A Pharmacy

Pharmacist, Ms B

A Report by the

Health and Disability Commissioner

(Case 04HDC13191)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Complainant
Miss A	Consumer
Ms B	Provider
Pharmacy	Pharmacy

Complaint

On 5 August 2004 the Commissioner received a complaint from Mrs A about the services provided to her daughter, Miss A. The issue identified for investigation was:

Whether pharmacist Ms B provided services of an appropriate standard to Miss A. In particular, whether Ms B dispensed penicillin rather than flucloxacillin to Miss A at the Pharmacy on 30 July 2004.

An investigation was commenced on 19 November 2004.

Information reviewed

- Miss A's prescription of 18 June 2004

Information from:
- Mrs A
- Ms B
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe)
- HealthPAC

Information gathered during investigation

Mrs A's account
On 18 June 2004 a general practitioner prescribed to Miss A, aged seven, flucloxacillin oral solution 250mg/5ml syrup up to 1800mls. 280mls of mixture was to be dispensed every two weeks. This medication was for her recurrent boils. Mrs A went to the pharmacy in a city on Friday 30 July 2004 to obtain repeat flucloxacillin for her daughter. Ms B, pharmacist, dispensed the medication. Mrs A alleged that Ms B mistakenly dispensed

phenoxymethylpenicillin 280mls for Miss A, although Mrs A recalled that the bottles were correctly labelled.

Mrs A was a little concerned on Friday evening when she administered the medication to Miss A as it was coloured orange and not pink (like the flucloxacillin Miss A had been taking). Mrs A is a registered nurse and thought that the pharmacist might have arranged for another drug company to supply Miss A's medication. However, she became more concerned when Miss A told her that the medication tasted better than her usual medication. By this time Mrs A had administered "maybe four doses" to her daughter (without adverse effect).

On Sunday 1 August Mrs A visited the pharmacy for another item and asked the retail assistant whether it had changed to another drug company. The assistant checked with Ms B, who informed Mrs A that there had been no change. Mrs A explained her concerns about Miss A's medication. Ms B checked and told her that she had given Miss A the wrong medication because flucloxacillin and phenoxymethylpenicillin were similiarly labelled. Ms B apologised and dispensed the correction medication, flucloxacillin.

Mrs A advised that she disposed of the bottles and medication dispensed to Miss A on 30 July.

Ms B's account
In her response to the complaint, Ms B, a registered pharmacist, acknowledged that she mistakenly dispensed a repeat phenoxymethylpenicillin mixture to Miss A instead of flucloxacillin. She was the only qualified pharmacist on duty at the time and was assisted by a pharmacy technician.

Ms B explained that Mrs A came to collect Miss A's medication at approximately 3.30pm on Friday 30 July. The pharmacy was busy because of the after-school rush. The other pharmacy staff were dispensing or involved with customers. Ms B wanted to minimise the waiting time because Mrs A was required to come in fortnightly to collect Miss A's flucloxacillin mixture. Therefore, Ms B told the technician, who was new, that she would make the flucloxacillin mixture.

Ms B recalled dispensing the medication from a repeat label (which was correctly labelled) printed by the technician from the computer. Ms B selected a bottle of medication from the shelf, read the manufacturer's label to ascertain the quantity of water required, then added 60mls of water to another bottle. The bottle was shaken and the contents added to a 300ml bottle. Ms B explained that this process was repeated twice more because 60mls of water produces only 100mls of antibiotic mixture, and Miss A required 300mls. The dosage of medication dispensed to Miss A was 280mls (rather than 300mls) because this amount could be taken in two weeks, after which the repeat would expire.

However, when selecting the medication Ms B misread the label on the phenoxymethylpenicillin bottle on the shelf and used it to prepare the medication. The flucloxacillin and phenoxymethylpenicillin mixtures were stored alphabetically in the

"antibiotics to be made up" section and were separated by Ospamox 125mg and 250mg solutions. Ms B advised that phenoxymethylpenicillin is orange and the flucloxacillin is pink when made up (the colour of the medications in powder form is the same). She noticed the difference in colour during the dispensing process but "this did not shout to me of an error" because flucloxacillin was coloured orange for most of her 19 years in practice until shortly before the incident, when it changed to pink. The change of colour eroded her "subconscious check". Flucloxacillin also required 60mls of water to mix.

Ms B described the labelling on the phenoxymethylpenicillin and flucloxacillin solution bottles as "atrocious". Both medications are provided in identical 100ml opaque plastic bottles, and the colour and shape of the labelling (orange print on white background) is identical.

Ms B admitted that "safety was compromised due to my haste in the dispensing process". She attributed her haste to being busy and the fact that Mrs A was watching and appeared to be in a hurry (something Mrs A denies). Consequently the correct checks were not made.

Ms B advised that the pharmacy formally reviews its procedures every two years. The pharmacy reviewed its procedures on 6 March 2004 but no changes were made (there is no record of this review). However, the repeat dispensing procedure was not reviewed at that time. Ms B recalled that the repeat dispensing procedure was altered in approximately January 2004, in response to suggestions made by a locum pharmacist. In addition to the usual procedure, the pharmacist is required to attach part of the label onto the daily record of repeats under the initials of the pharmacist checking the procedure. An "appropriate" pharmacist is also required to check that the medication is correct before giving it to the consumer. The policy was not altered in writing until 7 March 2005.

Ms B further advised that the daily record of repeats relating to the dispensing of Miss A's repeat medication, including part of the label and Ms B's signature, was forwarded to HealthPAC for payment, and a copy was not kept. HealthPAC advised that it received from the pharmacy only a computer log of the repeat medications dispensed.

Subsequent events

An incident reporting form was completed by Ms B on 2 August, and she conducted an internal review on 16 August. Ms B also apologised to Mrs A in a letter dated 2 August. In her letter Ms B commented: "I have been going over the incident and can put the error down to a culmination of constant changes in the medicine brands we are directed to dispense which eliminate small subconscious acknowledgements of the final product."

Ms B also advised that the prescribing general practitioner was notified of the incident, and staff involved in dispensing have been made aware of the similarities in the labels of bottles of phenoxymethylpenicillin and flucloxacillin. The medications are now stored at opposite ends of the shelf. An extra five-second "stop, look and check" procedure has been implemented and, where liquid is transferred from one bottle to another, the original bottle must remain on the bench. Further, a caution was placed on Miss A's file, which states:

"Double check this antibiotic – mistake made before." A full-time pharmacist has been employed to assist with the workload, and the pharmacy has developed an error policy.

Medsafe
Medsafe, a business unit of the Ministry of Health, advised me that the Pharmacy was audited by a medicines control advisor on 6 May 2004. All the areas reviewed concerning the dispensing process "met requirements". The advisor also checked a random sample of prescriptions and no deficiencies were detected.

Response to Provisional Opinion

In response to my provisional opinion, Ms B's lawyer accepted that she breached the Code by failing to appropriately check that the correct medication was dispensed to Miss A. However, he contended that this matter should be addressed by the Pharmacy Council, and that my proposal to refer the matter to the Director of Proceedings was not warranted. It was noted that Ms B had practised for many years without prior errors, and she acknowledged the dispensing error and took remedial steps immediately, which demonstrated her commitment to good practice.

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 *Code of Ethics* (Pharmaceutical Society of New Zealand, June 2001) Principle 2.6 states:

> "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 its suitability for the patient within the limitations of available information, and dispense it correctly."

Quality Standards for Pharmacy in New Zealand state:

> Standard 6.2:
>
> "The pharmacist maintains a disciplined dispensing procedure which ensures that the appropriate product is selected and dispensed correctly and efficiently."
>
> Standard 6.2a:
>
> "Procedures for dispensing and supply of pharmaceuticals are developed, documented and approved by the pharmacist."

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."

Pharmacy's repeat medication dispensing and checking policy

1. Details of repeat request or the old containers given to dispensary staff. Labels are generated on the computer checking the 20 day rule, and repeat is recorded in the computer. If 20 days are not to have passed, a duplicate CRC is printed and a reason for the early dispensing annotated and signed on the form.

2. The small third part of the label is stuck onto the daily record of repeats under the initials of the pharmacist checking the prescription.

3. Dispense script as per dispensing procedure. Appropriate pharmacist checks the final product.

Opinion: Breach – Ms B

Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Mrs A's daughter, Miss A, had the right to have pharmacy services provided 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 "Quality Standards for Pharmacy" places a duty on the pharmacist to maintain a disciplined dispensing procedure. Principle 2.6 of the Pharmacy Council's *Code of Ethics* holds the dispensing pharmacist responsible for ensuring that the appropriate product is selected, and dispensed correctly.

It is not disputed in this case that Ms B incorrectly dispensed phenoxymethylpenicillin mixture to Miss A, rather than flucloxacillin. This occurred because Ms B failed to properly read the label on the bottles of phenoxymethylpenicillin solution when selecting the medication for preparation and dispensing.

I accept that the shape and size of the bottles containing the phenoxymethylpenicillin and flucloxacillin powders were identical, and the labels were of the same colour and size. I also note Ms B's statement that the flucloxacillin solution had only recently changed colour from orange to pink, that both medications were stored within close proximity, and that the dose and mixture for both were the same (250mg/5ml syrup). I also appreciate that Ms B was busy. However, this does not excuse Ms B, as the dispensing pharmacist, from her professional obligation to dispense Miss A's medication correctly. She should have been more vigilant when selecting the medication from the shelf. Furthermore, Ms B was obliged by the pharmacy's repeat dispensing and checking policy to check the "final product" before the medication was given to Mrs A. It appears that an appropriate check did not occur.

Conclusion
I commend Ms B and the Pharmacy for the actions taken in response to this incident. Nonetheless, it is critical that a pharmacist is vigilant in the interests of patient safety when dispensing medications, particularly where they are stored in close proximity and in identical bottles with overtly similar labels. In this case, Ms B was not sufficiently vigilant, and her actions breached the Society's standards. Ms B's actions also probably contravened section 18(2) of the Medicines Act 1981 in that the supplied medication was not in accordance with the prescription given by a medical practitioner.

Therefore, in my opinion, Ms B breached Right 4(2) of the Code.

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 breaching the Code.

Ms B is a director of the Pharmacy and works at the Pharmacy as a pharmacist.

Medsafe informed me that the Pharmacy was audited by a medicines control advisor on 6 May 2004. All the areas reviewed concerning the dispensing process "met requirements". The advisor also checked a random sample of prescriptions and no deficiencies were detected.

I am concerned that although the pharmacy's repeat dispensing procedure was changed in approximately January 2004, the change was not documented until March 2005. Standard 6.2a of the Pharmaceutical Society of New Zealand Pharmacy Practice Handbook 2003 states: "Procedures for dispensing and supply of pharmaceuticals are developed, *documented* and approved by the pharmacist" (emphasis added). This is particularly important for inexperienced staff and locums.

Nonetheless, in light of the Medsafe audit and other evidence, I am satisfied that the dispensing error occurred mainly because of the mistaken selection by Ms B and a subsequent failure to check the medication she dispensed. The error did not result from an inadequate repeat dispensing procedure or other systems error (although the procedures for checking liquids were not ideal). Accordingly, no vicarious liability arises from Ms B's breach of the Code.

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 (19) years without (to her knowledge) any dispensing errors; the steps taken to improve the pharmacy's storage and dispensing procedures; the pharmacist's prompt admission of responsibility and offer of an apology; and the fact that the complainant simply wanted the mistake acknowledged and steps taken to prevent a recurrence.

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

Recommendation

A copy of this report, with details identifying the parties removed, will be sent to the manufacturer of flucloxacillin oral solution and phenoxymethylpenicillin oral solution with a recommendation that distinctive labelling be used to differentiate the two products.

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 sent to the Pharmaceutical Society of New Zealand Incorporated, the New Zealand College of Pharmacists, and the Pharmacy Guild of New Zealand, for educational purposes.
- 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.

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