to be followed in the dispensing process and stipulate that, when the prescription has been dispensed and checked, it should be signed. SOP 18 states that a qualified pharmacist must check the medication in accordance with SOP 23 "Final Prescription Check", which states:

> "**8.0 Procedure**
>
> …
>
> **8.5** Check label is correct, medicine name, dose, form, C&A labels, patient name, date, prescription number, directions are correct, clear and concise — check this against the prescription.
>
> …
>
> **8.6** Check that the content of each container is correct against the prescription."

Mr B provided the original prescription used to dispense Mrs A's medication. The prescription is stamped "the pharmacy company" and signed as checked. Mr B confirmed that the signature which appears on the prescription is his own. He also provided a copy of the labels for paracetamol and erythromycin, which were correct according to Dr C's prescription.

Mr B provided a copy of the revised SOP 18 (review date not recorded), which includes the following amendment:

> "If dealing with more than one item, take items from shelf one at a time, counting and labelling the first item before selecting the next item."

Mr B subsequently provided a copy of the pharmacy SOP "Client Complaints", dated 10 June 2005 with a proposed review date of 10 June 2006.

The pharmacy was audited by Medsafe on 16 February 2004 and was certified as compliant with pharmacy practice and quality standards in New Zealand.

Effects on Mrs A's health

Mrs A has been "very disturbed" by what occurred and particularly worried about the effects on her health – for example, the risks of having discontinued antibiotic treatment in the context of a penicillin allergy, and the possibility that she may have sustained organ damage as a result of using too much analgesic medication.

These matters are outside my jurisdiction but Mr B was asked to provide his views on the likely impact of the dispensing error on Mrs A's condition. I note that Mr B is not medically qualified and his comments should be read in light of his role as the dispensing pharmacist.

Mr B has commented that for the period of time that Mrs A took the increased dosage of erythromycin this should have assisted in resolving the infection earlier and any side effects she experienced would have been gastrointestinal, such as nausea or cramping. Mr B disputed that Mrs A took a "very high" dosage of paracetamol. He considered the tiredness Mrs A experienced could have been due to dehydration or a side effect of

codeine. Mr B also explained that the consequence of storing the paracetamol in the fridge would have been an increase in the thickness of the liquid, making it more difficult to pour. The erythromycin potency would not have suffered too greatly being stored at room temperature during winter months, so long as it was not stored close to a heater.

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 *Code of Ethics* (June 2001) Principle 2.6 stated:

> "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."[1]

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."

[1] After 18 September 2004, the Pharmacy Council of New Zealand *Code of Ethics* 2004 is applicable, which is to be read in conjunction with current Acts, regulations and Codes of Practice, including the Quality Standards.

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 were determined by the Pharmaceutical Society of New Zealand (as it then was).[2] Under principle 2.6 of the Code of Ethics (June 2001) prescriptions must be dispensed correctly. Standard 6.2 of the Society's practice guideline places a duty on a pharmacist to maintain a disciplined dispensing procedure which ensures that the appropriate product is dispensed.

On 14 June 2004 Mrs A was prescribed liquid paracetamol and erythromycin by general practitioner Dr C for severe tonsillitis. The liquid suspensions were correctly prepared by pharmacist technician Mrs F. Pharmacist Mr B correctly prepared the labels. However, Mr B inadvertently transposed the labels for paracetamol and erythromycin when placing them on the pharmacy bottles.

As a result of Mr B's error, the bottle marked "paracetamol" contained erythromycin. The bottle marked "erythromycin" contained paracetamol. There was nothing distinctive about the medication bottles to alert Mrs A to the error. Accordingly, she took the medication as directed by Dr C from the evening of 14 June and took more erythromycin than she intended (the precise quantity cannot be ascertained) and less paracetamol (a total of 60ml) over the following two-day period. On 16 June Dr C further advised Mrs A to increase her liquid paracetamol intake and to cross over to an oral form as soon as she could swallow. As a result, Mrs A unintentionally further increased her erythromycin dosage and (inadvertently) continued with 30ml per day paracetamol. When Mrs A began taking oral paracetamol, her antibiotic regime was interrupted (as she had inadvertently ceased taking erythromycin) and she took additional paracetamol (from the bottle labelled "erythromycin"). Mrs A received incorrect dosages until 21 June, when she obtained a repeat erythromycin prescription from another pharmacy and realised the error had occurred.

[2] On 18 September 2004 the Pharmacy Society of New Zealand was dissolved and the Pharmacy Council of New Zealand was established as the registration/complaint body for pharmacists in New Zealand. In addition, the Pharmaceutical Society of New Zealand Incorporated (the Society) was established as an independent non-statutory professional body which has retained responsibility for professional Codes of Practice.

Mr B provided the following explanation for what occurred:

> "[Mrs F] prepared both liquid preparations at the 'liquids bench' at the same time. The original bottles were left on the liquids bench so I could see what bottles were used. The prepared medicines were then brought to the dispensing bench and the labels were inadvertently transposed on the wrong medicine."

The standard operating procedures (SOPs) at the pharmacy state that medications are to be dispensed according to SOP 18 (Dispensing Medications) and SOP 23 (Final Prescription Check). The final prescription check includes checking that the content of each container is correct against the prescription. In this case, it appears that human error on the part of Mr B caused Mrs A's prescriptions to be incorrectly labelled and he did not correctly check the dispensed medication. It is critical when dispensing prescriptions in tandem, particularly for medications with no distinguishing features, that prescriptions are properly separated throughout the dispensing process to enable accurate dispensing and checking to occur. Although Mr B initialled the prescription as checked, he failed to ensure that the contents of each container were correct against the prescription.

Mr B did not detect that the labels had been transposed and that the medication in the bottles was therefore incorrect. He has appropriately accepted full responsibility for the error, as the dispensing/charge pharmacist.

Mr B failed to comply with the *Code of Ethics* (June 2001) and the Quality Standards, which required him to ensure that Mrs A's prescription was dispensed correctly. I note that the dispensing error also probably contravened section 18 of the Medicines Act in that Mrs A was supplied medicines otherwise than pursuant to a prescription.

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 Company

Vicarious liability

Mr B, pharmacist/proprietor of the pharmacy, breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code). The pharmacy is owned by the pharmacy company and Mr B is the sole director. In addition to any direct liability for a breach of the Code, employing authorities may be vicariously liable under section 72 of the Health and Disability Commissioner Act 1994 for any breach of the Code by an employee, agent or member.

The pharmacy standard operating procedures (SOPs) have been reviewed to highlight that, when dealing with more than one item, prescriptions should be dispensed sequentially. Mr B has also introduced the practice of transferring the original bottle to the dispensing

bench. These measures will be a useful safeguard for the dispensing and checking process, particularly when dispensing prescriptions with more than one liquid solution. However, there is no evidence to suggest that the pharmacy dispensing systems were not appropriate. I note that the pharmacy was audited on 16 February 2004 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. Overall, I consider that the pharmacy company had appropriate dispensing systems and the mistake was due to individual error by Mr B.

In these circumstances, the pharmacy company did not breach the Code.

Other comments

Review of incident
There was no further documentation of the dispensing error following the initial completion of the customer complaint form by pharmacist Mr G. (The customer complaint form is also designed to record the actions taken and the date on which the complaint is resolved.)

It is important that incident reports are completed to fully document the actions taken to ensure that the risk of repeated incidents is minimised. This was not done. I also note that Mr B has not included the new practice of transferring the original bottle to the dispensing bench in the revised SOPs, and so, because the customer complaint form was not completed, there is no written record of this change to pharmacy practice.

Standard operating procedures
The Chemist Standard Operating Procedures (SOPs) for dispensing were dated December 2000 and it is not apparent when they were reviewed. In my view, it is useful to record on the SOP documents when they have been reviewed, and when the next review is planned. This will enable all pharmacy staff to ascertain that the pharmacy SOPs are current. (Mr B has appropriately dated the reviewed SOP for complaints in this manner.)

Apology and information provided to Mrs A
Mr B stated that he "apologised profusely" to Mrs A on 25 June. It appears Mrs A was not satisfied with Mr B's apology, nor was she fully informed why the error occurred or the steps taken to prevent a further error. Mr B should have clarified with Mrs A whether she was satisfied with his apology rather than making that assumption. In addition, following receipt of a formal complaint he should have advised her of the results of the internal investigation.

Actions taken

Mr B has acknowledged the dispensing error and expressed dissatisfaction with his own performance. A customer complaint record was recorded by pharmacist Mr G on 24 June 2004, and Mr B verbally apologised to Mrs A on behalf of the pharmacy on 25 June 2004. The pharmacy has reviewed its dispensing and complaints procedure. A formal letter of apology was not provided to Mr and Mrs A. They have subsequently advised that they do not require a formal letter of apology.

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.