Pharmacist, Mr B

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 04HDC08685)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer/Complainant
Mr B	Provider/Pharmacist
Dr C	General Practitioner
Dr D	Ophthalmologist
Mr E	Pharmacist/Owner of the pharmacy
A Pharmacy	Employer

Complaint

On 25 May 2004 the Commissioner received a complaint from Mr A concerning the pharmacy services provided to him by Mr B, a locum pharmacist employed by a pharmacy. The following issue was identified for investigation:

- *Whether Mr B provided services of an appropriate standard to Mr A on 19 April 2004. In particular, whether Mr B dispensed Kenacomb ear drops to Mr A instead of chloramphenicol eye drops.*

An investigation was commenced on 30 June 2004.

Information reviewed

- Complaint written by Mr A to the Pharmaceutical Society of New Zealand
- Reply from Mr B
- Information from the pharmacy
- Report and CD from ophthalmologist Dr D
- Consultation and treatment prescription from Dr C, locum general practitioner
- Pharmaceutical Society of New Zealand Code of Ethics (2001)
- Quality Standards for Pharmacy in New Zealand (Pharmaceutical Society of New Zealand)

Information gathered during investigation

Background
On 19 April 2004 Mr A, a 58-year-old living in Invercargill, saw his general practitioner's locum, Dr C, complaining of "itchy eyes". Dr C diagnosed bilateral conjunctivitis and prescribed chloramphenicol eye drops, an antibiotic.

The prescription read as follows:

"**Rx:** chloramphenicol eye drops

Dose: 1 drop every 4 hours both eyes for 3 to 7 days

Qty: 1 item"

Mr A presented the prescription to the pharmacy on 19 April 2004. Mr B was employed as a regular locum pharmacist on behalf of Mr E (pharmacist/owner) and was the sole pharmacist on duty that day. Mr B assessed the prescription for eye drops and went to the refrigerator, took a bottle of drops from the bottom shelf, and placed it on the dispensing bench. Mr B understood that the eye drops were routinely stored at the bottom of the refrigerator. Mr B remembers being questioned by the technician as to whether drops or ointment should be dispensed and he confirmed the prescription as indicating drops. The pharmacy technician entered the prescription details from the prescription written by the general practitioner, and generated a computer label for the container with a receipt. The printed label stated:

> "10ml CHLORAMPHENICOL 0.5% EYE DR, Instil one drop into both eyes every four hours for three to seven days."

The label was affixed to the box, and the medication dispensed to Mr A by Mr B.

Later that day Mr A began putting the drops into his eyes every four hours as prescribed, at 5.30pm, 9.30pm and 2am. On awaking at 7am he felt in considerable discomfort and his eyes were swollen. Mr A checked the label on the eye drops and found them to be Kenacomb ear drops. Mr A explained, "This caused me a great deal of distress and with difficulty I read the label on the eye drops. It read Kenacomb ear drops and was not the antibiotic that had been prescribed."

Assessment by Dr C
On 20 April 2004 Mr A returned to Dr C. On examination Dr C assessed that Mr A's eyes were more itchy, swollen and red than they had been the previous day. A referral for an urgent assessment with an ophthalmologist, Dr D, was made for that day. Dr C's referral reads:

> "I would be grateful if you could see this patient urgently if possible regarding his red eyes, query infection or allergic? Both. I saw him yesterday with a history of irritated,

> itchy eyes for 4 days. He had been using drops from the chemist — a mild antibiotic. He had bilateral conjunctivitis. I gave him a prescription for chloramphenicol eye drops. Unfortunately what was dispensed instead was actually a bottle of Kenacomb ear drops, which he has used about 3 times. Today his eyes are more itchy and more red and the lids are moderately swollen."

Mr A described his eyes as swollen and uncomfortable. He was very anxious that his eyesight would be lost or damaged as a result of using the ear drops. The reaction suffered by Mr A was obviously painful and distressing.

Assessment by ophthalmologist

On examination Dr D found Mr A's eyes to have "a bilateral follicular conjunctivitis with redness more marked in the medial bulbar conjunctiva than temporally". Dr D's report states that the appearance and moderate itchiness suggested an allergic reaction and he provided Mr A with steroidal eye drops (Maxidex). Mr A said that the eye drops took some time to "fix the problem", but he has suffered no long-term effects. Photographs of the eyes were taken by Dr D and stored on CD.

Dr D is unable to confirm whether the conjunctivitis noted on 20 April was a declining presentation of the original diagnosis or whether the application of ear drops had caused an allergic reaction and a consequential exacerbation of the initial condition. Dr D advised that it is not uncommon for ear and eye drops to share the same formula and be manufactured as dual use. Dr D gained information from the manufacturer of Kenacomb ear drops (Bristol-Myers Squib of Auckland) confirming that the constituents of the formula do not contain any substance that would be considered damaging to the eye.

Return to pharmacy

Following the assessment by the ophthalmologist, Mr A returned to the pharmacy to inform the pharmacist that he had been given the wrong drops for his eyes. There is a discrepancy regarding the circumstances of Mr A reporting the dispensing error, which I am unable to resolve. According to Mr A, he informed Mr B of the error and Mr B replied, "Oh bugger!" Mr A was unhappy with this response and felt the error was not handled tactfully, and that Mr B was sarcastic and unhelpful.

Mr B emphatically disputes that he used the words "Oh bugger" when Mr A returned to the pharmacy. Mr B commented:

> "As a caring and compassionate pharmacist I can assure you that this is not the language I used."

Mr B reports that initially Mr A spoke with the shop assistant to enquire as to the identity of the pharmacist and informed her of the prescription error. The assistant then drew Mr B's attention to Mr A. Mr A explained to Mr B that the wrong drops had been dispensed. Mr B asked Mr A what drops he had been given, but Mr A refused to say. Mr B says that he again asked what drops had been given but Mr A shrugged and said the drops were in his car.

Mr B noted that Mr A was "visibly upset" and offered a sincere apology. Mr A replied that he would complain to Mr E (pharmacy owner). He then walked out of the pharmacy.

Mr B at this time was unable to identify the client and felt Mr A had been "uncooperative to discuss further issues". To try and identify Mr A appropriately the shop assistant reviewed the script batch of the previous day and was able to recognise the prescription for Mr A. Mr B checked the prescription and the refrigerator contents. In the refrigerator Mr B found Kenacomb ear drops on the same shelf as the chloramphenicol eye drops. As soon as workload permitted, Mr B telephoned the general practitioner, Dr C. Unable to speak directly with the doctor, Mr B, via the receptionist, explained the error and conveyed his apologies. Mr B then telephoned and informed Mr E as owner of the pharmacy.

Mr B then went back to the refrigerator to separate the eye drops and ear drops. He also completed a computer and physical check of the stock levels but found no discrepancies in stock numbers.

Pharmacy dispensing procedure
Mr E explained the procedure for stocking the fridge in practice at the time:

> "The ear drops in the fridge are normally kept on the top shelf in a shallow tray. The eye drops are normally on the bottom shelf ... normally we would stock about 12 bottles of chloramphenicol eye drops, but only 1 or 2 bottles of Kenacomb ear drops and chloramphenicol ear drops."

Mr E supplied:

1. Copy of a letter from Medsafe dated 16 October 2002 confirming the completion of a Pharmacy Quality Audit II. **Attached as Appendix 1**

2. Copy of the pharmacy's policy section 6.1 regarding dispensing. **Attached as Appendix 2**

Actions taken after the incident
Mr E contacted Mr A on 26 April to apologise and offered to reimburse Mr A for any medical fees arising from the dispensing error. However, on 12 May Mr A returned to the pharmacy to advise Mr E that he intended to lodge a complaint. Mr E provided Mr A with information about the Health and Disability Commissioner.

Mr A subsequently received a letter of apology from Mr E, dated 17 May 2004. Mr E reiterated his offer to reimburse Mr A for any medical fees arising from the dispensing error.

Mr B also sent a letter of apology to Mr A on 17 May 2004. An extract from the letter is as follows:

> "I want to extend to you my sincere apology for the error I made when dispensing your prescription last month. You were badly let down by my actions. I let myself down and also [Mr E's] business entrusted to me during the school holidays … Stock drops on the

shelf in the fridge were not separated and the wrong one picked. This situation was immediately rectified after your visit the next day. All dispensing and checking procedures were also reviewed at once … I am very concerned about your well-being and apologise again for the distress I have caused you and your family."

Mr B advised me that he considers himself a knowledgeable and careful professional and has felt "overwhelmed by the failure in dispensing Mr A the wrong eye drops". He deeply regrets the error.

In response to the error, Mr B advised that he "cancelled all work for two months, immediately investigating the underlying cause and reviewed all [his] checking procedures to ensure a mistake of this nature does not recur".

As a result of this incident the pharmacy has initiated a weekly check of the position of the stock items in the fridge to ensure the ear drops and eye drops are separated on their respective shelves, both of which are now clearly labelled.

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,[1] 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."

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 have pharmacy services provided in accordance with relevant standards, including those set out in the Pharmaceutical Society of New Zealand *Code of Ethics* and the *Quality Standards for Pharmacy in New Zealand.*

On 19 April 2004 pharmacist Mr B dispensed Kenacomb ear drops instead of the chloramphenicol eye drops prescribed by Mr A's general practitioner.

When Mr B received the prescription he went to the pharmacy refrigerator where the medication requiring refrigeration is stored. He mistakenly took Kenacomb ear drops off the shelf and placed the bottle on the dispensing bench. He did not check the item removed.

The pharmacy technician preparing the label queried the prescription with Mr B, asking whether drops or ointment were to be dispensed. Again Mr B did not re-check the prescription in response to this query. Had he done so at this time the error may have been avoided.

The pharmacy dispensing policy stated that the pharmacist must "check the labelling against the prescription".

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[1] This was the Code of Ethics applicable at the time of these events. Events occurring after September 2004 are now judged according to the Code of Ethics 2004, which is administered by the Pharmacy Council of New Zealand.

In failing to check the prescription against the item and dispensing ear drops instead of eye drops Mr B did not comply with the pharmacy's policy and the professional standards noted above. In these circumstances Mr B breached Right 4(2) of the Code.

Opinion: Breach — The Pharmacy

Vicarious liability
Under section 72(2) of the Health and Disability Commissioner Act 1994, employers are responsible for ensuring that their employees comply with the Code, and may be vicariously liable for an employee's failure to do so. 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 conduct that breached the Code.

Although the pharmacy had in place an adequate dispensing policy at the time, I am not satisfied that it had taken appropriate steps to prevent the sort of error that occurred. The lack of shelf labelling and the placement of stock in the refrigerator appear to have contributed to the error. I note that when Mr B undertook a check of the stock levels after the misdispensing of the ear drops he found no discrepancies, ie, there was not the expected shortfall in the number of bottles of ear drops. As a result of this incident, the pharmacy has initiated a weekly stocktake of the refrigerator items, and has labelled the shelves. These actions are to be commended.

In the circumstances, the Pharmacy is vicariously liable for Mr B's breach of the Code. In response to my provisional opinion, Mr E has accepted this finding.

Actions taken

The pharmacy has recognised the scope for error with unlabelled refrigerator shelves and has already put in place labelling and storage protocols for refrigerated medications. In addition, there are now weekly checks of the contents to ensure proper placement.

One outstanding issue of concern is that Mr B's stock check after the dispensing error in this case did not reveal a discrepancy (ie, the ear drops stock level should have been one bottle fewer, and the eye drops one more). This suggests that the stock records were inaccurate. A pharmacy's stock check should be consistent with the stock records at any time, confirming that the items actually held match the original number less the number of items dispensed.

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.

When the error was drawn to Mr B's attention by Mr A, Mr B checked the contents of the refrigerator and took a stock check of eye and ear drops. He promptly notified Mr A's general practitioner and the pharmacy owner of the error. Although there is dispute about Mr B's immediate response when informed of the complaint, I note that Mr B did offer a sincere and prompt apology to Mr A after these events, and has taken steps to review his practice.

Given Mr B's acknowledgement of the error, his prompt action to prevent further dispensing errors, and his apology to Mr A, I do not consider it necessary to refer Mr B to the Director of Proceedings.

Follow-up actions

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

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

Appendix 1

16 October, 2002

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Dear

PHARMACY QUALITY AUDIT II
OF
ON 30 JULY 2002

Thank you for your signed declaration of implementation form confirming you have fully actioned all the recommendations contained within your Audit Report and for the copies of the documentation supplied.

I reviewed the documentation supplied and this letter confirms that the Pharmacy Quality Audit II undertaken with your pharmacy on 30 July is completed.

Please note this audit has made no evaluation of any other aspects of your performance beyond those considered by the audit tool on the day of the audit. The audit evaluated only those procedures, systems and processes seen at that time.

Once again, thank you for your assistance and co-operation with this audit. We wish you every success in continuing to provide pharmacy services to your patients.

If you have any queries please contact me on 03-479-2561.

Yours sincerely

Denise Martin
Advisor Medicines Control

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Appendix 2

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6. PHARMACEUTICAL SERVICES
6.1 DISPENSING

The Pharmacist maintains a disciplined dispensing procedure that ensures the appropriate product is selected and dispensed correctly and efficiently.

When **receiving** the prescription or order from the patient or the patients agent, the pharmacist shall :-

* Ensure its completeness regarding patient details, legibility, contract requirements (looking at medicine availability etc), legal requirements.

* Determine its priority for dispensing.

When **dispensing** the prescription the pharmacist shall :-

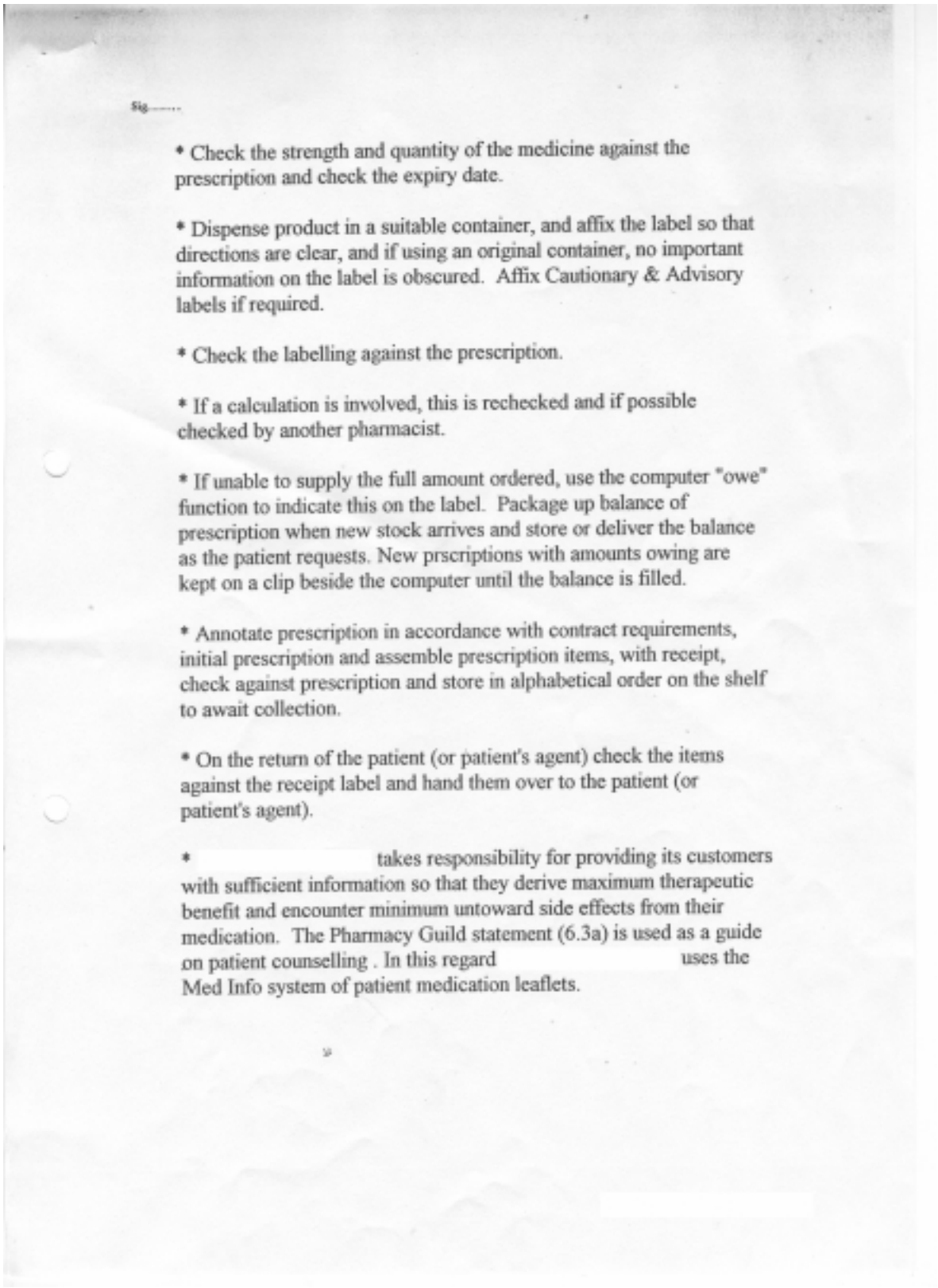
* Mentally review the suitability of the prescribed medicine with regard to its therapeutic use, adverse effects, contraindications, dosage and possible interactions with other medication or food.

* Check acquired medication history for consistency of treatment, interactions and evidence of misuse eg calling for repeats too early or too late.

* Key relevant data into the computer and produce labels which are legible and complete in the information which they provide. Labels should be prepared in accordance with the recommendations of the Pharmaceutical Society Council, and should ensure that the intentions of the prescriber are properly represented.

* Select a product which best serves the interest of the patient ie maintains continuity of treatment and bioavailability.

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



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* Check the strength and quantity of the medicine against the prescription and check the expiry date.

* Dispense product in a suitable container, and affix the label so that directions are clear, and if using an original container, no important information on the label is obscured. Affix Cautionary & Advisory labels if required.

* Check the labelling against the prescription.

* If a calculation is involved, this is rechecked and if possible checked by another pharmacist.

* If unable to supply the full amount ordered, use the computer "owe" function to indicate this on the label. Package up balance of prescription when new stock arrives and store or deliver the balance as the patient requests. New prscriptions with amounts owing are kept on a clip beside the computer until the balance is filled.

* Annotate prescription in accordance with contract requirements, initial prescription and assemble prescription items, with receipt, check against prescription and store in alphabetical order on the shelf to await collection.

* On the return of the patient (or patient's agent) check the items against the receipt label and hand them over to the patient (or patient's agent).

* takes responsibility for providing its customers with sufficient information so that they derive maximum therapeutic benefit and encounter minimum untoward side effects from their medication. The Pharmacy Guild statement (6.3a) is used as a guide on patient counselling . In this regard uses the Med Info system of patient medication leaflets.

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* If preparing an extemporaneous mixture all ingredient details will be recorded in the manner set out in the NZ Code of Good Manufacturing Practice Part 3. An appropriate expiry date will be determined. This is normally 3 months unless any information indicates otherwise.

* When a prescription is dispensed by the pharmacy technician or pharmacist student under training, the above steps will be followed. In addition the pharmacist will monitor the progress and check the dispensed products against the prescription, and take responsibility for any counselling .

* Prescriptions for delivery will be packaged with an invoice slip and receipt label. Delivery will be undertaken by pharmacy staff, according to appropriate standard procedures.