Pharmacist, Mr B

Pharmacy Technician, Ms D

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 05HDC03953)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Miss A	Consumer
Mr A	Complainant/Consumer's father
A pharmacy	Provider/Pharmacy
Mr B	Provider/Pharmacist
Ms C	Provider/Pharmacy technician
Ms D	Provider/Pharmacist
Ms E	Provider/Pharmacist
Ms F	Provider/Pharmacy technician
Ms G	Provider/Pharmacist

Complaint

On 17 March 2005 the Commissioner received a complaint from Mr A about the services provided by a pharmacy to his daughter, Miss A (when she was 10 years old). The issues investigated by the Commissioner arising from Mr A's complaint were initially identified as follows:

- *Whether staff at the pharmacy provided services of an appropriate standard to Miss A in or around December 2004 by dispensing Recormon 6000 IU syringes, instead of the prescribed Recormon 3000 IU syringes.*

- *Whether staff at the pharmacy provided services of an appropriate standard to Miss A in or around March 2005 by dispensing tacrolimus 5mg capsules, instead of the prescribed 1mg capsules.*

An investigation was commenced on 15 April 2005.

The investigation was extended on 31 January 2006 to include consideration of the following issues:

- *Whether pharmacist Ms D provided services of an appropriate standard to Miss A in or around November 2004 by dispensing Recormon 4000 IU syringes, instead of the prescribed Recormon 3000 IU syringes.*

- *Whether charge pharmacist Mr B provided services of an appropriate standard to Miss A in or around February 2005 by dispensing tacrolimus 5mg capsules, instead of the prescribed 1mg capsules.*

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

Information reviewed

- Information provided by:
  - Mr B
  - Mr A
  - Pharmacy Council of New Zealand
  - Ms D
  - Ms G
  - Ms E.

Independent expert advice was obtained from Mr John Fraser, pharmacist.

Information gathered during investigation

Overview
Miss A suffers from renal nephrotic syndrome which, in her case, resulted in kidney failure. Miss A received a kidney transplant from her mother prior to these events, and requires regular medication to keep her condition stable.

Mr A's complaint involves two separate dispensing errors involving Miss A's medications when she was ten years old.

Two of Miss A's medications are Recormon 3000IU/0.3mL (millilitres) injections (used to treat anaemia) and Prograf (tacrolimus) 1mg capsules (immunosuppressant used to prevent rejection of transplanted organs). The prescriptions are written by doctors at a renal unit of a public hospital, and filled at the pharmacy. Due to the infrequent use of the medications, Recormon and Prograf are ordered in by the pharmacy on request.

As Miss A takes regular medicines, her prescriptions include monthly repeats to cover a three-month period. In these circumstances, the initial prescription is treated as a "first issue" and repeats are entered on certified repeat copy forms (CRC forms) by the pharmacy. CRC forms are then processed and signed by pharmacists as if they were original prescriptions.

The pharmacy is a registered incorporated company and Mr B is the sole director. In addition to being the owner/operator, Mr B is also a registered pharmacist and has a team of pharmacists and dispensary technicians working at the pharmacy. Mr B stated that at the time of the dispensing errors the pharmacy was understaffed and overworked owing to the pharmacy being very busy, and the difficulties of attracting pharmacists to a rural pharmacy.

Recormon error

Mr A said that in late November 2004, a repeat prescription of Recormon 3000IU/0.3mL for Miss A was requested from the pharmacy, and the medication was ordered in. This prescription also included repeats of two other drugs, Ventolin and Flixotide. The pharmacy does not record when prescriptions are collected, and it is unclear when Mr A collected the prescription. Mr A does not recall exactly when he collected the medications for Miss A, but it appears he took them home around 1 December.

About a week later, Mr A opened the Recormon box of prefilled syringes. He found that, despite the box being correctly labelled by the pharmacy as 3000IU/0.3mL Recormon, the six syringes inside the box contained 6000IU/0.3mL Recormon. (As discussed below, Mr B has confirmed that they were in fact 4000IU/0.3mL Recormon.) Mr A returned the box to the pharmacy and informed Mr B of the error. Mr B apologised, stated that he did not know how the error had occurred, and reassured Mr A that it would not happen again. Mr B then dispensed the correct strength of Recormon.

The label for a prescription is computer-generated and comprises three parts. One part is placed on the medication container; one part is an address label placed on the bag for delivery; and the third part summarises the dispensing and is placed on the prescription form. Each part of the label contains the unique identifier number for that prescription.

In this instance, the third part labels and stamp on the CRC form are all dated 30 November 2004. Ms C, a trainee pharmacy technician, initialled the CRC form, indicating that she had prepared the Recormon for checking by a pharmacist. However, the third part label for Recormon was not ticked as correct (by a pharmacist). The other two items on the prescription, Ventolin and Flixotide, were both ticked as correct. The dispensing stamp was signed off as being checked by pharmacist Ms D. The 30th of November 2004 was a Tuesday; however, Ms D usually worked on Wednesdays. Mr B confirmed that Ms D did not work on 30 November, but did work on 1 December 2004.

Mr B explained that even though Ms D signed the checked box on the CRC form, she may not have been the pharmacist who checked all of the medications for Miss A. When the pharmacy is very busy and staff numbers are low, an informal practice had developed whereby other pharmacists would help to process items on a prescription. As Recormon was a rarely used medication, it had to be ordered in. Mr B said that Ms D might have initialled the CRC form to indicate that the other medications on the prescription had been checked, prior to the arrival of the Recormon.

The dispensary and duty pharmacist around the time of the error was Ms E. She and Mr B worked most days during the week. In these circumstances Mr B is not sure whether Ms D was responsible for the error involving the Recormon, as it may have been checked by Ms E. However, there is no documentation of Ms E having any

involvement with the prescription, and she does not remember anything about the Recormon dispensing.

The pharmacy incident form (dated 30 November 2004) states:

> "Recormon 4000 dispensed instead of Recormon 3000 on repeat prescription. Staff pointed out more than one strength of Recormon. Redispensed and apology. New strength in stock from mid November."

There is no record of who dispensed the medication or any analysis of the cause of the error. Mr B said he discussed the error in a staff meeting, and established that they believed the Recormon 3000IU/0.3mL was not in stock at dispensing time. The pharmacy does not record when stock arrives, so it is unclear exactly when the Recormon 3000 IU/0.3mL ordered for Miss A arrived at the pharmacy. However, when the Recormon 4000 IU/0.3mL did arrive it was prepared and labelled by the technician.

Mr B has provided pharmacy records that indicate that the Recormon dosage that was dispensed would have been 4000 IU/0.3mL, because the pharmacy had never stocked 6000 IU/0.3mL. The records show that Recormon 4000 IU/0.3mL was first dispensed on 16 November 2004 for another patient, and was processed for a repeat on 29 November 2004 with the stock arriving about the time Miss A's repeat prescription was presented. The incident form also states that Recormon 4000 IU/0.3mL was dispensed instead of Recormon 3000IU/0.3mL. In any event, it is agreed that the strength of Recormon dispensed to Miss A was incorrect, and was an increased strength from what she should have received.

In light of the doubt surrounding the identity of the dispensing pharmacist, Mr B, as proprietor, has accepted responsibility for the error, even though his signature is not on the prescription.

Tacrolimus error

A second dispensing error occurred in February 2005, and involved Miss A's tacrolimus 1mg capsules. A repeat prescription for tacrolimus 1mg capsules was requested from the pharmacy for Miss A. The third part labels and the pharmacy stamp are dated 22 February 2005. Trainee pharmacy technician Ms F initialled the third part label and the certified repeat copy form, which indicated that she had prepared the medication for the pharmacist to check. Ms F prepared a partial dispensing of 20 capsules, with 100 capsules to be collected at a later date. However, she incorrectly dispensed 5mg capsules instead of 1mg.

Mr B said that the computer would have indicated that the correct strength of tacrolimus was not in stock and that this should have signalled alarm bells. He also advised that, pursuant to the standard operating procedures, it was the pharmacy technician's responsibility to sort the prescriptions and track down a pharmacist to sign the prescription by the following day. Mr B acknowledged, however, that

although the technician may have been involved in the error process, "it is the pharmacist who is responsible for the final check and [with] whom the responsibility rests".

Miss A's tacrolimus CRC form was not signed by either pharmacist on duty that day — Mr B or Ms G. Therefore, the identity of the checking pharmacist is not known, and Mr B advised that he cannot be certain that this prescription was actually checked by a pharmacist. Ms G informed me that she was working at the back of the pharmacy that day processing methadone prescriptions. Mr B said that was possible, but even if someone does work out the back all day, he or she may help out in the front part of the pharmacy when needed. He said that it is likely that, if a pharmacist checked the prescription, it was him, but because there is no signature on the script he cannot be sure who it was, or that it was checked at all. Mr B is unaware of any other occasion where a prescription has left the pharmacy without having been checked by a pharmacist. As charge pharmacist and proprietor, he accepts responsibility for the error.

Mr B stated that the 20 tablets of incorrect 5mg tacrolimus were collected from the pharmacy the same day the script was presented. The remaining 100 tablets of correct 1mg tacrolimus were collected the following day. On 16 March 2005, Mrs A was unpacking the tacrolimus and placing the capsules in Miss A's weekly medicine trays, when she noticed the capsules were a different colour from usual. The capsules were a greyish-pink instead of the usual white.

Mrs A checked the box label and found the details and the dose to be correct, but on closer inspection of the capsule packets, she found that the capsules were 5mg tacrolimus, not 1mg.

Mr A returned the capsules to the pharmacy and talked to the pharmacist on duty. The pharmacist advised Mr A of his rights as a consumer. An incident report dated 16 March 2005 was completed regarding the error, stating: "Label correct. But dispensed x 20 tacrolimus 5mg tabs instead of 1mg tabs. Patient did not take. 2nd error for same patient (last time Recormon dose wrong). Patient going to Disciplinary Board." There is no record of who dispensed the medication or analysis of the cause of the error.

Mr A was asked to return to the pharmacy the next day for replacement capsules.

Mr B subsequently wrote a letter of apology to Mr A, and reviewed the pharmacy systems and procedures. Pharmacists now use green pens to clearly initial beside each individual item on a prescription to identify which pharmacist carried out the check; a stamp is used to prioritise the order of dispensing of prescriptions; a slip is used to minimise dispensing interruptions; dispensed and checked prescriptions are now placed in a transparent Zip bag in which additional written information can be included for the patient; pharmacists now sign each third part label; technicians only sign the left side of third part labels and dispensing stamps; and a dedicated

prescription and information counter is planned to streamline the process and reduce pharmacist interruptions.

Mr A is concerned that the dispensing errors could have caused serious harm to Miss A's new kidney, endangering her life, or requiring her to go back on dialysis.

Mr B has expressed his sincere remorse and advised that the errors occurred in circumstances where the staff at the pharmacy were working under the pressure of a very heavy work load. Mr B believes Mr A is satisfied with the way his complaint has been handled and that there is a cordial ongoing relationship.

Independent advice to Commissioner

The following expert advice was obtained from Mr John Fraser, pharmacist:

"**Introductory comments**

1.1 Introduction

I would like to thank the Commissioner for allowing me to review case number 05/03953/WS. This matter was referred to me for my opinion on 30th August 2005.

1.2 Qualifications, training and experience of expert advisor

I am John Fraser, a registered pharmacist. I am a member of the New Zealand Pharmaceutical Society and I also hold the degree of Bachelor of Science in Physiology (Otago). I am a practising rural pharmacist with about 45 years' experience working in pharmacy in New Zealand, the United Kingdom and the United States. I have worked in pharmacy at all levels from apprentice to owner/manager.

I am a past President of Southland Pharmacists' Association; a pharmacy Preceptor (a person involved in the tuition of pharmacy interns); a Member of the Southland Rural Health Committee; and a Member of the Joint Trans-Tasman Expert Committee on Drug Labelling.

I have had a long-standing professional interest in the safe and effective labelling and use of pharmaceutical agents. I have been involved as a label safety consultant to the pharmaceutical industry although at the present time I have no professional or financial interests in this area.

1.3 Declarations

I have read and agree to follow the HDC Guidelines for Independent advisors. I have also previously entered into a confidentiality agreement with the HDC.

I have compiled this report in good faith based on the information available to me.

1.4 Directions from the Commissioner

I have been directed by the Commissioner to consider the following questions:

1. In your professional opinion, was the service the staff at [the pharmacy] provided to [Miss A] appropriate? Please give reasons for your opinion, with reference to the individual staff members involved.

2. What standards apply in this case?

3. Were those standards complied with?

If not covered above, please answer the following:

4. Are there any comments that need to be made regarding the pharmacy's organisation and systems in light of the dispensing error involving: a) the Recormon; and b) the tacrolimus?

5. Were appropriate steps taken to prevent further dispensing errors after the Recormon dispensing error?

6. Were the steps taken after the tacrolimus dispensing error appropriate?

7. Should any other steps be taken to improve the systems at [the pharmacy]?

If, in answering any of the above questions, you believe that staff at [the pharmacy] did not provide an appropriate standard of care, please indicate the severity of departure from that standard.

To assist you on this last point, I note that some experts approach the question by considering whether the providers' peers would view the conduct with mild, moderate or severe disapproval.

Are there any aspects of the service provided by the staff at [the pharmacy] that you consider warrant additional comment?

1.5 Material examined

In providing my opinion, I have examined the following material:

1.5.1 General

- Case notes from the Health and Disability Commissioner (dated 30 August 2005)
- Letter of complaint to Health and Disability Commissioner from [Mr A] on behalf of [Miss A] (received by HDC on 21 March 2005)
- Letter to [Mr A] from [Mr B] (dated 17 March 2005)

- Letter to Health and Disability Commissioner from [Mr B] (dated 20 April 2005)
- [The pharmacy's] Certificate of Audit (dated 30 October 2002)
- [The pharmacy's] 'old' standard operating procedure (dated 17 October 2002)
- [The pharmacy's] 'new' standard operating procedure (dated 29 March 2005)
- Copies of stamps and checklists developed by [the pharmacy] in response to medication errors (undated)
- Notes taken during a telephone interview with [Mr B] (16 June 2005)
- Martindale Pharmacopoeia, 32nd Edition (Pharmaceutical Press, London, 1999)
- New Ethicals Compendium, 7th Edition (Adis International, Auckland, 2000)
- Pharmacy Council of New Zealand Code of Ethics 2004
- Pharmacy Practice Handbook 2003
- Medicine Regulations 1984

1.5.2 Material specific to Recormon error

- A copy of [Miss A's] original prescription for Recormon and other drugs (stamped 28 October 2004)
- A copy of [Miss A's] CRC for Recormon (stamped 30 November 2004)
- Dispensing intervention form 6a (dated 30 November 2004)
- [The pharmacy] usage report for Recormon, Jan–Dec 04 (dated 20 April 2005)
- Recormon boxes as supplied by manufacturer

1.5.3 Material specific to Tacrolimus error

- A copy of [Miss A's] prescription for tacrolimus and other drugs, (stamped 27 January 2005)
- A copy of [Miss A's] certified repeat copy for tacrolimus and other drugs (stamped 22 February 2005)
- Copy of the tacrolimus box and label (dated 22 February 2005)
- A pharmacy prescription copy for tacrolimus and other drug (dated 23 February 2005)
- Dispensing incident report form 6a (dated 16 March 2005)
- [The pharmacy] usage report for tacrolimus, Jan 04–Mar 05 (dated 22 April 2005)
- Tacrolimus box as supplied by manufacturer

2 Summary of Facts

2.1 Patient background

The patient involved was [Miss A], a 10-year-old girl. [Miss A] suffers from renal nephrotic syndrome, a class of diseases that damage the glomeruli, the filtration system of the kidneys[1]. In [Miss A's] case, the syndrome led to total kidney failure and approximately three years ago she received a kidney transplant from her mother. According to her father, [Mr A], [Miss A] enjoyed good health but required medication to remain in a stable condition.

Among [Miss A's] regular medications were Recormon (Epoetin Beta) 3000IU/0.3mL for injection, and Prograf (tacrolimus) 1mg capsules for oral consumption. These drugs were prescribed by physicians at [the public hosptail renal unit] and were dispensed by [the pharmacy] in [a town].

2.2 Pharmacy Background

[The pharmacy] is a retail pharmacy in [a rural town] in New Zealand. The town has a population of approximately […].

[The pharmacy] is owned and operated by [Mr B] and is serviced by a team of staff including duty pharmacists and dispensary technicians.

2.3 Recormon dispensing error

Recormon is a drug used to treat anaemia, a condition in which the number of red blood cells is reduced. The active ingredient in Recormon is a hormone, Epoetin Beta, which stimulates the production of red blood cells[2].

On 29 November 2004, a repeat prescription for Recormon 3000IU/0.3mL (#722666/2) was requested from [the pharmacy] on behalf of [Miss A]. (A repeat prescription is one where a prescribed medication is dispensed from the pharmacy in portions. This usually entails the patient having to visit the pharmacy at monthly intervals to pick up the next 'repeat' of medication without necessitating a visit to the doctor for a new prescription.)

On 30 November 2004, pharmacy technician in training [Ms C] 'initialled' the certified repeat copy (CRC) form, which would be taken to indicate that she had prepared the drugs for a pharmacist to check. However, she apparently chose the wrong strength of Recormon, selecting 4000IU/0.3mL instead of 3000IU/0.3mL (which was out of stock). This erroneous dispensing was 'signed off' by pharmacist [Ms D] and labelled 'Recormon 3000iu/0.3ml Injection' with the directions 'Administer the contents of ONE injection (3000 units) ONCE each week as directed.' [Ms E] was the dispensary manager and duty pharmacist at the

[1] Eddy, A. A. and Symons, J. M. (2003). *Nephrotic Syndrome in Childhood.* Lancet, 362, 629–639.
[2] Parfitt, K. (ed) (1999). *Epoetins*. Martindale: The Complete Drug Reference. Thirty-second edition. Pp. 717–720. London: Pharmaceutical Press.

time the error occurred, but there is no suggestion she was actively involved in the error. [Mr A] collected the medication and returned home.

To summarise, [Miss A] was dispensed Recormon 4000IU/0.3mL by [the pharmacy] although her repeat prescription was for Recormon 3000IU/0.3mL. This was an overdose of 33%.

Fortunately the dispensing error was detected by [Miss A's] father the next week, before she had received any of the incorrect strength of the drug. [Mr A] immediately returned to [the pharmacy] where [Mr B], the pharmacy's proprietor, acknowledged the error and apologised before dispensing the correct strength of Recormon. He later discussed the error in a conference with pharmacy staff.

(Although it is not strictly relevant to the investigation at hand, I am of the opinion that even if [Miss A] had taken the overdose, she would have been unlikely to suffer serious long-term harm. I mention this fact only for the peace of mind of all parties involved in this incident.)

2.4 Tacrolimus dispensing error

Tacrolimus is a potent immunosuppressant drug used to prevent rejection of transplanted organs. It is nephrotoxic (that is, toxic to the kidneys) and hence must be used with caution in a renally vulnerable patient such as [Miss A][3].

On 22 February 2005, a repeat prescription for tacrolimus 1mg capsules (#735661/2) was dispensed for [Miss A] by [the pharmacy].

Pharmacy technician in training [Ms F] 'initialled' the Third Part Label and dispensing check box on the CRC, which would be taken to indicate that she had prepared the drugs for a pharmacist to check. However, she apparently chose the wrong strength of tacrolimus, selecting 5mg capsules instead of 1mg. [Ms F] created a partial dispensing of 20 capsules with an 'owing' of 100 — meaning that the patient would (in a normal situation) return later to collect the remainder of their prescription when the pharmacy could supply it.

At this point, the situation becomes somewhat unclear. Normally the prescription would be checked by a pharmacist. Charge pharmacist [Mr B] and part-time pharmacist [Ms G] were on duty that day, but neither initialled the CRC. [The pharmacy] was subsequently unable to identify the checking pharmacist.

The outcome of this confusion was that the incorrect strength of tacrolimus was partially dispensed for [Miss A]. Although the prescription was for tacrolimus 1mg capsules, she was in fact dispensed tacrolimus 5mg capsules, a five-fold

[3] Parfitt, K. (ed) (1999). *Tacrolimus.* Martindale: The Complete Drug Reference. Thirty-second edition. Pp.562–563. London: Pharmaceutical Press.

overdose. The medicine box was labelled 'Tacrolimus 1mg Capsules' with the directions 'Take TWO capsules twice a day as directed.'

The prescription was received by [Miss A's] parents. Fortunately the error was detected by [Miss A's] mother, three weeks after the error occurred but before any of the incorrect strength of the drug was administered.

[Mr A] returned to [the pharmacy] on 16 March 2005 (23 days after initial dispensing), where he spoke to a duty pharmacist identified as '[…].' The duty pharmacist explained [Mr A's] rights as a consumer and filled in a prescription error form. [Mr A] described this pharmacist as 'very helpful'.

Subsequently [Mr B] wrote a letter of apology to [Mr A] in which he acknowledged and expressed contrition for the errors. He also instituted an extremely thorough review of pharmacy systems, and improved several pharmacy procedures.

(Although it is not strictly relevant to the investigation at hand, I have discussed this situation with [an overseas consultant nephrologist] and have developed the opinion that even if [Miss A] had taken the overdose, she would have been fairly unlikely to suffer serious long-term harm. I mention this fact only for the peace of mind of all parties involved in this incident.)

3. Commissioner's questions

3.1. In your professional opinion, was the service the staff at [the pharmacy] provided to [Miss A] appropriate? Please give reasons for your opinion with reference to individual staff members involved.

As two distinct errors occurred, I will deal with each of these separately.

3.1.1. Recormon dispensing error

The staff at [the pharmacy] did not provide an appropriate level of service to [Miss A] on the occasion when she was dispensed the incorrect strength of Recormon.

Trainee technician [Ms C] appears to have made a mistake in selecting the wrong drug strength, and should be reminded of the importance of consistent accuracy. I am sure she feels very unhappy about her error. However under current pharmacy standards (further outlined below), it is entirely the role of a supervising pharmacist to check a prescription is appropriate before dispatching it to the patient; this is doubly true when the technician is a trainee. Therefore, [Ms C] cannot be said to have breached any standards of service.

Although the pharmacy's proprietor [Mr B] is noble in assuming responsibility for this error (as per his letter to the HDC), ultimately the failure in service resulted from a lapse in the pharmacist who dispensed the prescription. Pharmacist [Ms D] failed to identify and correct an error made by a pharmacy technician in training.

It was her responsibility as the checking and supervising pharmacist to detect and ameliorate this error.

In my opinion, [Ms D] did not provide [Miss A] — a special and vulnerable patient on a rare drug — with an appropriate standard of care on this occasion. I believe pharmacy peers would regard the departure from care with mild disapproval.

Unfortunately, errors like this will happen in even the best pharmacy, and I am certain that the error was a momentary lapse in a good pharmacist, with no suggestion of malice. [Ms D] has my genuine sympathy, as do [Miss A's] family for any distress they have suffered.

3.1.2 Tacrolimus dispensing error

The staff at [the pharmacy] did not provide an appropriate level of service to [Miss A] on the occasion when she was dispensed the incorrect strength of tacrolimus.

Trainee technician [Ms F] appears to have made a mistake in selecting the wrong drug strength, and should be reminded of the importance of consistent accuracy. I am sure she also feels very unhappy about her error. However under pharmacy standards (further outlined below), it is entirely the role of a supervising pharmacist to check a prescription is appropriate before dispatching it to the patient; this is doubly true when the technician is a trainee. Therefore, [Ms F] cannot be said to have breached any standards of service.

Unfortunately, it is not clear which pharmacist was responsible for the tacrolimus prescription. The responsibility must fall on one of the two pharmacists in the pharmacy at the time — either [Mr B] or [Ms G]. However, there is no clear identifier on the tacrolimus CRC. I do not know how one would apportion responsibility for this lapse in service.

The fact that the dispensing pharmacist was unable to be identified was a failure of service in itself, and this specific failure is the responsibility of the charge pharmacist on duty, [Mr B].

In my opinion, the staff at [the pharmacy] did not provide [Miss A] with an appropriate standard of care on this occasion. As this was the second medication error that had occurred to [Miss A] in a four-month period, and as it was a significant error with an immunosuppressant drug, I believe pharmacy peers would regard this departure from care with moderate disapproval.

3.2. What standards apply in this case?

The standards that apply in this case are the standards that would apply to all practising pharmacists in New Zealand at the time that the incidents occurred. There are a number of applicable rules and regulations affecting pharmacy, but the following are particularly relevant to this case:

- Pharmacy Council of New Zealand Code of Ethics 2004[4]
- Pharmacy Council of New Zealand Competence Standards[5]
- Pharmacy Practice Handbook 2003[6]
- Medicines Regulations 1984[7]

3.3 Were those standards complied with?

Unfortunately, several components of the standards I have listed do not appear to have been complied with. I have outlined the precise areas of concern and explained why I think they were not complied with. (Note that some of the areas below are essentially repetitions of each other; I have listed them all for completeness.)

3.3.1 Pharmacy Council of New Zealand Code of Ethics 2004

Principle 2.6 — Dispensing

'The pharmacist who is responsible for the dispensing of a 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.'

This standard was not complied with in either of the two errors that occurred to [Miss A]: in both cases, a drug was incorrectly dispensed with the wrong strength.

Principle 3.8 — Dispensing

'The Charge Pharmacist must ensure that all dispensing is under the supervision of a pharmacist who must be ready and available in the professional area and willing to intervene, advise or check the dispensing and issuing of any prescription.'

This standard was complied with in the Recormon error, as although an error occurred, the dispensing was under the supervision of a pharmacist ([Ms D]). However, there is insufficient evidence to say whether this standard was complied with in the tacrolimus error.

Principle 3.9 — Identifiers

'The Charge Pharmacist must ensure that the identity of the pharmacist who has taken final responsibility for a dispensed prescription is able to be determined.'

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[4] Pharmacy Council of New Zealand (2004). *Code of Ethics 2004*. Available on the world wide web at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/CODEofEthics20044preps.pdf.
[5] Pharmacy Council of New Zealand Competence Standards Available on the world wide web at http://www.pharmacycouncil.org.nz/pharmacists/standard/documents/Standards1-7Sept04.pdf.
[6] Pharmaceutical Society of New Zealand (2003). *Pharmacy Practice Handbook 2003.* Wellington: Pharmaceutical Society of New Zealand.
[7] New Zealand Govt Legislation.

The official commentary to this principle states, '*The Charge Pharmacist must ensure that the identity of the pharmacist who has taken final responsibility is able to be determined. For example, if there is a paper copy of a prescription then the Charge Pharmacist must ensure that it bears an annotation or code that identified the pharmacist who has taken final responsibility for the dispensed medicine. For good practice, the pharmacist may also choose to have a record of others such as technicians who have been involved in the dispensing process. However, from a discipline perspective, only pharmacists can be considered in breach of the Code of Ethics.'*

This standard was complied with in the Recormon error as the checking pharmacist ([Ms D]) could be identified. However, this standard was not complied with in the tacrolimus error, as the dispensing pharmacist could not be identified.

Principle 6.4 — Supervision
'The pharmacist must provide appropriate direct supervision for other personnel for whom they have responsibility.'

Both errors resulted from mistakes made by technicians, which were not caught and corrected by a pharmacist working in a supervisory capacity. Therefore, the level of supervision cannot be said to be appropriate and thus this part of the standard was not complied with in either incident.

3.2.2 Pharmacy Council of New Zealand Competence Standards

Standard 1.1.2 — Maintains a consistent standard of work
'Examples of evidence: expects consistent standard of work from self & others; leads by example; explains quality systems & who is responsible in workplace'

Unfortunately, two errors for the same patient in a four-month period cannot be described as a consistent standard of work.

Standard 1.1.3 — Accepts responsibility for own work tasks and performance
'Examples of evidence: owns the results of her/his work; identifies tasks / aspects of practice for which she/he is personally responsible'

This standard was breached in tacrolimus error, as the identity of the pharmacist could not be established. By not signing the CRC, the dispensing pharmacist was not overtly accepting responsibility for his or her work.

Standard 1.1.5 — Works accurately
'Examples of evidence: minimises mistakes; acts immediately to rectify harm arising from mistakes; documents errors & steps taken to prevent their recurrence'

Unfortunately, two errors in the same patient in a four-month period cannot be described as an accurate standard of work.

4.1.2 — Takes responsibility for the work of non-pharmacist staff

'Examples of evidence: describes roles & responsibilities of non-pharmacist staff; supervises work of non-pharmacist staff e.g. technicians & assistants; works with others to prioritise & organise workflow'

Unfortunately, this standard does not appear to have been complied with, as in both instances errors were made by non-pharmacist staff but were not corrected by pharmacists in a supervisory role.

6.1.3 — Annotates prescriptions
'Examples of evidence: annotations as defined in DHB's Procedures Manual e.g. ensures annotations are distinguishable from what doctor has written; annotates according to hospital pharmacy procedures (e.g. SOPs)'

This standard was not met in the tacrolimus error as the pharmacist failed to fully annotate and sign the CRC form.

6.6.2 — Maintains a logical, safe and disciplined dispensing procedure
'Examples of evidence: selects correct product, dose form & quantity for each prescribed medicine; dispenses off prescription, not label'

This standard was not met in either case, as both involved incorrect dose strength of the prescribed drug. Although the pharmacy SOP on paper was adequate, the actual procedure taken by pharmacists involved in this case was obviously deficient.

3.2.3 Pharmacy Practice Handbook 2003
Part 2, Section 2.2, Standard 6 (Pharmaceutical Services)
'6.2 The pharmacist maintains a disciplined dispensing procedure which ensures the appropriate product is selected and dispensed correctly and efficiently.
6.2a Procedures for dispensing and supply of pharmaceuticals are developed, documented and approved by the pharmacist
6.2b The pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies their authenticity and appropriateness and determines their priority for dispensing

6.2c The pharmacist ensures that the dispensed medicine is selected correctly, packaged and stored appropriately and that sufficient information is given to ensure its appropriate use.'

The standard was not met in either case for reasons already outlined above.

Part 4, Section 4.1, 4.1.1 (Dispensing)
'… dispensary technicians … may only dispense under the direct personal supervision of a pharmacist.'

This standard was complied with in the Recormon error, as although an error occurred, the dispensing was under the supervision of a pharmacist ([Ms D]). However, there is insufficient evidence to say whether this standard was complied with in the tacrolimus error.

Part 6, Section 6.11 (Roles of Dispensary and pharmacy Technicians)
'... technicians must be supervised by a pharmacist at all times when involved with the dispensing and supply of medicines …'

'… under no circumstances will a technician give a prescription to a patient unless it has been checked and initialled by a pharmacist …'

This standard was complied with in the Recormon error, as although an error occurred, the dispensing was under the supervision of a pharmacist ([Ms D]). However, there is insufficient evidence to say whether this standard was complied with in the tacrolimus error.

3.2.4 Medicines Regulations 1984 — Part 7 (Prescriptions) 42(1)(a)
'The following persons may not dispense prescription medicines unless under the direct supervision of a pharmacist: a) dispensary technicians'

This standard was complied with in the Recormon error. Although an error occurred, the dispensing was under the supervision of a pharmacist (Ms D).
There is insufficient evidence to say whether this standard was complied with in the tacrolimus error.

3.4 Are there any comments that need to be made regarding the pharmacy's organisation and systems in light of the dispensing error involving: a) The Recormon; and b) The Tacrolimus?

In both cases, I believe the pharmacy's organisation and systems were adequate. I note the pharmacy passed a Pharmaceutical Society audit in 2002 and their 'old' SOP seems to be perfectly satisfactory if adhered to. Both errors in this

unfortunate case resulted from a deviation from the pharmacy's systems by individuals. The pharmacists responsible simply failed to detect the error.

Here I must note that [the pharmacy] appeared to be understaffed and overworked through no fault of [Mr B]. [Mr B] said the pharmacy was 'extremely busy' and he 'lamented the difficulties in attracting pharmacists to our rural pharmacy'. This is by no means an excuse, but is a very important context for the error.

The errors with [Miss A's] prescriptions should now have alerted the pharmacy that, although adequate operating procedures were in place, they were not functioning effectively. This prompted [Mr B] to undertake a comprehensive review and I am confident that he has done everything possible to remediate the situation.

3.5 Were appropriate steps taken to prevent further dispensing errors after the Recormon dispensing error?

Yes. The Pharmacy Defence Association spells out clearly the appropriate steps to take in response to a medication error[8,9]:

- If patient notifies an error, the appropriate response is to express immediate concern;
- If the error is obvious, the pharmacist should acknowledge the error;
- The pharmacist should ask questions of the patient to find out whether he or she has taken any of the incorrect medication, and, if so, what symptoms have been experienced;
- The pharmacist should inform the patient about what the incorrectly dispensed medication is normally used for and its possible side effects [note this action may not be entirely necessary in this instance as the error concerned dosage rather than a new medication];
- The pharmacist should notify the prescriber of the situation, how the patient is, and what actions have been taken to date [note this action may not be entirely necessary as the patient did not consume any of the wrong medication];
- All aspects of the incident should be documented;
- Investigate to ascertain the possible cause of the error;
- Keep the patient informed of the outcome of the investigation; and
- If necessary, implement further checking systems to prevent a similar error occurring again.

[8] Pharmaceutical Society of New Zealand (2002). Pharmacy Defence Association: How to respond when a dispensing error occurs. *Interactions.* Vol 60, p.2.
[9] Pharmacy Defence Association of New Zealand (2005). How to respond when a dispensing error occurs. *The Pharmacist's Guide to Member Benefits*, p.10; available on the world wide web at: http://www.pharmacydefence.co.nz/errors.cfm.

Based on the information I have relating to this incident, I believe the steps taken by [Mr B] — acknowledging the error and apologising, discussing the error with staff and checking procedures — were appropriate and reasonable steps to prevent further errors.

It is therefore very unfortunate to note that a further error occurred with the same patient. The best SOPs in the world have little value if they are not followed precisely.

3.6. Were the steps taken after the Tacrolimus dispensing error appropriate?

Yes. I refer to my previous answer. In this case, [Mr B] not only took appropriate actions but also instituted a very thorough review of pharmacy systems and instituted extra error-prevention procedures, with improvements in annotation procedures, production of stamps and checklists, and use of transparent bags for dispensing to enable last-minute checks.

3.7 Should any other steps be taken to improve the systems at [the pharmacy]?

I believe that the current systems in place at [the pharmacy] are adequate. However, I must emphasise that such systems are only effective if they are adhered to by all staff. I can only suggest that [Mr B] impresses on his staff that procedures must be followed religiously (and I am quite certain he has already done so).

However, I would make some suggestions for improvement. I emphasise these are *suggestions* and should not be interpreted as addressing a deficiency. I simply wish to make some constructive comments that [Mr B] may consider implementing, at his discretion.

- An expert advisor in case HDC10717 suggested that pharmacy bags should be stamped with words to the effect, 'if you have any concerns or questions about your medicine, please do not hesitate to contact our pharmacy at 123-4567.' This encourages patients to respond pro-actively to questions they may have, for instance if they discover their capsules have unexpectedly changed colour.
- Implement an additional final 'five-second' check where drug and strength are reviewed. Although this may seem unnecessary, I have it implemented in my pharmacy and it has proved invaluable in preventing errors 'slipping through the cracks'.

4. Auxiliary Comments

I wish to make some auxiliary comments in my report.

4.1 Manufacturers' labelling of drug boxes

Although not an overbearing factor in this case, I urge the HDC to consider the adequacy of manufacturers' box labels in this and any future cases of prescription error.

I have reviewed the manufacturers' boxes for Recormon and tacrolimus and I am concerned that the tacrolimus (Prograf) packaging, while meeting all legal requirements under the Medicines Regulations 1984, is far from ideal. The letters for drug strength are barely 2mm high when there is ample room on the box for a clearer, larger, bolder typeface. I contrast the Prograf box with those of the drug Betaloc, which I consider to have superior manufacturer's labelling.

Pharmacists expect drug containers to be clear and straightforward to minimise stress in dispensing. While manufacturers' labels have to meet legal requirements, they are sometimes 'just sufficient' and could be improved to everyone's benefit. I suspect that the small size of lettering on the Prograf box may have been a contributory factor in this error. Ultimately, however, all responsibility must rest with individuals in [the pharmacy].

I refer to appendix A where I have reproduced the box 'nets' with additional comments.

4.2 Identifiers on prescriptions with owings

The situation regarding pharmacist identifiers on prescriptions with 'owings' can be particularly unclear. It is important in all pharmacies that each owing item is identified to a particular pharmacist who takes responsibility for it. This is not just a comment for [the pharmacy], but for all pharmacies.

4.3. Emphasising the importance of methodical records

This is not an isolated incident — in doing background research on this error, I found several cases where the dispensing pharmacist could not be identified due to insufficient paperwork. No one wants to see pharmacy 'bogged down' in bureaucratic box ticking, but I think a reminder on the importance of simple stamp-and-signature procedures would be timely. This is not just a comment for [the pharmacy], but for all pharmacies.

5. Conclusion

All patients are entitled to expect and receive a good standard of care. However, a young patient with a chronic and potentially life-threatening condition, taking a regimen of rare and expensive drugs, should be afforded a special standard of care.

Considering all the evidence, it is obvious that [the family] have been distressed by the two errors that have occurred in [Miss A's] dispensings, and naturally want to ensure their daughter is well looked after.

> Similarly, [the pharmacy] also desire to provide optimum care for their patients — a goal that can be difficult in the overworked, understaffed and often hectic environment of rural pharmacy.
>
> [Mr B] appears to be a hard-working and conscientious pharmacist. I wish to commend him for the way he has positively and constructively responded to this unfortunate chain of events. This incident has clearly resulted in a stronger emphasis on correct procedure at [the pharmacy].
>
> My wish is that this incident should be seen as a learning experience for all parties and that a stronger pharmaceutical profession will emerge from the lessons of these unfortunate mistakes."

Addendum

A member of my staff telephoned Mr Fraser on 25 January 2006 to clarify a number of issues raised by the investigation.

Mr Fraser was asked to comment on the informal practice that arises when a pharmacy is very busy and staff numbers are low, whereby other pharmacists help with processing individual items on a prescription. Mr Fraser advised that the practical reality is that this type of practice does occur when pharmacists get very busy. However, even if other pharmacists process and check individual items on the list, it is still the responsibility of the person who signs off on the prescription to carry out a final check that all of the items on the list match up with the medicines that are being dispensed. Accordingly, it is an acceptable practice provided that one pharmacist ultimately takes responsibility for the correct dispensing of the medicines.

Mr Fraser was asked whether the fact that Recormon and tacrolimus were rare medicines had any bearing on this matter. Mr Fraser advised that these are medicines that most pharmacists deal with only occasionally. In his experience, pharmacists are usually accurate with very common and very rare medicines, but that it is the occasional medicines that require the greatest diligence.

Responses to provisional opinion

Ms D
In response to the provisional opinion, Ms D submitted that she followed the procedure for partially dispensed scripts as had been previously advised by Ms E, the dispensary manager at the time of the Recormon dispensing error. She described this procedure as follows:

> "The available items in stock are to be dispensed off the script.
> Those available dispensed items are to be ticked when done.

> The script is then to be signed off by the Pharmacist who has checked these ticked available items.
> The dispensing for that time is then complete.
> The unavailable item is left until stock arrives, with the partially completed script remaining on the back bench.
> When stock arrives it is to be initialled beside the third part sticker by the technician and or pharmacist and given out."

Ms D said she ticked the Ventolin and Flixotide and signed off the script for these items. She left the third part label for the Recormon to be issued later. The Recormon was not ticked but was later initialled by the technician, Ms C. The last step should have been for another pharmacist to sign the third part label when the stock arrived.

Ms D said that the Recormon would have been ordered and unpacked by a technician, and put in the refrigerator when it arrived.

Ms D submitted that she was not present when the Recormon arrived so was not supervising the technician at that time, nor was she involved in the dispensing. She was not involved in any discussions about the error. The first time she became aware of the error was when the tacrolimus error was reported. Ms D understands that the reason she "was not informed because I was not at work when the Recormon arrived and was unaware of any such error having had occurred".

Ms E

Ms E was contacted on 9 March 2006 and confirmed that the informal practice for partial dispensings that Ms D described was the system that the pharmacists followed, but it was not written down. She said that partial dispensings were rare, and it was also unusual for pharmacists to start a script and not finish it. Ms E said that anything that was put on the back bench was frequently checked.

Mr B

In response to the provisional opinion, Mr B submitted that Ms D's signature may have misled another pharmacist into believing that the entire prescription had been authorised.

Mr B stated that the new procedure that has been implemented is for the pharmacist to sign the right-hand side of the third part label. The technician checks that this has been done.

Ms E was the dispensary manager and charge pharmacist at the time of the Recormon error. Mr B stated that she was responsible for the audit protocols, standard operating procedures and reviews. The error was not reviewed owing to it being a very busy period just before Christmas, and then Ms E resigned in January.

Mr B said he undertook a full review of procedures following the tacrolimus error in March.

The tacrolimus error involved the dispensing of 20 tablets of the incorrect strength on 22 February; 100 tablets of the correct strength were dispensed the following day. Mr B said that the technician failed to check that a pharmacist had signed the prescription. The error may well have been picked up had this check been performed. As a result, it cannot be established whether the 20 tablets dispensed on 22 February were checked by a pharmacist before being given to Mr and Mrs A.

Mr B informed me that a major reason for both dispensing errors was that pharmacy staff were unaware at the time of dispensing that both Recormon and tacrolimus came in different strengths. They were both rare drugs.

Mr B also commented on the packaging of the medications. He said that the size of the manufacturer's labelling could have been a factor. He noted that the Recormon boxes are identical except for the strength. Mr B suggested that the boxes should be the same colour as the syringes.

Further information
Mr B was contacted on 17 March 2006 to clarify a number of issues raised by the responses to the provisional opinion.

Mr B confirmed that Ms D did not work on 30 November but did work on 1 December. He outlined what he thinks happened — that the script was processed on 30 November by the technician, and was put aside on the bench because the Recormon was not in stock. Processing the script would have initiated ordering the stock. Ms D worked on 1 December and ticked the Flixotide and Ventolin, which were given to the customer, and signed the stamp (dated 30 November 2004) as checked. He said that they do not record when a customer collects their medication or part of it. The time when the medication was picked it up could be traced only if the customer had to pay a charge for it.

Mr B said that the Recormon would have come in later on 1 December and been prepared by the technician and put in the refrigerator. It is most likely that when the customer came in to pick up the script, whoever picked it up saw that it had been initialled as checked, and handed it out.
The Recormon that was handed out was the Recormon that had been ordered for another customer on 29 November, and had not been picked up by the time Mr A collected Miss A's prescription.

Further independent advice

Mr Fraser provided the following further advice regarding issues raised by Ms D and Mr B:

"**1. Introductory Comments**

Thank you for the opportunity to offer further advice to the Commissioner on case 05/03953/WS regarding [Miss A]. This further advice should be read in conjunction with my first advice (dated 12th October 2005). Where this further advice differs from my advice in the original report, then the latter advice should be seen as superseding the former.

2. Information Reviewed

I have reviewed the following information:

1. Letter of complaint from [Mr A], received by HDC office on 21 March 2005, marked with an 'A'.

2. Copy of a letter sent to [Mr A] by pharmacist [Mr B], dated 17 March 2005, faxed to HDC office by [Mr A] on 4 April 2005, marked with a 'B'.

3. Letter in response to the Commissioner from [Mr B], with supporting documentation, received on 27 April 2005, marked with a 'C'.

4. Notes taken during a telephone interview with [Mr B] on 16 June 2005, marked with a 'D'.

5. Response to the provisional opinion dated 9 February 2006 from [Mr B], marked with an 'E'.

6. Response to provisional opinion dated 14 February 2006 from [Ms D], marked with an 'F'.

8. File note of a telephone conversation with [Ms G] on 21 February 2006, marked with an 'H'.

9. File note of a conversation with [Mr B] on 8 March 2006, marked with an 'I'.

10. File note of a conversation with [Ms E] on 9 March 2006, marked with a 'J'.

11. File note of a conversation between [HDC investigator] and [Mr B], dated 17 March 2006.

12. My original report to the Commissioner, dated 12 October 2005.

3. Directions

After reviewing the above material, I have been directed to make any additional comments I might have. In particular, I have been asked to comment on the system [Ms D] describes for partially completed scripts while waiting for stock to arrive, and whether she should have signed the stamp or the third part labels.

4. Further Advice and Comments to the Commissioner

4.1. Clarifying 'owings' and 'partial dispensings'

In my original report to the Commissioner, I may have been slightly ambiguous when referring to 'owings' and 'partial dispensings'. To dispel any confusion, I will thoroughly define both terms now.

An **owing** situation (or 'owe') occurs when a prescription is requested by a patient, and less than the complete amount of drug is able to be supplied. This is usually because the pharmacy does not have sufficient stock of the drug on hand. The normal procedure for an owing entails entering the prescription into the pharmacy computer, and giving the patient a proportion of the prescribed medication with instruction to return and collect the remainder when it becomes available. Pharmacies will have varying procedures for managing the 'owe'.

The Tacrolimus error related to an owing. [Miss A] had a prescription for 120 tablets of Tacrolimus. She was given 20 tablets (of incorrect strength) with an owing of 100. The remainder was later dispensed correctly.

A **partial dispensing** occurs when a patient requests multiple prescription items on a single prescription form, and some of the items are dispensed, while others are not. There are varying reasons for this — for instance, if none of the medication can be supplied, or if the doctor has asked the pharmacy to wait for a few days before dispensing. At a later time, the remaining items on the prescription form may be dispensed. Procedures for partial dispensing will vary depending on the pharmacy involved.

The Recormon error involved a partial dispensing on a repeat prescription. Miss A's caregivers requested repeats of Flixotide and Ventolin (asthma medications) as well as Recormon. The Flixotide and Ventolin were dispensed immediately while the Recormon was not. When the Recormon was later dispensed, an error occurred and was not detected. (I elaborate on this situation below.)

While owings and partial dispensings have many aspects in common (and are occasionally referred to synonymously), they are in fact two distinct situations with different procedures for each.

4.2. Re-considering the Recormon Error

It is apparent that some matters of fact have been clarified since I submitted my first opinion to the Commissioner. In particular, the involvement of pharmacist [Ms D] in the Recormon dispensing error needs to be completely reviewed.

In my original advice to the Commissioner (p. 4 of my first report) I had assumed that [Ms D] had 'signed off' on the Recormon error, as this fact was stated in the case summary supplied to me. In her response to the provisional opinion, [Ms D] vociferously denies that she was involved (letter dated 14 Feb 2006, marked 'F'), and [Mr B] now seems to fully corroborate her version of events (in his conversation on 17 March 2006).

After fully reviewing [Ms D's] explanation, I can now state with a high degree of confidence that she did **not** have any direct involvement in the error, and as such did not breach any applicable standards of care.

The confusion seemed to stem from an unusual combination of factors:

- The Recormon Certified Repeat Copy (CRC) form for the Recormon also referred to prescriptions for Ventolin and Flixotide (asthma medications). These drugs were dispensed on a different day to the Recormon. That is, a partial dispensing occurred. On the first partial dispensing (for Ventolin and Flixotide), Pharmacist [Ms D] oversaw the dispensing according to standard operating procedure at [the pharmacy].
- The Recormon was dispensed on a later date, and the wrong strength of Recormon was somehow selected. This was prepared by trainee technician [Ms C] and **not** checked by Pharmacist [Ms D], as she was not present.
- Somebody (it is not clear who) gave the Recormon to [Mr A]. They probably looked at the script and saw [Ms D's] initial, and assumed the Recormon had been checked and approved by a pharmacist when in fact that approval *related to the earlier partial dispensing*. Thus, the Recormon was dispensed without being properly checked, although it appeared on paper that it had been.
- The error is slightly complicated by the fact that both Pharmacist [Ms D] and trainee technician [Ms C] have names starting with an '[…]' and the initial on the CRC next to the Recormon and on the pharmacy stamp is an '[…]'. It may have been obvious to staff at [the pharmacy] but to an outsider it is rather confusing to follow the chain of events leading up to the error. Only when the circumstances are explained in detail, and viewed in context of a partial dispensing, is the true situation clear. Therefore, I think we can be forgiven for mistakenly attributing responsibility to [Ms D] when in fact she had no involvement in the error.

In my original report, I concluded that [Ms D] did not provide [Miss A] with an appropriate standard of care (p.7) and further stated that the pharmacy's organisation and systems were adequate (p.11). However, in light of the

significant new understanding I now have, I must say that [Ms D] provided a perfectly satisfactory standard of care.

It seems clear to me that, upon fully considering these new facts, no individual directly involved in the error fell short of the requisite standard of care that would be expected of them by their pharmacist peers.

Pharmacist [Ms D] was simply following standard operating procedure during the first partial dispensing, and was not present when the second, erroneous, partial dispensing happened.

Trainee technician [Ms C] made a potentially serious mistake in selecting the wrong Recormon, but she did not fall short of any formal pharmacy standard. As I discussed in my first report, trainee technician errors are almost always the responsibility of the supervising pharmacist. Unfortunately [Ms C] was operating under an inadequate operating procedure that, in this fairly unusual situation, left her dispensing in a semi-unsupervised state while giving the illusion that she was fully supervised.

It is not clear who actually handed out the Recormon to [Mr A], but this is irrelevant. Whoever gave out the medication was probably following procedure correctly, but the procedure itself was inadequate.

In summary, I conclude that the Recormon error was the result of a *systemic failure* at [the pharmacy] due to a series of errors and oversights that was not anticipated in the pharmacy's standard operating procedures.

4.3. [Mr B's] letter

[Mr B's] letter in response to the provisional opinion (dated 9 Feb 2006 and marked 'E') places the errors in context and clarifies certain matters of fact.

Points to note are:

- [Mr B] corroborates [Ms D's] version of events, and acknowledges that the pharmacy standard operating procedure was inadequate.
- The inadequate dispensing procedure had been prepared by pharmacist [Ms E] — but [Mr B] believes 'justice would be better served by all aspects of blame being attributed to [him] as pharmacist proprietor'.
- [Mr B] once again noted the very heavy workload his pharmacy was facing. While this does not excuse the errors, it is an important context.

Upon further analysis, it is clear that the pharmacy's standard operating procedures were inadequate in the case of the Recormon error. They did not adequately deal with partial dispensings on different occasions and [Mr B] acknowledges this.

4.4. Evaluating the pharmacy's Dispensing Procedure

The inadequacy in [the pharmacy's] dispensing procedure at the time of the Recormon error was largely one of omission – that is, it failed to fully anticipate a rather complex and improbable sequence of events leading to error in the second part of a partial dispensing.

The question to ask now is whether the pharmacy's standard operating procedure at the time of the Recormon error departed from an expected standard of care.

In developing this advice to the Commissioner, I very carefully weighed up what is expected of a pharmacy's standard operating procedure. I discussed this issue with colleagues, including a [law] professor specialising in administrative law.

Points suggesting an appropriate standard was not adhered to

- Through omission, [the pharmacy's] dispensing procedure at the time of the Recormon error failed to anticipate, detect and correct a serious error, resulting in a vulnerable patient receiving the wrong drug strength.

Points suggesting an appropriate standard was adhered to

- The dispensing procedure was checked and passed a quality audit by the Pharmaceutical Society of New Zealand.
- The situation that the dispensing procedure failed to prevent was, in my opinion, a reasonably complex and improbable one. I imagine that most pharmacies in New Zealand would not anticipate this sequence of events in their procedures. It seems unfair to hold [the pharmacy] to a higher standard than the rest of the pharmacies in New Zealand.
- It is unreasonable to expect a standard operating procedure to anticipate every possible eventuality. If that were the case, the S.O.P. manual would probably be two feet thick and completely unmanageable.

After considering these points, I must arrive at the conclusion that although the pharmacy's dispensing procedure at the time of the Recormon error contained an omission, the procedure was still adequate by current standards.

In this instance, it is clear that a chain of mistakes and oversights led to the error. It is very difficult for me as a pharmacist to single out any one individual and say they failed to offer an adequate standard of care. I can only say that the pharmacy as a whole suffered a systemic failure and as a result failed to provide an appropriate standard of care to [Miss A].

As I explained in my first advice to the Commissioner, I feel that my pharmacy colleagues would regard the Recormon dispensing error as a departure from standard warranting mild disapproval.

4.5. Raising Standards and Preventing Error Recurrence

As I mentioned in Section 4.2 (page 14) of my original report, I feel it is important to educate pharmacists about the importance of good procedures for owings and partial dispensings. This case should be a 'wake up call' for pharmacies to revise and expand their policies and procedures in this area.

I also believe that all pharmacies should have a 'fail safe' policy that ensures no matter what happens, a pharmacist always actively vets some point in the dispensing process. (For instance, in my pharmacy, technicians and assistants can do various tasks but they must never place prescriptions into the dispensing bag. That is a task reserved for a pharmacist, who must actively check the prescription before bagging it.)

4.6. Conclusion

In closing, I want to add a personal note. I have reviewed this case in good faith and from the position of an impartial pharmacist peer. I know that a similar series of mistakes could have happened to any pharmacist, including myself. I know that it could just as easily be me under the media spotlight with [Mr B] reviewing my case.

I think it is worthwhile repeating my closing statement from my first advice to the Commissioner:

Considering all the evidence, it is obvious that [the family] have been distressed by the two errors that have occurred in [Miss A's] dispensings, and naturally want to ensure their daughter is well looked after.

Similarly, [the pharmacy] also desire to provide optimum care for their patients — a goal that can be difficult in the overworked, understaffed and often hectic environment of rural pharmacy.

[Mr B] appears to be a hard-working and conscientious pharmacist. I wish to commend him for the way he has positively and constructively responded to this unfortunate chain of events. This incident has clearly resulted in a stronger emphasis on correct procedure at [the pharmacy].

My wish is that this incident should be seen as a learning experience for all parties and that a stronger pharmaceutical profession will emerge from the lessons of these unfortunate mistakes.

I hope that with my advice the Commissioner can now bring this case to a speedy resolution. I am always available to offer more advice on this case if needed."

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 Pharmacy Council of New Zealand *Code of Ethics* (2004) states:

"**Principle 2.6 — Dispensing**
The pharmacist who is responsible for the dispensing of a 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.

Principle 3.9 — Identifiers
The Charge Pharmacist must ensure that the identity of the pharmacist who has taken final responsibility for a dispensed prescription is able to be determined.

Principle 7.3
The Charge Pharmacist is the pharmacist who is present in the pharmacy or other place from which pharmaceutical services are provided, and at any particular time is responsible for overall control of the provision of pharmaceutical services from that place."

Opinion: Breach — The pharmacy

Recormon dispensing error
Under Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code), Miss A had the right to pharmacy services that met professional and ethical standards. The standards that apply in this case are determined by the

Pharmacy Council of New Zealand and state that all dispensed prescriptions must be finally checked to ensure accuracy, and the checking pharmacist must be identifiable.

Miss A was dispensed an incorrect dose of Recormon. It is not disputed that the technician in training, Ms C, made a mistake when selecting the strength of the Recormon when she chose Recormon 4000, which had arrived for another patient, rather than the Recormon 3000 prescribed for Miss A.

However, my expert advisor, Mr Fraser, explained that it is the role of the supervising pharmacist to check that the prescription has been correctly processed before it is given to the patient. This is particularly important when the technician is a trainee. Mr Fraser advised that Ms C cannot be said to have breached any standards of service in this case. Ms C's mistake was not identified and corrected by the supervising pharmacist, and only pharmacists can be considered to be in breach of the Code of Ethics.

In this case, the pharmacy had Standard Operating Procedures in place to cover the processing and checking of prescriptions. Mr Fraser confirmed that these procedures were adequate. However, the procedures did not cover what occurred in relation to the Recormon dispensing error, and the failure to clearly sign and date the scripts has created difficulties establishing exactly how and when each dispensing error occurred, and who was responsible for those errors.

In his response to my investigation, Mr B explained that he could not be sure that it was Ms D who had checked the Recormon on Miss A's CRC form. This was because an informal practice had developed at the pharmacy during busy periods, whereby other pharmacists would help to process prescriptions. The medicines were selected by the pharmacy technicians, and the pharmacists would share the role of checking the medicines against the prescription or CRC form. One of the pharmacists would then sign the bottom of the prescription to authorise the medicines being dispensed.

Mr Fraser advised that the practical reality is that this type of practice does occur when a pharmacy is busy and staff numbers are low. He said it is acceptable for other pharmacists to assist with checking provided that one pharmacist takes the time to carry out a careful final check of the medicines and the prescription before the medicines are placed into the dispensing bag. It is that pharmacist who should sign the prescription and take overall responsibility for accuracy. Mr Fraser also noted that Recormon is one of those medicines that pharmacists deal with only occasionally. He advised that pharmacists are usually very accurate with very common and very rare medicines, but that it is the occasional medicines that require the greatest diligence.

Mr B stated that Ms D may have also authorised the other items on the prescription in anticipation of the Recormon on order arriving. Ms D described the informal practice that had developed at the pharmacy for partial dispensings (where some of the medicines are in stock, but other items are ordered in). She said that the available items were dispensed and ticked when completed, and the pharmacist signed off the

script for those items. The partially completed script remained on the back bench until the other stock arrived. When the stock arrived it was processed and the third part sticker for that item(s) was initialled by the technician and/or pharmacist, and checked before being given to the customer. Ms E confirmed this was the practice at the pharmacy at the time. Mr B stated that there was no strict procedure in place because it did not occur very often, and usually a pharmacist would check an entire script.

I note that the practice for partial dispensings was not covered by the Standard Operating Procedures. There was an informal practice, but in the case of the Recormon error, it was inadequate because it did not identify which pharmacist had checked individual items on the prescription, when the checks were made, or who was responsible for checking the prescription overall. The system of signing the pharmacy stamp for a partial dispensing, prior to all the items being checked, was clearly open to misinterpretation.

This explains why Mr B is not sure whether Ms D checked the Recormon, even though it was her signature that had authorised dispensing of the medicines by initialling the pharmacy stamp.

I note that the new Standard Operating Procedures that were introduced by the pharmacy after the second dispensing error require pharmacists to initial in green pen each item they have checked, so it is clear who has checked each item.

In my view, the pharmacy was required to have a clear system for partial dispensings. Given the informal practice of sharing responsibility for checking that had developed, it was important to ensure that when the responsibility for processing a prescription was shared, individual pharmacists were accountable for the items they checked, and that one pharmacist undertook responsibility for performing a final overall check.

As there was no adequate system in place to cover the informal practice of sharing responsibility for prescriptions at the time when the Recormon was incorrectly dispensed, I consider that the pharmacy is liable for the failure to provide Miss A with an appropriate standard of care and therefore breached Right 4(2) of the Code.

Opinion: Breach — Mr B

Tacrolimus dispensing error
The Pharmacy Council of New Zealand *Code of Ethics* (2004) states in Principle 2.6:

> "The pharmacist who is responsible for the dispensing of a 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."

Principle 3.9 of the Pharmacy Council of New Zealand *Code of Ethics* states that the charge pharmacist must ensure that the identity of the pharmacist who is responsible for a dispensed prescription is ascertainable.

It is not disputed that Miss A was dispensed an incorrect dosage of tacrolimus on 22 February 2005.

The trainee technician, Ms F, selected the wrong strength of tacrolimus. My expert commented that technicians in training cannot be found to have breached any standards of service, as it is the responsibility of the supervising pharmacist to ensure the dispensing is correct. Ms F's error was not identified by the supervising pharmacist. However, it is unclear which pharmacist was responsible for checking the prescription before the medication was given to Miss A. Neither of the pharmacists on duty on that day (Mr B or Ms G) signed the certified repeat copy. Ms G stated that she worked on methadone prescriptions at the back of the pharmacy that day, and so would not have been involved in the error. Mr B said that it was likely Ms G was not involved, although if the pharmacy had been busy she may have helped out. He said that if a pharmacist did check the tacrolimus, it was most likely that it was him. However, there is no evidence that the prescription was actually checked by a pharmacist.

Principle 7.3 of the *Code of Ethics* states that the charge pharmacist is responsible for the overall control of the pharmacy. Principle 3.9 states that the charge pharmacist must ensure that the identity of the pharmacist who has taken final responsibility for a dispensed prescription is able to be determined.

Mr Fraser advised that staff at the pharmacy did not provide an appropriate level of service to Miss A when it dispensed the incorrect strength of tacrolimus to her. By failing to ensure that the tacrolimus was the correct strength, the supervising pharmacist did not comply with Principle 2.6 of the *Code of Ethics*, the Pharmacy Council Competence Standards, or the Pharmacy Practice Handbook 2003.

My expert stated that the inability to identify the supervising pharmacist in this instance was, in itself, a failure, and was the responsibility of the charge pharmacist on duty, Mr B.
Mr Fraser stated:

> "In my opinion, the staff at [the pharmacy] did not provide [Miss A] with an appropriate standard of care on this occasion. As this was the second medication error that had occurred to [Miss A] in a four-month period, and as it was a significant error with an immunosuppressant drug, I believe pharmacy peers would regard this departure from care with moderate disapproval."

I agree with my expert that the failure to check that the correct strength of tacrolimus was dispensed to Miss A was below the standard of care to be expected from staff at the pharmacy. Unfortunately, it is not possible to identify who the checking pharmacist was

in this instance, because there is no pharmacist signature on the certified repeat copy. It was Mr B's responsibility to ensure that the dispensing pharmacist was able to be identified in accordance with Principle 3.9 of the *Code of Ethics*.

Mr B explained that both dispensing errors occurred in circumstances where the pharmacists were under the pressure of a very heavy workload and staff shortages. While I am aware that rural pharmacies experience significant difficulties in trying to attract and retain staff, it is the overriding responsibility of the charge pharmacist to enure that pharmaceutical services are being provided safely at all times. In situations where resources are under pressure, it may be necessary to review standard operating procedures to ensure that quality is not being compromised.

As the charge pharmacist, Mr B was under an obligation to take steps to analyse the Recormon error and ensure that pharmacy systems were reviewed, to avoid a repetition. This should have involved accurate incident reporting and relevant, timely discussions with staff immediately after the Recormon dispensing error occurred. It is not clear from the incident report at the time who the staff members involved in the error were, or precisely how the error occurred. Mr B stated that all dispensing staff were alerted to the fact of multiple strengths. However, it does not appear that any further steps were taken to investigate the cause of the error or prevent it occurring again. The standard operating procedures provided by Mr B were not reviewed until after the tacrolimus dispensing error.

Mr B was also responsible for the overall provision of pharmaceutical services from the pharmacy. In those circumstances, he was responsible for improving the pharmacy's systems after the Recormon dispensing error occurred. He was also responsible for the tacrolimus dispensing error, and for the failure of his staff to follow standard operating procedures on 22 February 2005. In these circumstances, Mr B breached Right 4(2) of the Code.

Opinion: No Breach — Ms D

Recormon dispensing error
As explained above, it has not been possible to establish whether a pharmacist did check the Recormon before it was dispensed, or, if it was checked, by whom.

Ms D was not working in the pharmacy when the Recormon arrived. The dates on the CRC form suggest that the repeat prescription was requested on Tuesday, 30 November 2004. It is not clear whether the Ventolin and Flixotide were collected that day. Ms D did not work on Tuesdays and yet she said she checked these items, ticked them as correct, and signed the pharmacy stamp. Mr B confirmed that Ms D worked on Wednesday, 1 December 2004, and believes she checked the Ventolin and Flixotide that day.

Mr Fraser advised that it is possible that the documentation for the prescription was prepared on 30 November 2004 in readiness for the Recormon arriving the next day. That would explain why Ms D signed documentation dated 30 November even though she was not there on that date.

In my view, the most reasonable explanation of what happened was that Ms D checked the Ventolin and Flixotide on 1 December 2004. The 4000IU Recormon arrived, was prepared by the technician, and was given out without being checked by a pharmacist, because Ms D had signed the stamp to indicate the prescription had been checked. Ms D explained that this was the informal system at that time, and this was confirmed by Ms E.

As Ms D was not present when the Recormon arrived, and she appears to have followed the informal practice at the time, I do not find her to be in breach of the Code.

I am pleased to see Mr B's confirmation that all staff have reviewed their practice and received specific instruction in relation to dispensing, supervision and record-keeping. I trust that Ms D has done so in light of the lessons to be learned from this case.

Other comment

The pharmacy
Although the standard operating procedures and pharmacy systems at the pharmacy were generally adequate, these procedures were not followed by individual staff members in either instance. I note my expert's comment that "[t]he best SOPs in the world have little value if they are not followed precisely". Clearly, the systems were not followed correctly and were therefore not operating effectively.

I note Mr B's comments about the high workload at the pharmacy, the dedication of staff, and the struggle to provide a high standard of service despite the difficulties of attracting professional staff. These are important background factors, but they do not detract from the professional and ethical responsibilities of staff and the pharmacy to provide services of an appropriate standard.

Identity of pharmacist
It is important for pharmacists who are responsible for "owed" items on a prescription to be able to be clearly identified. My expert stated that there were other instances in the documentation provided by the pharmacy where the dispensing pharmacist was not clearly identified. This case highlights the need to remind staff of the importance of following simple stamp and signature procedures. Clear and distinctive signatures are essential where two staff members have similar initials, to ensure that staff signatures are clearly distinguishable.

Incident reports
My investigation revealed that the quality of incident reports and the investigation into the first error was poor. The incident reporting forms do not identify the staff members involved in either dispensing error, or the underlying cause of the first error. The first incident report dated 30 November is not signed, and the second incident report dated 16 March 2005 is signed by "[…]". I note Mr B's comment that the first dispensing error occurred during a very busy time prior to Christmas, and the dispensing manager left the pharmacy in January. This would have impacted on the review. While I acknowledge the difficult context, appropriate steps should still have been taken to determine the cause of the error. Future errors are unlikely to be prevented if the causes are not clearly identified and explained for staff to learn from.

There is also no evidence that any steps were put in place after the Recormon error, to ensure that future prescriptions were appropriately annotated so that the responsible pharmacist could be identified. Staff were alerted to the different strengths of the medication, but no other steps appear to have been taken. Steps were taken after the second dispensing error. However, had appropriate investigations and improvements been made after the first error, the second one might never have occurred.

Both errors in this case involved rare and expensive medication for a young and vulnerable patient. Extra care should have been taken by pharmacy staff in both cases.

Media impact
Mr B informed me:

> "We have also been subjected to grossly unfair attention, speculation and comment from television and media and information we have supplied as part of the process requirements was handed to TV1 news. We have had staff leave in the time of this process and this could be unfair to them. The duress we have had to suffer has been excessive to say the least. Because of the nationwide nature of the media frenzy, we will never be able to get over the damage to our professional reputation and personal grief. We have become victims of the process.
>
> We do feel that it is unfair that information required and submitted to us as part of this investigation requirement has been given to new media (by the family) before you have presented your final report. I do not believe that you will ever understand the damage and grief this has caused because of false and grossly over exaggerated claims."

It was unfortunate that the media became involved in this matter before the final outcome of the investigation was reported. As this case illustrates, premature publicity prior to the completion of an investigation is necessarily incomplete, often inaccurate and frequently unfair and prejudicial.

Actions taken

Mr B
Mr B has already apologised to Mr A (both verbally and in writing), discussed the errors with his staff, and reviewed the pharmacy's standard operating procedures and made a number of improvements. He is to be commended for these actions.

Mr B has confirmed that:

- staff have reviewed their practice and received specific training in relation to dispensing, supervision, and record-keeping, in light of this case;
- the pharmacy now has higher pharmacist and technician staffing levels than at the time of both dispensing errors (140 normal pharmacist hours and 120 normal technician hours per week, compared to 80 pharmacist hours and 80 technician hours);
- a system has been implemented whereby each dispensed item is clearly identified, and a daily check is made to ensure that this has occurred;
- a daily checking regime for all repeat prescriptions has been implemented, and where CRC forms are used for repeats the instructions are double-checked;
- a review of standard operating procedures will investigate the best wording on bag labels, and a five-second check for drug and strength; and
- The pharmacy is due for its third pharmacy audit.

Recommendations

I recommend that the pharmacy take the following action:

- Confirm that it has a clear process in place for documenting prescription items that are owed or partially dispensed to patients, and for recording when each medication has been checked, eg, on what date, and by whom.

- Implement my expert's suggestions for a final "five-second" check for drug and strength, and for including additional wording on pharmacy bags to encourage patients to be pro-active if they have queries.

- Report to the Commissioner the results of the upcoming pharmacy Quality Audit of the pharmacy by the Ministry of Health.

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 sent to the Pharmaceutical Society of New Zealand Incorporated, the Pharmacy Guild of New Zealand, and Medsafe, for educational purposes.
- A copy of this report, with details identifying the parties removed, will be sent to Roche Products (New Zealand) Ltd and Janssen-Cilag Pty Ltd recommending a review of the labelling of their medication boxes.
- 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

A number of features of this case indicate that a referral to the Director of Proceedings may have been warranted. However, I have considered Mr B's response (he has apologised and reviewed his practice), the impact of the media publicity, and the inability to identify the individual pharmacists involved in both dispensing errors. Given these factors, I have not referred Mr B to the Director of Proceedings.

Addendum

The pharmacy confirmed that it had complied with the Commissioner's recommendations.

Appendix A: Box Net Analysis

Figure 1. Box net for Recormon (Epoetin Beta) 3000IU/0.3mL. Box is not actual size. I have identified no obvious problems with this box or label design relevant to this case.

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

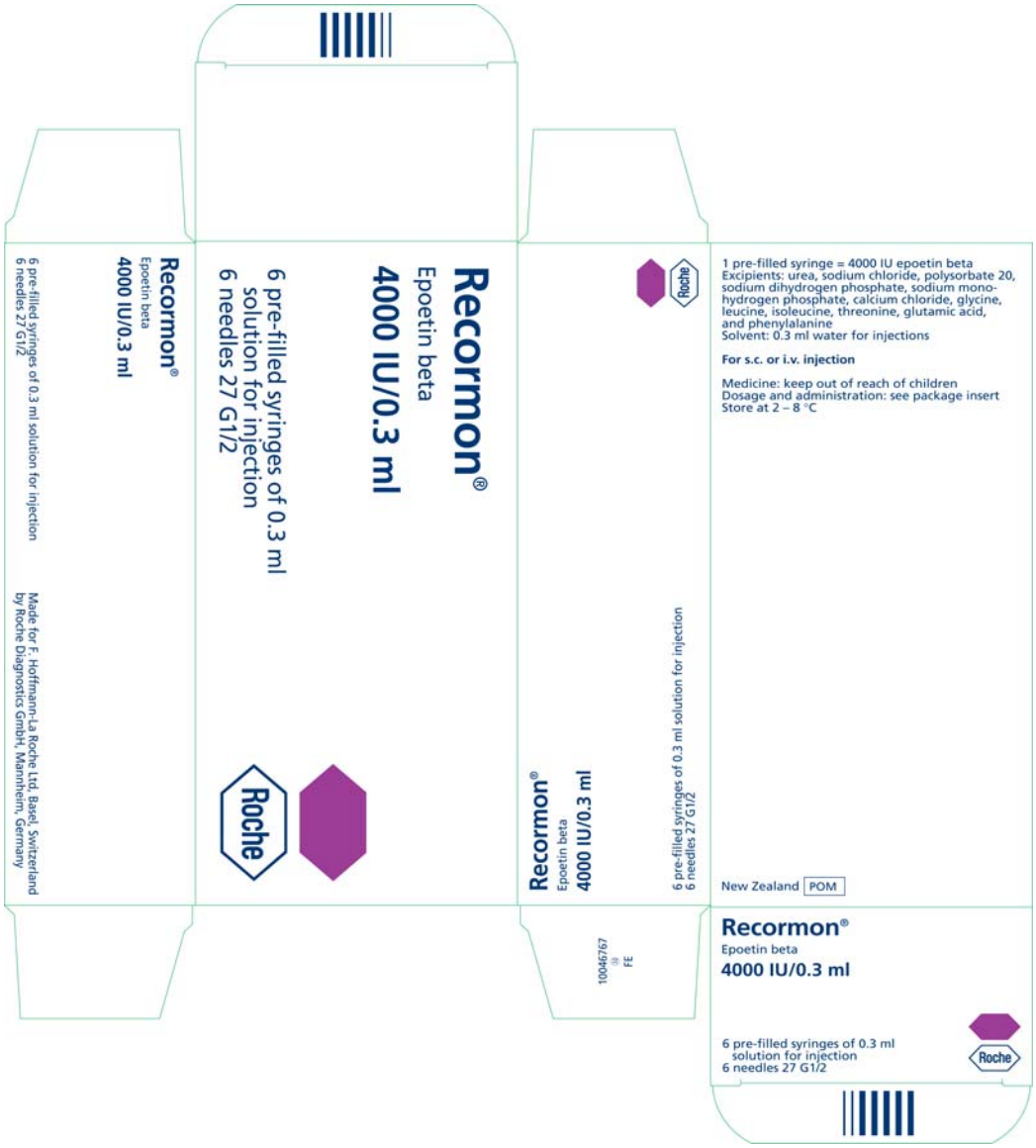

Figure 2. Box net for Recormon (Epoetin Beta) 4000IU/0.3mL. Box is not actual size. I have identified no obvious problems with this box or label design relevant to this case.

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

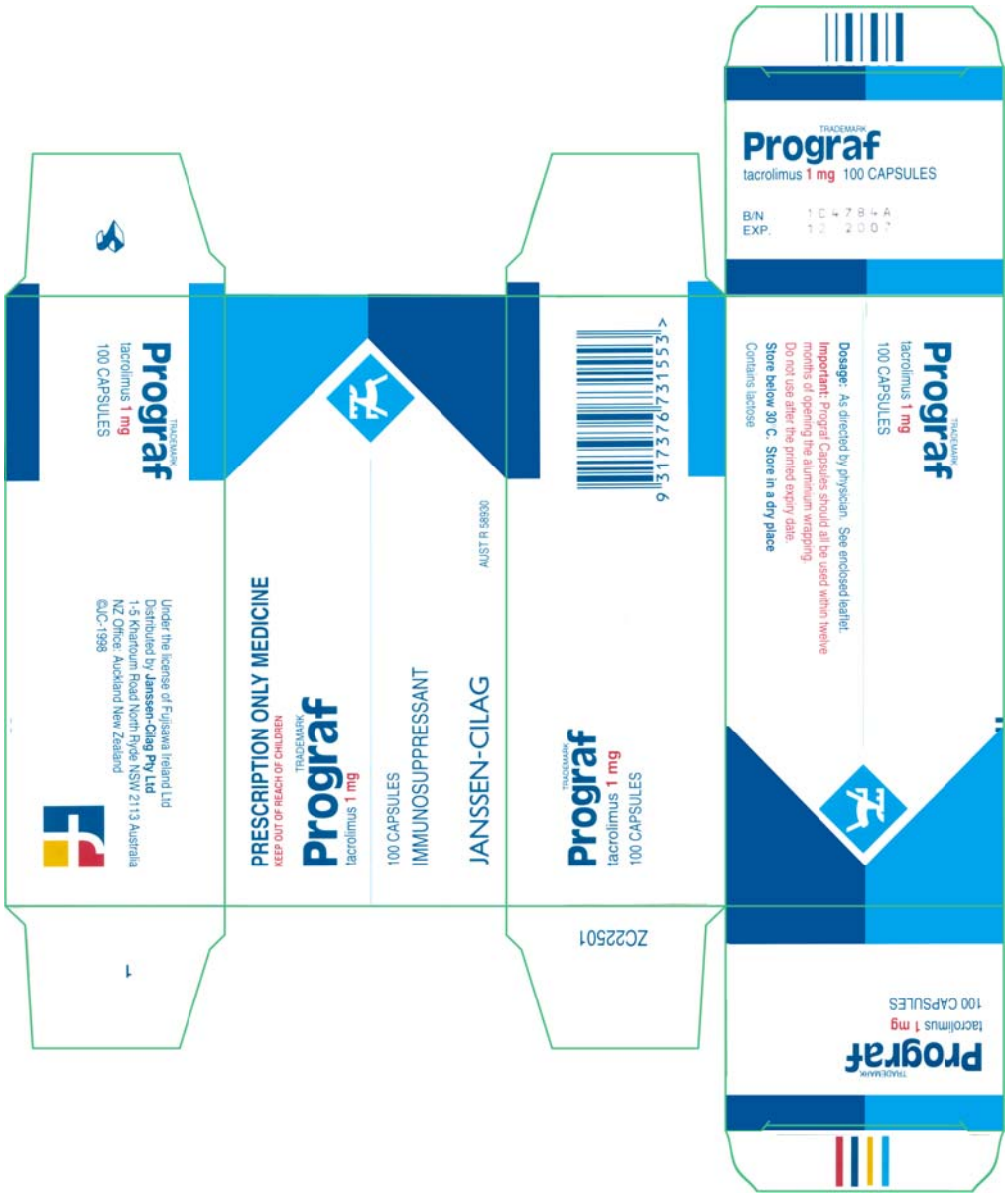

Figure 3. Box net for Prograf (Tacrolimus) 1mg. Box is not actual size. I note that the typeface for drug strength is very small when there is ample space on the box for a more prominent font size and colour.

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

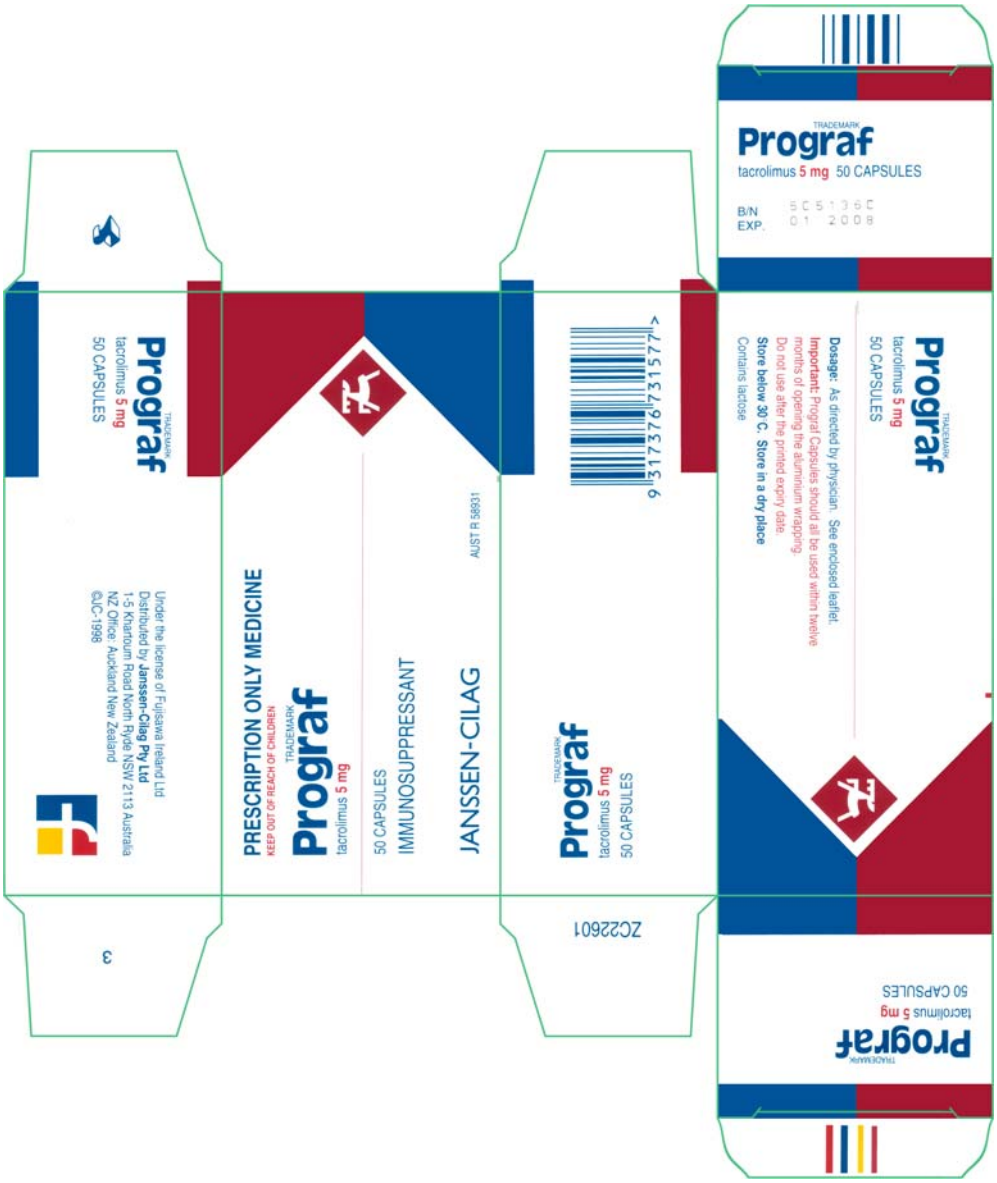

Figure 4. Box net for Prograf (Tacrolimus) 5mg. Box is not actual size. I note that the typeface for drug strength is very small when there is ample space on the box for a more prominent font size and colour.

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

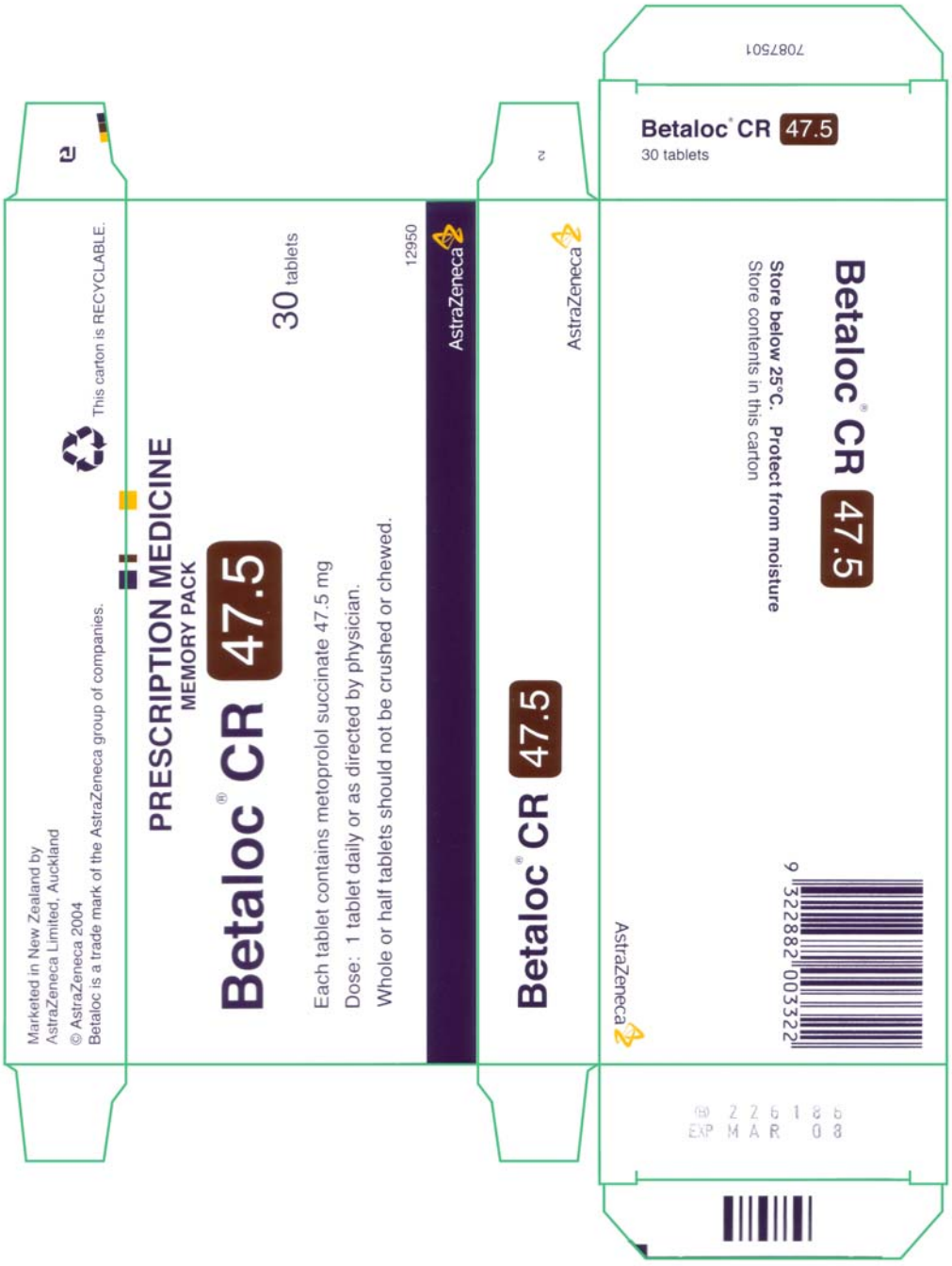

Figure 5. Box net for Betaloc 47.5mg. I refer to this drug box purely as an example of excellence in manufacturer's labelling. Note the prominent colour and size of drug strength.

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

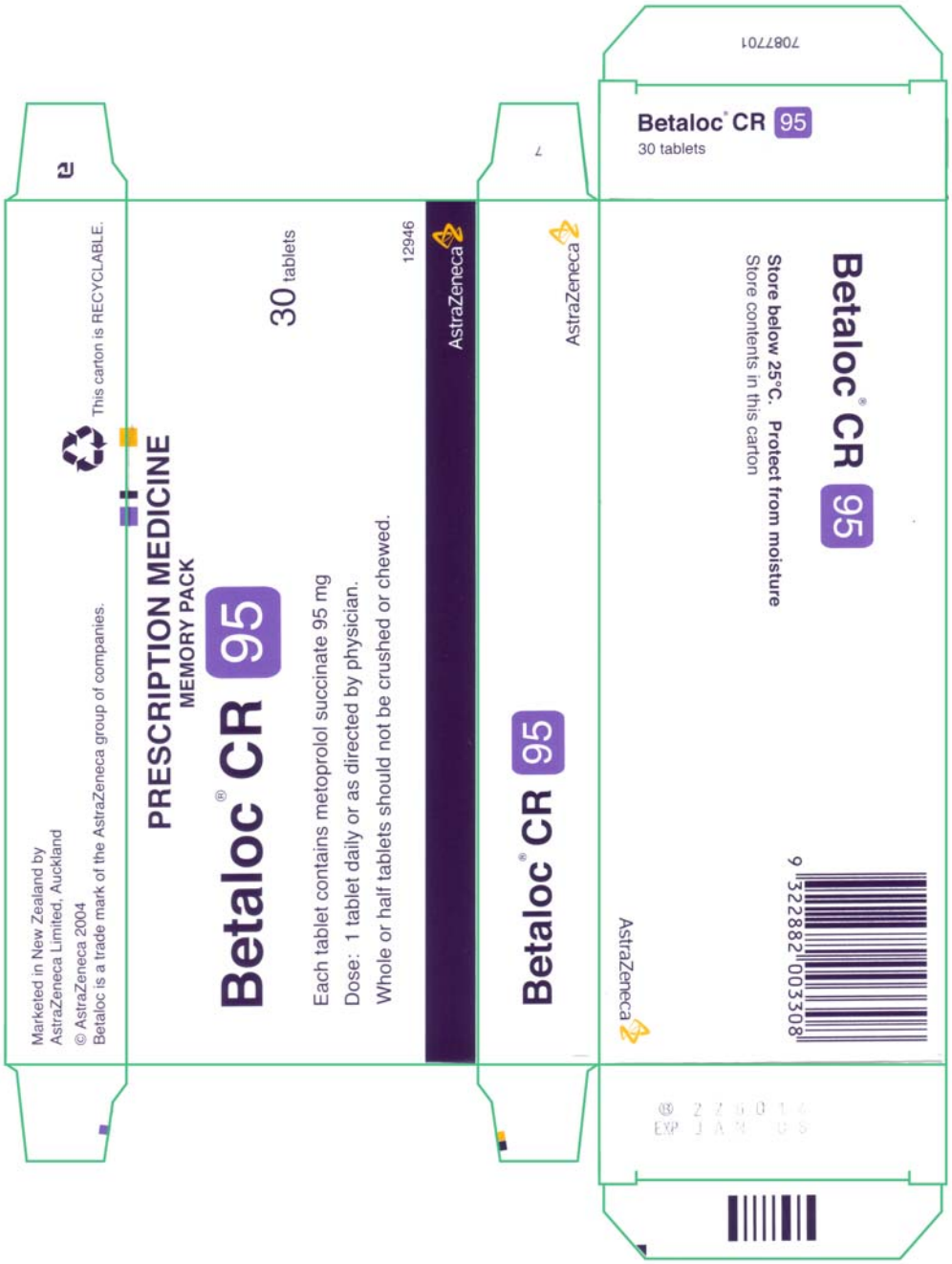

Figure 6. Box net for Betaloc 95mg. I refer to this drug box purely as an example of excellence in manufacturer's labelling. Note the prominent colour and size of drug strength.

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