Pharmacist, Mr B

A Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 06HDC12613)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mr B	Provider/pharmacist
Dr C	Obstetric registrar, a hospital
Ms D	Pharmacy manager
Mr E	Pharmacy owner
Ms F	Pharmacy technician
Ms G	Pharmacy technician
Dr H	General practitioner
Pharmacy	The Pharmacy
Ms I	Medsafe representative

Complaint

On 23 August 2006, the Commissioner received a complaint from Ms A about the services provided by a pharmacy and pharmacist Mr B. The following issue was identified for investigation:

Whether the Pharmacy and registered pharmacist Mr B provided services of an appropriate standard to Ms A on 5 August 2006.

An investigation was commenced on 1 September 2006.

Information reviewed

- Information from:

  Ms A
  Mr B
  Ms D
  Mr E
  Ms F
  Dr C
  Dr H (Ms A's general practitioner)
  Medsafe
  The Pharmacy

Independent expert pharmacist advice was obtained from Mr John Fraser.

Information gathered during investigation

Summary
This case involves three members of pharmacy staff misreading or mistaking a prescription for labetalol (a blood pressure medicine) for Largactil (the brand name for chlorpromazine hydrochloride, a medication used in the treatment of schizophrenia and other psychoses). Mr B was the charge pharmacist who was responsible for ensuring that the patient, Ms A, had her prescription accurately dispensed. As a result of the error, Ms A required admission to hospital overnight because of the side effects of Largactil, which include drowsiness.

Chronology
On 5 August 2006, Ms A, aged 31 years, was discharged from hospital having given birth to her daughter. The obstetric registrar, Dr C, hand-wrote a prescription for one 325mg ferrous sulphate,[1] tablet once a day; and one 200mg tablet of labetalol, three times a day. Ms A attended a pharmacy to have the prescription dispensed.

When technician Ms F entered the prescription on the computer, she incorrectly read the prescription, and typed "Largactil" instead of "labetalol".

Ms F stated that she was concerned about the prescription because Largactil does not come in 200mg tablets, and the prescription said that Ms A was to have *one* 200mg tablet, three times a day. She checked the shelves and the computer system to confirm that only 100mg tablets were available, annotated the prescription accordingly, and took a box from the shelf to place by the prescription for dispensing. Ms F noted that, according to the computer record, Ms A had not previously been prescribed Largactil. Ms F stated that normal procedure would be to write "N" on the prescription to indicate that it was a "New" prescription, but she did not do so on this occasion, and instead mentioned this fact in person to the charge pharmacist, Mr B.

Ms F was "pretty sure" that Mr B asked her to print out a drug information sheet for Largactil. In this instance, Mr B cannot recall whether he gave Ms A an information sheet, and Ms A cannot recall being given one. Ms F stated that Mr B very often provided drug information sheets for new prescriptions. She entered the prescription onto the computer as 200mg Largactil, three times a day. She correctly entered the prescription for ferrous sulphate onto the computer. Labels to place on the box of dispensed drugs were created for the Largactil and the ferrous sulphate. The former stated:

[1] Ferrous sulphate: iron supplement.

May cause sleepiness: limit alcohol
168 LARGACTIL Tablets 100mg
Take TWO tablets THREE times daily. Don't take with antacids, iron or calcium. Protect yourself from too much sunlight. Do not stop taking this medicine.
[Ms A] $3.00
1006847/0 5 Aug06 SI [Dr C]

Ms F then passed the prescription along to the next phase in dispensing medications, where the drugs were to be dispensed from the stock containers and put into the boxes to be given to Ms A. This was performed by pharmacy technician Ms G, who also incorrectly read the prescription as "Largactil", and dispensed this medication. She correctly dispensed the ferrous sulphate. The prescription then passed to the next phase, where the charge pharmacist, Mr B, checked the prescription against the dispensed drugs.

Mr B also misread the prescription as being "Largactil" rather than "labetalol". However, he noted that the dosage was high (600mg per day),[2] and placed a red sticker on the prescription, which meant that he was going to speak with the patient when the drug was dispensed.

When Ms A collected her dispensed medications, Mr B went to speak to her. Ms A said that during this conversation she told Mr B that she was taking medication for high blood pressure, but Mr B cannot recall that she made this comment. Ms A said that Mr B advised her to take two 100mg tablets instead of the one 200mg tablet that she had taken in the past. Ms A questioned this, so Mr B went back to check the prescription before he gave out the medication. He stated:

> "My impression is sometimes the hospitals use different brands [of drugs] so you're not sure as to whether you're actually giving the same brand even."

However, when questioned further, Mr B confirmed that a 100mg tablet is the largest tablet dose of Largactil available. Despite this further check, he did not notice that the wrong drug had been dispensed.

As noted above, the label placed on the Largactil box dispensed to Ms A stated, "Don't take with antacids, iron or calcium." Mr B cannot recall whether he warned

[2] *The New Ethicals Compendium*, 7th Edition, states the adult dosage of Largactil: "Initially 25mg three times daily or 75mg at bedtime increasing by daily increments of 25mg to an effective maintenance dose. This is usually in the range 75 to 300mg daily, but some patients may require up to 1g daily."

Ms A about not taking ferrous sulphate (iron) at the same time as Largactil, but stated, "I may not have, I was focussing all on [the Largactil prescription]."

Mr B said that he did not question Ms A about the reason for the prescription of Largactil as "she looked depressed". He cannot recall whether he warned Ms A about the possible side effects, including the risk of driving.[3] Mr B stated that there would be a warning on the label.

In response to the provisional opinion, Ms A disagreed with Mr B's description of her as "depressed". She stated that although she may have been tired, she was happy with her new baby daughter.

Ms A said that while she was talking with Mr B, her baby was in the car seat (taken from the car) by her side, and she had also bought some Lansinoh cream[4] and two dummies. Mr B stated that he could not recall these details. The receipt produced by Ms A gives details of the dispensed medications, the dummies, and the Lansinoh cream. The receipt notes, "You have been served by [Mr B]", and "[Mr B's initials]" is also printed next to the time and date of the receipt.[5]

Mr B said that he was not aware of the precautions of dispensing Largactil to women who were breast-feeding.[6] Ms A stated that Mr B did not provide her with any information about the possible side effects of taking Largactil.

Subsequent events
After Ms A had taken the first dose of Largactil in the evening, she began to feel drowsy. She described the effect that the Largactil had on her:

> "Within an hour [of taking the Largactil] I became very sleepy for no apparent reason. In this hour I breastfed my daughter and had driven to get pizza for my two other children. I had started feeling strange while I was waiting for the pizza, but had to drive home. Once home a friend called in, and I told them I had to go to sleep and hopped on the couch and went straight to sleep. … I don't remember much from this point other than becoming very distraught because I felt so bad and was very worried. My son was very concerned and contacted two of my friends. One to take me to hospital and one to take him and his sister. My friends were very concerned, I was shaking and slurring my words. It felt like my whole system was crashing."

---

[3] "May cause drowsiness, do not drive or operate machinery if affected." *MIMS New Ethicals* (November 2005).
[4] Lansinoh cream: lanolin-based cream used to prevent or treat cracked nipples for breast-feeding women.
[5] 4.23pm, 5 August 2006.
[6] "LARGACTIL is excreted in milk. Breastfeeding should be suspended during treatment unless the expected benefits outweigh any potential risk." *New Ethicals Compendium*, 7th Edition.

Ms A was taken to the Emergency Department at the local hospital, and was admitted. She remained in hospital overnight, and was discharged the following day.

On the morning of 6 August, Dr C telephoned the pharmacy and spoke to Mr B. Dr C informed Mr B that Ms A had been admitted to hospital because of her reaction to the Largactil she had been incorrectly dispensed, and described her to Mr B as hypertensive and generally unwell. After the telephone call, Mr B mentioned the error to Ms F, who was also on duty.

At 3pm, when pharmacy manager Ms D commenced work, Ms F told Ms D about the dispensing error. Ms D spoke to Mr B, and as he said he had not yet completed an incident form, she asked him to do so. Ms D stated that Mr B told her that he would get in touch with Ms A and follow through with the incident reporting. Ms D agreed and asked him to get back to her. Ms D understood following her discussion with Mr B that Ms A had been admitted to hospital with "symptoms of anxiety". Her view was confirmed by the initial incident form completed by Mr B, which stated, "[Ms A] had been seen in hospital with symptoms of anxiety." Ms D stated:

> "[I] did not interpret the [incident] form as indicating that there had been a hospital admission due to the error."

Mr B said that he attempted to find Ms A's telephone number to contact her, but the number was not in the telephone book. He stated that he drove to her home address to talk to her, but no one was at home.

On 7 August, Mr B circulated the prescription and the incident report to dispensary staff to make them aware of the error. The documents were filed for staff training purposes. He said that he made a further visit to Ms A's home, but she was again not at home. It does not appear that Mr B took any further action in the following two and a half weeks to contact Ms A or to complete the incident form.

Mr E, the owner and licensee of the pharmacy, was not aware of the dispensing error until informed by HDC on 24 August, when he received a copy of the Commissioner's report into an earlier dispensing error,[7] which noted that there had been complaints regarding further dispensing errors. Ms D stated that she intended to inform Mr E of the error at the end of the month (which was her usual practice), and that she had not done so earlier as she "did not realise the seriousness of [the error and] the patient had been hospitalised". Mr B had not contacted Mr E as he thought that this was Ms D's responsibility.

[7] See 06HDC01037.

On 25 August, Ms I of Medsafe telephoned the pharmacy. Ms I made notes of the conversation with Mr B. Part of those notes, which are not a verbatim record of the conversation, state:

> "[Mr B]: The hospital rang on Sunday and I was working. They said the lady had gone back to hospital that night. The hospital confirmed the script was for labetalol but did not suggest any follow-up so I thought it was all resolved.
>
> [Ms I]: So what follow up action have you taken?
>
> [Mr B]: We have done nothing. I got the impression it was all sorted out. I thought she looked like a nervy person, and that she had gone back to the hospital to check it out.
>
> [Ms I]: No, she was admitted to hospital.
>
> [Mr B]: That's right, she went back to hospital to get it checked out.
>
> [Ms I]: No, [Mr B], as I understand it she was actually admitted to hospital.
>
> [Mr B]: Yes, she only took one dose and it is all sorted out now."

Following this conversation with Ms I, Mr B made a further visit that same day to Ms A, on this occasion finding her at home. He apologised for the dispensing error, and on the following day hand-delivered a written apology.

On 26 August, Mr B completed the incident reporting form he had commenced on 6 August. As he believed the original form was unclear, he completed a new form, which omitted the previously written sentence, "Patient had been seen in hospital with symptoms of anxiety." He stated that he omitted this sentence as he could not recall whether this had been said when he was contacted by a member of staff at the hospital on the morning of 6 August.

Having reflected on the error, Mr B stated:

> "I believe that fatigue was a contributing factor.
>
> My error was made at about 4.30pm on a Saturday afternoon — an hour and a half into my 3pm to 10pm shift. I had picked up a cold the previous day and had taken two Sinutabs prior to my shift starting.
>
> I had taken a week's holiday from the 11th to 18th July. In order to get the days off I had to swap shifts, which resulted in me having to work 22nd and 23rd July. My normal roster is 4 shifts over 7 days, although this can vary from 5 or 6 days in a row to 1 day on its own."

Mr B provided his duty roster, which showed that he had not worked on the two days prior to the day the dispensing error was made, 3 and 4 August.

Mr B was interviewed as part of the investigation. He stated:

> "I'd just like to say I've felt really bad making this error, and I've realized we didn't follow the procedure with regards to trying to get hold of [Ms A] earlier, and I regret that. We did go and get to see her in the end and I've been able to apologise to her …
>
> It's made me think a bit more about my Practice, even though you're experienced, you still don't necessarily go through a lot of these things. We've instituted some different checking procedures into the Pharmacy on John Fraser's system, and I think that's making everyone a bit more careful, which is good, but I'm still, still having trouble getting through the fact that I didn't read [the prescription] right.
>
> …
>
> Even when all my self checks were there, normally I'm very particular and careful, and my alarm bells were ringing and yet I still did not do what needed to be done."

Medsafe audit
A Medsafe audit was performed on 7 September 2006 as a result of a recommendation from the Commissioner's report into an earlier dispensing error at the same pharmacy. No critical or high-risk issues were identified that required addressing. However, as a result of the recent dispensing errors, the pharmacy was required from 15 September 2006 "to forward dispensing 'near miss' documentation to [Medsafe] on a monthly basis, until advised otherwise".

The pharmacy standard operating procedures (SOP)
The pharmacy had several standard operating procedures in place that set out how staff were expect to report incidents and handle medicine errors.

"Incident reporting [SOP 3.320]

> PROCEDURE:
> Use one Incident Report form per incident

- Incidents are defined as adverse events related to security, quality complaint, dispensing errors (if not reported as Customer Complaint), faulty goods, accident, fire, abuse or neglect etc.
- Do not use the Incident Report form for prescription interventions.
- Fill out all relevant areas on the Incident Report form, sign and hand in to the Pharmacist manager.

- Complete forms as soon as possible after the incident occurs.
- The appropriate expertise or emergency services will be called on at the discretion of the Pharmacist manager.
- After the situation is resolved any necessary people or agencies will be informed.
- Incidents are reviewed by the Pharmacist Manager with the staff members involved.
- Confirm that the correct action was taken or discuss procedures that should have taken place.
- Make sure all required procedures are documented for future reference.
- De-brief all staff to ensure everyone knows how to deal with the situation if it re-occurs.
- Document outcomes on the Incident report form and file."

"Handling an incident — Medicine error [SOP 3.322]

PROCEDURE:

1. Your main concern is the patient — check if the patient is ok before anything else.

…

9. Use phone contacts list SOP 3.323 for serious incidents.

…

11. Debriefing to be arranged as soon as possible with manager and/or proprietor and staff involved. At least within 2 weekdays.

…

14. Follow up letter to the patient/family concerned within a week. Informing them of steps taken to rectify the problem."

The contact list for a serious incident (SOP 3.323) requires that Mr E be contacted. His mobile phone number and home number are given.

Dispensary audit

Mr B performed a dispensary audit for the pharmacy in relation to a previously investigated dispensing error.[8] His report dated 9 March 2006 stated:

"I believe that the numbers of Pharmacists and Technicians rostered on are more than adequate to cope with the current volume of prescriptions.

…

[8] See 06HDC01037.

> The pharmacy has a comprehensive and usable set of Standard Operating Procedures …
>
> In my opinion the dispensing systems that the pharmacy is using are on the whole robust and safe."

Independent advice to Commissioner

Expert advice was obtained from registered pharmacist John Fraser.[9] It is attached as Appendix 1.

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.
(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

Other relevant standards

Pharmacy Council of New Zealand Code of Ethics (2004):
Obligation 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

[9] Mr Fraser also provided expert advice on files 06HDC011037 and 06HDC09528, involving dispensing errors at the Pharmacy on 27 January and 8 June 2006.

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

Pharmacy Council of New Zealand Competence Standards (2004):
Sub-element 4.2.1 — Works with the documented procedures and systems

"Examples of evidence: works within organisation's Standard Operating Procedures (SOPs); uses computer programmes and other systems in workplace."

Sub-element 6.9.2 — Acts to minimise the effects of his/her dispensing errors

"Examples of evidence: identifies potential/actual errors in own dispensing; acts to minimise effect on patient, e.g. contacts patient, contacts prescriber, supplies correct medicine; documents own dispensing errors and actions undertaken to minimise their effects; complies with workplace procedures for documenting dispensing errors."

Response to provisional opinion

Through his lawyer, Mr B stated:

"[Mr B] remains very upset at the error which he made. [He] does not have a clear recollection of all that took place during his conversation with [Ms A]. One of his concerns has been that he actually identified the need to speak with [Ms A] and discuss the medication yet still did not identify the error. It seems once the initial technician had misread the prescription at the outset then the others involved continued the error. [Mr B] continued this line of error and once he had determined (mistakenly) that the drug to be dispensed was Largactil, he then proceeded without recognising signals pointing to the error. He deeply regrets this fact and accepts that there were opportunities to find out the true position. However, [Mr B] was attempting to do his best to maintain accuracy and did not recognize those opportunities at the time.

In addition, [Mr B] acknowledges he should have taken further action to contact [Ms A] and to comply with the SOP in place at the time. This was not an attempt to conceal or minimize the seriousness of the error. [Mr B] has now identified the fact that he effectively froze when he found out the extent of the error. He found it difficult to cope and did not communicate this inability with his colleagues at the time."

Opinion

This report is the opinion of Rae Lamb, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

Opinion: Breach — Mr B

Introduction
Under Rights 4(1) and 4(2) of the Code, Ms A had the right to pharmacy services provided with reasonable care and skill, and in compliance with professional standards. The professional standards that apply in this case are determined by the Pharmacy Council of New Zealand (the Council), and have been set out in detail by my independent expert, Mr John Fraser, in his report (see Appendix 1).

For the reasons set out below, Mr B breached Rights 4(1) and 4(2) of the Code. In my view the errors made by Mr B were serious, because he not only missed a number of clues that should have indicated that an error had been made, he also dispensed the incorrect drug in an unsafe manner. Of additional concern is the fact that Mr B failed to follow up the error in a manner set out both by his professional body, and the Pharmacy standard operating procedures.

Dispensing error
Mr Fraser has advised that, although two pharmacy technicians were involved in the dispensing error, "the full responsibility for the error rests with supervising pharmacist Mr B". This is consistent with the standards set by the Pharmacy Council, and I accept his advice.

I also agree with Mr Fraser that although the doctor's prescription for labetalol was not perfect, "it [was] sufficiently legible for dispensing purposes".[10]

There is no doubt that a dispensing error occurred. Mr B has accepted that the error was his responsibility and unreservedly apologised to Ms A. However, this does not excuse the fact that Mr B was not alert to the error during the dispensing process. In fact, he missed several significant opportunities to have noted it.

The first opportunity was when the technician informed Mr B that Largactil was a new drug for Ms A. Mr B also noticed that the dosage was high, and marked the prescription with a red sticker to show that he would speak with Ms A when she

[10] See Appendix 2 for prescription.

collected it. When he spoke to Ms A, she informed him that she was on blood pressure medication yet, as Mr B would have seen if he had checked it, no such medication was being dispensed. Ms A also said that she took only one tablet rather than the two being dispensed. This prompted Mr B to look at the prescription again, but he still did not notice the error.

To further compound matters, having erroneously accepted that the prescription was for Largactil, Mr B failed to dispense that drug in a safe manner. Although he had been alerted that Largactil was a new drug for Ms A, and the dose was unusually high, there appears to have been no discussion with her about the drug, the dose, or the side effects, and there is no evidence that Mr B gave Ms A an information sheet. In addition, particular caution should be used when drugs such as Largactil are prescribed for mothers who are breast-feeding. A number of factors should have alerted Mr B to the possibility that Ms A was breast-feeding. For instance, when he served her, Ms A not only bought dummies and cream, which breast-feeding mothers would use, she had her new baby with her. Mr B did not provide Ms A with advice regarding breast-feeding while concurrently taking Largactil. While I accept that Mr B could not be expected to know the detailed risks of giving Largactil to a breast-feeding mother, I agree with Mr Fraser's advice that:

> "He should have consulted appropriate resources to confirm the safety of the drug, and counselled her about safe nursing guidelines. Under the circumstances, he probably should have referred her to consult with her hospital obstetrician/paediatrician or family doctor for more advice.
>
> …
>
> [T]he evidence suggesting [Ms A] was breastfeeding was almost overwhelming, and [Mr B] should have been alerted to the fact."[11]

Furthermore, there was an additional warning sign in that the advice on the box advised that Largactil was not to be taken with iron, yet ferrous sulphate was also prescribed. Although Mr B explained to my Office that this meant that they could not be taken at the same time of day, this was not something he explained to Ms A, and again he failed to notice the dispensing error.

Mr B was well aware of the Pharmacy SOPs, as he had performed an audit for an earlier dispensing error involving other staff at the Pharmacy,[12] and concluded that the SOPs were "comprehensive and usable". During that audit, he also gave his view that the number of pharmacists and technicians on duty was "more than adequate" to manage the workload. Although Mr B suggested that fatigue may have been a cause of his error in relation to Ms A, he had not been on duty the two days prior to the day the error was made.

[11] See Appendix 1.
[12] See 06HDC01037.

Mr Fraser identified 17 professional standards that Mr B failed to comply with during the dispensing process. In particular, he identified that Mr B failed to comply with Obligation 2.6 of the Council's Code of Ethics, which states:

> "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."

It is clear that Mr B failed to comply with this professional standard when providing services to Ms A.

Reporting procedure

Having been alerted to the dispensing error on the morning of 6 August (when Dr C telephoned), Mr B was required by the Pharmacy SOPs and his professional obligations to accurately follow the procedure for incident reporting. He did not.

When the Manager, Ms D, came on duty later that day, Mr B informed her of the dispensing error, but failed to give her the full details, as he knew them, of the effects of the error. Ms D was left with the belief that Ms A's admission to hospital was because she was having symptoms of anxiety, and nothing to do with the dispensing error. As a result, she was unaware of the seriousness of the dispensing error, and did not notify the Pharmacy owner, Mr E, at once. Her view would have been confirmed by Mr B's first incident form.

Ms D understood that Mr B was to deal with the follow-up of the error as he was a senior pharmacist. However, Mr B did not contact Mr E, and said that he believed that this was Ms D's role. There may well have been genuine confusion between Ms D and Mr B as to who would contact Mr E, but in the circumstances I consider that Mr B did not adequately follow up his dispensing error. The Pharmacy SOPs set out who to contact in the event of a serious incident, and this list includes Mr E.

Mr Fraser advised:

> "[Mr B] was personally responsible for following up the error that had occurred under his supervision. It was his responsibility to make personal contact with [Ms A] as soon as possible. It was his responsibility to inform the pharmacy proprietor, [Mr E], about the situation. It was his responsibility to follow the pharmacy's standard procedures for responding to errors — procedures that he had helped to develop. Yet he did none of these things."

I am concerned that Mr B did not take any further action after he had twice failed to find Ms A at home. Only when Ms I of Medsafe contacted him on 25 August did Mr B take further action, which included, finally, the completion of the incident form and

contacting Ms A. Taking into account the relevant SOPs, Mr B's senior position, and his delay in following up the matter with Ms A, it seems disingenuous for him to state that it was up to Ms D to inform Mr E of the incident and that he had no responsibility for doing so.

In his response to the provisional opinion, Mr B explained his failure to communicate with Ms D and Mr E by stating that he "effectively froze when he found out the extent of the error". He said that he found it difficult to cope and did not communicate this inability with his colleagues at the time. Although I understand that Mr B may have been shocked into inaction when he first became aware of the error on the morning he was called by the hospital, his failure to respond appropriately over the following 19 days is unacceptable.

Summary
This was a serious dispensing error compounded by the fact that despite various warning signs, Mr B missed a number of opportunities to identify the mistake — a situation he has acknowledged and said he deeply regrets. Even once the Largactil was dispensed, this was done in an unsafe manner. Furthermore, once Mr B was made aware of the error, he failed to act appropriately. By failing to comply fully with the reporting procedures, Mr B appeared to be trying to conceal or at least minimise the seriousness of his error.

By failing to provide pharmacy services with reasonable care and skill, and in compliance with professional standards, Mr B breached Rights 4(1) and 4(2) of the Code.

Opinion: No breach — the Pharmacy

Mr Fraser has previously advised[13] that the SOPs in place at the pharmacy are of an appropriate standard.

Having reviewed the available information, I am satisfied that no act or omission by the pharmacy could, in this case, be considered a breach of the Code. However, I bring to the pharmacy's attention Mr Fraser's comments regarding the need to refine the incident reporting SOP to explicitly state that the proprietor is informed of an error, and that the supervising pharmacist is responsible for ensuring that the resulting procedures are followed.

Vicarious liability
In addition to any direct liability for a breach of the Code, an employing authority may be vicariously liable under section 72(2) of the Health and Disability Commissioner Act

[13] See 06HDC01037.

1994 for any breach of the Code by an employee. Section 72(5) affords a defence for an employing authority if it took such steps as reasonably practicable to prevent the act or omission in question. Mr B was an employee of the pharmacy. The pharmacy had clear policies and guidelines, set out in the SOPs, which Mr B was aware of.

Although Mr B to some extent attributed the error to his work schedule and his consequent fatigue, I have noted Mr Fraser's advice that a pharmacist should recognise when his or her performance may be impaired, and take actions to ensure safe practice. I also note that Mr B had two days off work immediately prior to the day on which the error was made.

In my opinion, the Pharmacy took reasonable steps to prevent the act in question and is therefore not vicariously liable for Mr B's breaches of the Code.

Other matter

Despite the findings outlined above, I am concerned at the number of errors[14] involving the pharmacy that have been reported to this Office during 2006. I specifically asked Mr Fraser, a nationally recognised expert in error prevention, to comment on this. Mr Fraser advised:

> "I do note that all three errors were committed by technicians, and missed by pharmacists during the final check. In my opinion, the nature of the first error [06HDC01037] meant it was unreasonable to hold the supervising pharmacist to account. However, the subsequent two errors could, and should, have been detected by the supervising pharmacists. These errors are a potential warning that the activities of technicians at the pharmacy need closer attention and supervision."

Mr Fraser goes on in his advice to suggest that the occurrence of errors at the pharmacy may be statistically in line with what would be expected from any pharmacy. His concern is not the number of errors that have been reported, but that they have been "particularly significant". Despite this concern, Mr Fraser has not identified any systemic faults from his expert review of all three cases.

Ultimately, I am also unable to reach a view on why there have been three serious dispensing errors in the same pharmacy in such a short time. It appears that the Standard Operating Procedures are adequate to prevent errors, yet two pharmacists

[14] See 06HDC01037, 06HDC09528.

and four pharmacy technicians have failed to follow them in these three investigated cases. Without accurate comparative data on dispensing errors in other pharmacies, it is not possible to conclusively state whether the pharmacy makes more errors than other pharmacies. Even so, I draw the pharmacy's attention to the comments made by Mr Fraser regarding the activities of pharmacy technicians. In my view, an independent review of this aspect of the dispensing process is warranted. Although I accept that a pharmacist carries the ultimate responsibility for ensuring that the correct medication is dispensed, this does not lessen the technicians' obligation to dispense accurately.

Recommendations

- I recommend that the pharmacy arrange for an independent review of the work practices and training of pharmacy technicians in the dispensing process, to be reported back to me by **1 April 2007**.
- I recommend that Medsafe consider the requirements for pharmacies to record and report dispensing errors as part of the regular audit process.

Follow-up actions

- Mr B will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.
- 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, but naming Mr B and the Pharmacy, will be sent to Medsafe and the relevant District Health Board.
- A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society, the Pharmacy Industry Training Organisation, and the Quality Use of Medicines Group, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1

Independent advice to Commissioner

The following expert advice was obtained from registered pharmacist John Fraser:

"1. Introductory comments

1.1. Introduction
I would like to thank the Commissioner for asking me to review this case, number 06/12613, regarding [Ms A] and [the Pharmacy]. This matter was referred to me for my opinion on 11 October 2006.

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 with a Diploma in Pharmacy; 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 junior apprentice to proprietor/manager.

I am a Past President of the 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 moment I have no financial interests in this area.

In June 2006, my work in developing an error prevention program for New Zealand Pharmacies led to me receiving the New Zealand Pharmacy Award for Innovation in Pharmacy Practice, and the Overall Pharmacy Award.

1.3. Declarations
I have read, and agree to follow, the Commissioner's Guidelines for Independent Advisors.

I understand that my report is subject to the Privacy Act 1993 and the Official Information Act 1982, and that under those statutes my advice may be requested and disclosed. I understand that the Commissioner's policy is to name his advisors where any advice is relied upon in making a decision.

I have previously entered into a formal confidentiality agreement relating to any advice I give the Commissioner.

I have compiled this report in good faith, based on the information available to me. Although I may have consulted professional colleagues in preparing aspects of this report, all opinions stated herein are solely my own.

1.4. Directions from the Commissioner

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

…

[At this point Mr Fraser lists the questions asked, which he repeats in his advice.]

1.5. Material examined

In providing my opinion, I have examined the following material supplied to me by the HDC:

1. Letter of complaint (page 1 to 5);
2. Notification letters (page 6 to 10);
3. Information from [the Pharmacy] (page 11 to 51);
4. Information from [Mr B], including interview transcript (page 52 to 77);
5. Information from Medsafe (page 78 to 97);
6. The original copy of [Ms A]'s prescription.

I have also examined the following resources:

7. *New Ethicals Compendium* (Adis International, 2004).
8. *Martindale: The Complete Drug Reference* (Sweetman, 2006).
9. *Drugs in Lactation and Pregnancy* (Briggs, Freeman and Yaffe, 1998).

2. Summary of Facts

On Saturday, 5 August 2006, [Ms A] was discharged from [hospital], having given birth to her daughter. On discharge, [Dr C], obstetric registrar, provided her with a prescription for 325mg ferrous sulphate (taken once daily), and 200mg labetalol (taken three times daily).

Ferrous sulphate tablets are better known as 'iron tablets' and are generally used to treat or prevent iron-deficiency anaemia.[15] Labetalol hydrochloride is a non-cardioselective beta blocker used to control blood pressure.[16] Neither of these medications would be considered unusual for an adult patient.

At about 4.10pm, [Ms A] attended [the Pharmacy] in [a city] to have the prescription dispensed.

The prescription was given to technician [Ms F], who was responsible for entering its details into [the Pharmacy] computer system and printing each medication's label. She incorrectly entered 'Largactil' instead of 'labetalol.' Largactil is a formulation of chlorpromazine hydrochloride, a typical antipsychotic drug.[17]

Technician [Ms G] was responsible for selecting and counting the medication. She did not notice the error and prepared Largactil instead of labetalol, as the erroneous label suggested. She put the tablets into a skillet (a small cardboard box).

Pharmacist [Mr B] checked the dispensing and noted that the dosage of the Largactil was high. This concerned him, so he placed a red tag on the prescription, which meant that he was to speak with [Ms A] when the medicines were given to her.

There are several important aspects of the conversation between [Mr B] and [Ms A]:

- According to [Ms A], she told [Mr B] that she was taking medication for blood pressure. (Largactil is not normally used for control of blood pressure.) The pharmacist, [Mr B], cannot recall being told this.
- [Ms A] states that while she was talking with [Mr B], she was holding her new baby; she also bought some Lansinoh cream (a product for breast-feeding mothers) and two dummies. Despite these fairly obvious clues, [Mr B] did not investigate nor discuss what effect [Ms A's] medications might have on breast-feeding.
- [Ms A] commented that she had previously only taken one tablet (*of labetalol*) per dose, whereas the current dispensing (*of Largactil*) was to take two tablets per dose. [Mr B] went back to the dispensary to re-check the prescription.

[15] Sweetman, S. (2006). "Ferrous Sulphate." *Martindale: The Complete Drug Reference*. London: Pharmaceutical Press.
[16] Sweetman, S. (2006). 'Labetalol Hydrochloride.' *Martindale: The Complete Drug Reference*. London: Pharmaceutical Press.
[17] Sweetman, S. (2006). 'Chlorpromazine.' *Martindale: The Complete Drug Reference*. London: Pharmaceutical Press.

However, he still did not realise that Largactil had been erroneously dispensed instead of labetalol.

- The dose of Largactil was very high. The typical dose range is 25–300mg daily; [Ms A's] dispensing was for 600mg daily. Despite this obvious warning sign, [Mr B] did little to re-check the appropriateness of the dispensing.
- The Largactil had a printed label which stated (in part), 'Don't take with antacids, iron or calcium,' yet [Ms A] was also dispensed ferrous sulphate, an iron tablet. [Mr B] says that he did notice this warning, but he did not give [Ms A] any verbal advice on what the warning meant, or how to take the two medicines appropriately.
- It is safe to presume that [Ms A] had never before received Largactil from [the Pharmacy]. As such, it would have appeared to [the Pharmacy] that the Largactil was a new medication for [Ms A]. Despite this, it appears she was not given any printed material or additional advice about the medicine.

[Ms A] left [the Pharmacy] with the Largactil and ferrous sulphate.

At approximately 6.00pm, [Ms A] took 200mg of Largactil. This is a large dose. At about 6.30pm [Ms A] breast-fed her baby, and at about 7.00pm she drove to a pizza store to get dinner. While she was waiting for the pizza, she started 'feeling strange.' After driving home, she became extremely somnolent, 'shaking and slurring her words.' Ultimately, she was admitted to [hospital]. The dispensing error was discovered when [Ms A's] medicines were brought to the hospital and it was realised she had been given the wrong drug. [Ms A] stayed in hospital overnight, suffering from acute Largactil overdose. She recovered uneventfully.

On the following day, [Dr C] telephoned [the Pharmacy] and spoke to [Mr B]. [Dr C] advised [Mr B] that [Ms A] had been admitted to hospital following the dispensing error. He said [Ms A] had taken the wrong medication, and she was hypertensive and 'generally unwell.'

[Mr B] informed [the Pharmacy] manager, [Ms D], about the mistake that had occurred. [Ms D] understood from [Mr B] that [Ms A] had been admitted with 'anxiety.' She asked [Mr B] to complete an incident form. [Mr B] started to fill out this form, but did not complete it.

Over the next few days, [Mr B] allegedly attempted to get in touch with [Ms A], but he never succeeded in making contact with her.

On 14 August, [Ms A] made a written complaint about the error. Details of this error were forwarded to the Health and Disability Commissioner and Medsafe.

[Mr E], the owner of [the Pharmacy], was not aware of the dispensing error until 24 August, at which time he was informed of the situation by a letter from the Health and Disability Commissioner.

On 25 August (20 days after the error occurred), [Ms I] of Medsafe contacted [the Pharmacy]. She spoke to [Ms D] and [Mr B] about the error. When [Mr B] was asked about what follow-up action he had taken, he admitted, 'we have done nothing.'[18]

On 25 August, following the telephone conversation, [Mr B] visited [Ms A], wrote a letter of apology, and completed the incident form that he had started to fill out on 6 August. [Mr B] also contacted [Ms A's] GP, [Dr H], who had been unaware of the dispensing error to that point.

This mistake was the third significant dispensing error to occur at [the Pharmacy] in 2006.

3. Commissioner's questions

3.1. Please comment generally on the care provided to [Ms A].

The standard of care provided to [Ms A] by [the Pharmacy] between 5 August and 25 August 2006 was neither appropriate nor acceptable.

[Ms A] had the right to expect her prescription to be dispensed in an accurate manner. Unfortunately, in this case, that did not happen.

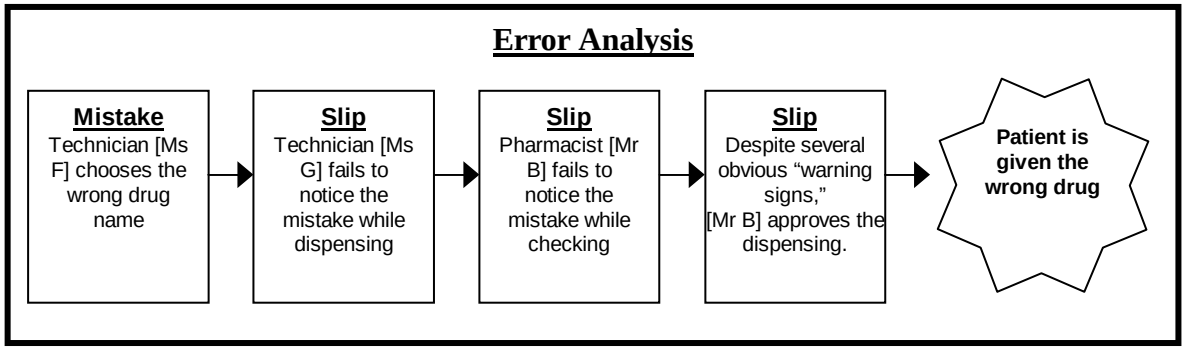
[Ms A] also had the right to expect that if any errors did occur in the dispensing of her medicines, the situation would be treated with the utmost promptness and professionalism. Unfortunately, in this case, that did not happen either.

3.2. Please comment specifically on the standard of care provided to [Ms A] by [Mr B].

[Mr B], the supervising pharmacist, has in part been let down by his technicians. Technician [Ms F] committed an error in mis-identifying the drug name, and entering the wrong details into [the Pharmacy] computer. Technician [Ms G] failed to detect that error when preparing the medicine. However, in situations where such errors occur, and barring exceptional circumstances, the responsibility falls entirely on the supervising pharmacist.[19]

[18] As stated in a transcript of the telephone conference between [Ms I] and [Mr B], 25 August 2006

[19] I believe there are cases where exceptions to this rule exist, but they are rare. For more details on this aspect, refer to my answer to question 3.11 below.



This error is notable because several warning signs went unheeded; [Mr B] was clearly aware that something was wrong with the dispensing before he gave it to the patient, yet the error was not detected. The warning signs included:

- According to [Ms A], she told [Mr B] that she was taking medication for her blood pressure. (Largactil is not normally used for control of blood pressure.) The pharmacist, [Mr B], cannot recall being told this. If [Ms A's] claim is accurate, then [Mr B] should probably have been alerted to the fact that something was wrong with the dispensing.
- [Ms A] states that while she was talking with [Mr B], she was holding her new baby; she also bought some Lansinoh cream (for breast-feeding), and two dummies. These were obvious cues that [Ms A] was probably breast-feeding. However, [Mr B] did not investigate or discuss what effect the medications might have on breast-feeding. (This issue is further discussed in sections 3.8 and 3.9 below.)
- [Ms A] commented that she had previously only taken one tablet (*of labetalol*) per dose, which was different to the instructions stated on her current prescription (*of Largactil*). [Mr B] went back to check the prescription. However, he still did not realise that Largactil had been erroneously dispensed instead of labetalol. (This issue is further discussed in section 3.5 below.)
- The dose of Largactil was very high. The normal dose range for regular users of the medication is 25–300 mg daily; the dose given to [Ms A] was 600mg daily. This fact alone (and irrespective of any other errors in the dispensing process) should have prompted [Mr B] to confirm that the prescription was safe and appropriate. Under the circumstances, I believe [Mr B] should have telephoned [Dr C] to confirm the dose. (This issue is further discussed in section 3.6 below.)
- The Largactil had a printed label which stated (in part), 'Don't take with antacids, iron or calcium,' yet [Ms A] was also dispensed ferrous sulphate, an iron tablet. [Mr B] says he saw this warning, yet he did not give [Ms A] any advice on how to take the two medicines safely and appropriately. In the circumstances, he should have given [Ms A] verbal advice on how to take the medicines. (This issue is further discussed in section 3.7 below.)

- It is safe to presume that [Ms A] had never before received Largactil from [the Pharmacy]. As such, it would have appeared to [the Pharmacy] that the Largactil was a new medication for [Ms A]. Despite this, she was not given any printed material or additional advice about the medicine. (This issue is further discussed in section 3.4 below.)

[Mr B], as supervising pharmacist, is clearly responsible for the actions of his technicians and failed to detect an error that was made.

I also note that [Mr B's] response to the error when it was discovered was highly inappropriate. I discuss this aspect separately in section 3.10 below.

In my opinion, [Mr B] clearly did not provide [Ms A] with an adequate standard of care. I believe pharmacy peers would regard the departure from care with moderate-to-severe disapproval.

3.3. What standards apply in this case? Were these standards met?

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 incident occurred. There are a very large number of applicable rules and regulations affecting pharmacy, including at least 20 separate statutes; but the following are particularly relevant to this case:

- Pharmacy Council of New Zealand Code of Ethics 2004[20]
- Pharmacy Council of New Zealand Quality Standards, Second Edition 2004[21]
- Pharmacy Practice Handbook 2003[22]
- Medicines Regulations 1984[23]

While most aspects of these standards **were** met, there were unfortunately some breaches of these standards. I have outlined the precise areas of concern and explained why I think the cited standards were not fulfilled.

---

[20] 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

[21] 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

[22] Pharmaceutical Society of New Zealand (2003). *Pharmacy Practice Handbook 2003*. Wellington: Pharmaceutical Society of New Zealand.

[23] New Zealand Government Legislation, available online at http://legislation.govt.nz

(Note that I will further discuss regulations on information given to patients in section 3.4, and on the responsibility of pharmacy technicians in section 3.11, below.)

Pharmacy Council of New Zealand Code of Ethics 2004

Obligation 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 met. The prescription was obviously not dispensed correctly.

Obligation 3.10 — Inappropriate or erroneous prescribing

'Where a pharmacist has reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient's health, the pharmacist must confer with the prescriber and document the details and outcome. If the prescriber verifies the prescription but the pharmacist's concerns remain unresolved the pharmacist must consult with their Medicines Control Advisor or the Medical Officer of Health and document this action.'

In this situation, there was nothing wrong with the prescription for labetalol. It was legible, authentic, legal and appropriate.

However, given that [Mr B] believed that the prescription was for Largactil instead of labetalol, the dose (200mg three times daily) was so high that he should have been prompted to confirm this dispensing with the prescriber. This is doubly true since the patient had no previous history of receiving any Largactil from [the Pharmacy].

As such, considering the circumstances surrounding the dispensing, I believe that this standard was breached.

Obligation 3.12 — Adverse reactions and interactions

'The pharmacist must be alert to potential adverse drug reactions and drug interactions and respond appropriately.'

[Ms F], the pharmacy technician who produced the label, had printed a standard warning on the prescription label stating, 'Don't take with antacids, iron or calcium.' (This warning is automatically prompted by [the Pharmacy] software.) However, the dispensing pharmacist, [Mr B], did not discuss this warning with [Ms A].

Although the interaction between iron and Largactil is not a particularly dramatic one, I still believe that [Mr B] had a clear obligation to give a brief verbal explanation on how to take the two medicines. As such, this standard was not met.

Obligation 4.1 — Standards of service

'The pharmacist must provide high standards of service and patient focused care within the resources available.'

This standard was not met. Although the resources of [the Pharmacy] may have been under strain due to high workload and [Mr B's] fatigue, this does not excuse the lapse in the standards of service. (Nor do these factors excuse [Mr B's] failure to follow up on the error after it was discovered.)

Obligation 6.4 — Supervision

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

The error that occurred resulted from a basic mistake made by a technician, which was neither detected nor corrected by supervising pharmacist [Mr B], despite his being in a position to do so (and despite several obvious factors that should have warned him about the dispensing). Therefore, the level of supervision on this occasion cannot be said to be appropriate, and thus this part of the standard was technically breached.

Obligation 10.1 — Compassion for patients

'The pharmacist must demonstrate a caring, empathetic attitude towards the patient and acknowledge their expression of concerns or worries in order to provide holistic care.'

[Mr B] initially failed to 'follow up' this error: he did not contact the patient or any of her family members or representatives, or her other healthcare providers. He only did so after regulatory authorities contacted [the Pharmacy], some 20 days after the error occurred. While it is easy to understand that [Mr B] was fatigued and highly stressed, his failure to act does *prima facie* seem to lack compassion for [Ms A's] circumstances. Therefore, I feel this standard may have been breached. I understand that [Mr B] eventually did contact [Ms A] and offer a written apology.

Pharmacy Council of New Zealand Competence Standards 2004

Sub-element 1.1.2 — Maintains a consistent standard of work

'Examples of evidence: expects consistent standard of work from self and others; leads by example; explains quality systems and who is responsible in workplace.'

This error cannot be seen as a 'consistent' standard of work — especially when viewed in the context of other significant errors that have occurred in the same pharmacy in 2006.

Sub-element 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; Identifies wider effect of his/her actions on individuals and the community.'

In this case, there has been some confusion over who (if anyone) was responsible for 'following up' the error. In a telephone interview, [Mr B] said, '[The hospital] didn't suggest any follow-up so I thought it was all resolved.' This is not an acceptable attitude to a significant error.

In a subsequent interview, [Mr B] suggested that follow up was at least partly the responsibility of [the Pharmacy] manager, [Ms D]; while [Ms D] believed that [Mr B] was handling the incident himself.

It is quite clear to me that [Mr B] was personally responsible for following up the error that had occurred under his supervision. It was his responsibility to make personal contact with [Ms A] as soon as possible. It was his responsibility to inform [the Pharmacy] proprietor, [Mr E], about the situation. It was his responsibility to follow [the Pharmacy's] standard procedures for responding to errors — procedures that he had helped to develop. Yet he did none of these things.

Therefore, I believe that before being contacted by Medsafe on 25 August 2006, [Mr B] had not accepted full responsibility for the error and thus failed to meet this standard.

Sub-element 1.1.5 — Works accurately

'Examples of evidence: minimises mistakes; acts immediately to rectify harm arising from mistakes; documents errors and steps taken to prevent their recurrence.'

Unfortunately, the error that occurred cannot be described as an accurate standard of work, so in that aspect the standard was not met. Furthermore, it seems the actions taken in response to the error were extremely unsatisfactory. Neither the

patient, nor her healthcare providers, nor [the Pharmacy] owner was contacted; and documentation was not completed properly. It was only after being prompted by authorities that [Mr B] took the appropriate steps to resolve the error.

Sub-element 1.2.1 — Solves own problems

'Examples of evidence: differentiates between personal and professional problems; recognises indicators of impaired personal performance; ensures safe personal practice.'

As already discussed, [Mr B] had failed to resolve his problems in an appropriate and timely manner.

[Mr B] alleges he was suffering from fatigue. Judging by his work schedule, I do not doubt him. However I note that pharmacists are obligated to recognise when their performance may be impaired (be it by fatigue, illness, or other agency) and take actions to ensure their practice is safe. While fatigue puts the error in context, it is not a complete excuse.

Sub-element 2.3.2 — For each medicine, checks the dosages and methods of administration are optimal

'Examples of evidence: assesses efficacy and safety of medicine recognising pharmacokinetic factors, e.g. age, weight, pregnancy, other therapies; assesses the suitability of dosage form with respect to efficacy, safety and compliance, e.g. tablets in a child, inhaler type for asthmatic.'

As I have already mentioned, there were several factors relating to this dispensing that should have been checked. The warning signs included: [Ms A's] comments and actions during the dispensing; clues about her breast-feeding; the unusually high dose of the drug; and the notice about taking the medicine with iron.

Given all of these 'red flags,' [Mr B] still failed to check that the medicine was optimal.

Sub-element 3.1.2 — Identifies the immediate problem with which the patient presents

'Examples of evidence: makes an assessment of patient's condition on basis of history.'

Pharmacists rarely have access to patients' complete clinical details. This can sometimes present a thorny medico-legal problem. On one hand, pharmacists need to respect the privacy of patients and avoid probing too deeply into sensitive issues, especially in the public environment of a pharmacy. On the other hand, it is

important for pharmacists to understand the condition being treated, to offer informed advice and form a constructive part of the healthcare team.

I can understand [Mr B's] reticence to ask too many personal questions about [Ms A's] medication (after all, Largactil is usually prescribed for reasonably serious mental disorders, and as such it might have been an embarrassing or upsetting matter to discuss). However, on balance, I think that [Mr B] should have made more of an effort to understand the clinical picture that [Ms A] was presenting. This is especially in light of the abundance of warning signs associated with the dispensing, and considering the reasonably large dose of the medicine that she was being given with no prior dispensing history. As such, I feel this standard was breached.

Sub-element 4.2.1 — Works with the documented procedures and systems

'Examples of evidence: works within organisation's Standard Operating Procedures (SOPs); uses computer programmes and other systems in workplace.'

Almost all of the pharmacy errors I have seen in my professional capacity have been inadvertent, accidental breaches of SOP; usually, it turns out that [the Pharmacy]'s procedures are adequate, and that somebody has just made a momentary, unintentional lapse in good practice. These sorts of errors cannot be completely excused, but they can be understood by any pharmacist in the country, who would surely think, 'there but for the grace of God go I.'

This case is unfortunately somewhat different. While the initial mistake was clearly an unintentional lapse, the *response* to the error was not unintentional. Frankly, it looks like an attempt to 'sweep things under the carpet.' [Mr B] failed to follow SOPs after the dispensing error was revealed, did not contact the patient or her doctor and did not fill out appropriate paperwork. [Mr B] knew, or ought to have known, that such a response was inappropriate.

[Mr B] clearly had intimate knowledge about the appropriate SOP for dealing with errors, as he had personally reviewed the SOPs shortly before the error occurred. I do not accept his claim that, "[he] got the impression it was all sorted out."

It seems [Mr B] failed to work within [the Pharmacy's] SOPs, so consequently this standard was breached.

In [Mr B]'s defence, I note that he was under a lot of stress and fatigue, and he was feeling unwell at the time the error happened. I also think, that following the previous errors at [the Pharmacy] and the subsequent media attention, he may have been shocked and frightened at the consequences he might face if the error were made public. This is not an excuse, but an insight into his probable state of mind during August 2006.

Sub-element 6.2.1 — Determines whether individual prescriptions should be dispensed

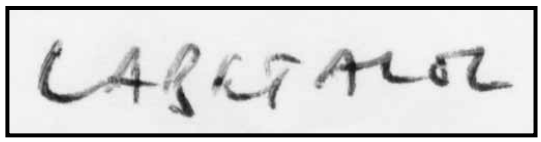
'Examples of evidence: recognises problem prescriptions, e.g. incorrect/inappropriate prescribing.'

This error was a 'text-book example' of a problem prescription. As I have already explained, there were numerous warning signs. Despite all of these warnings — and despite [Mr B] himself being concerned about the prescription — the error was not caught. That suggests that this standard was not met.

Sub-element 6.3.1 — Identifies prescribed medicines

'Examples of evidence: identifies trade, generic and common names for prescribed medicines; uses reference sources to find medicine names.'

The basic mistake made in [Ms A's] dispensing was the failure to distinguish between Largactil and labetalol. Both names have the form LA—T—L. On the actual prescription, the word 'LABETALOL' was handwritten and the legibility was not perfect; for instance, the "B" could be interpreted as an 'R.'



Actual handwriting from the prescription

However, after closely examining the original prescription I am satisfied that while it is not perfect, it is sufficiently legible for dispensing purposes. (I will discuss the issue of handwriting legibility further in section 3.13.)

Given the nature of the error, it is obvious that this standard was not met.

Sub-element 6.4.4 — Identifies patient factors likely to affect the efficacy or safety of specified medicines

'Examples of evidence: e.g. age, weight, pregnancy, breast-feeding, disabilities, allergies, risk factors, other medicines.'

As already mentioned, [Mr B] did not discuss [Ms A's] clinical details and did not discuss breast-feeding or how to take the medication with iron. Clearly, this standard was not met.

Sub-element 6.5.1 — Confirms that each selected medicine is suitable for the patient

'Examples of evidence: confirms that dosage, route of administration and duration of therapy are suitable; identifies possible interactions or incompatibilities.'

For obvious reasons already mentioned in depth, this standard was not met.

Sub-element 6.6.2 — Maintains a logical, safe and disciplined dispensing procedure

'Examples of evidence: selects correct product, dose form and quantity for each prescribed medicine; dispenses off prescription, not label.'

As already mentioned, this standard was not complied with — as dispensing the wrong medicine cannot be considered a safe procedure; and failing to catch the error despite numerous warning signs suggests a (temporary) lack of discipline.

Sub-element 6.9.2 — Acts to minimise the effects of his/her dispensing errors

'Examples of evidence: identifies potential/actual errors in own dispensing; acts to minimise effect on patient, e.g. contacts patient, contacts prescriber, supplies correct medicine; documents own dispensing errors and actions undertaken to minimise their effects; complies with workplace procedures for documenting dispensing errors.'

For reasons already outlined in detail, it is obvious that this particular standard was compromised. The breach of this standard is of particular concern to me.

Sub-element 6.9.3 — Rectifies dispensing errors immediately

'Examples of evidence: alters own dispensing procedure to prevent recurrence of previous errors.'

For reasons previously discussed, it is clear that this standard was breached. [Mr B] knew, or ought to have known, that he had an obligation to follow up on his dispensing error.

As with [Mr B's] breach of sub-element 6.9.2, the departure from this standard is of particular concern to me.

Pharmacy Practice Handbook 2003

Many aspects of the Pharmacy Practice Handbook 2003 have been superseded or supplemented by the updated Code of Ethics 2004 and Professional Competence

Standards 2004. Nevertheless (and at the risk of being repetitious), the following standard, expressed in the handbook, is worth outlining:

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 …

…

6.2(b) The pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies their authenticity and appropriateness and determines their priority for dispensing.

6.2(c) 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.

This standard was not met, for obvious reasons that have already been outlined in detail.

3.4. When dispensing Largactil, what information should a pharmacist provide the patient? Did [Mr B] provide [Ms A] with appropriate information when dispensing Largactil?

Two pharmacy standards, from the Pharmacy Council of New Zealand Competence Standards 2004, are especially relevant to this question.

Sub-element 5.3.1 — Explains the pharmacology and therapeutic use of common medicines

'Examples of evidence: either from memory or reference sources, explains therapeutic use, patient factors, ADRs, interactions and contraindications for common medicines; provides references to substantiate information.'

Sub-element 5.3.2 — Advises about the use of medicines

'Examples of evidence: explains the safe use of medicines, including warnings and precautions and special storage requirements of specific medicines.'

Pharmacists have a responsibility to ensure that their patients know what their medication is for, give clear usage instructions, and outline essential details such as common side effects. It is not necessary to 'bombard' the patient with information;

nor is it always necessary to give extra printed material to accompany the medication; verbal advice often suffices.

As a rule of thumb, pharmacists should find out how much information a patient *wants.* This should guide them in how much extra information to provide.

However, there are situations where it is practically mandatory to give additional information, and make sure that the patient (or caregiver) understands it. For instance, when a patient is receiving their first dispensing of a less-common drug, when a dose is outside the normal range, when the therapeutic margins are narrow, or when there is a risk of clinically significant drug interactions. In those cases, the pharmacist has a clear duty to make extra details clear to the patient. This duty can be a demanding one in a busy pharmacy, but it is an important one.

Considering this specific case, and bearing in mind all of the above details, I believe that [Mr B] should have provided [Ms A] with much more information on her medication.

In my opinion, he should have explained to [Ms A] about taking the medication with iron. He probably should have realised that [Ms A] was breast-feeding and given appropriate information on this aspect. Given the high dose, he should have cautioned [Ms A] that Largactil is a sedating medication, and that she should take care if driving or operating machinery after taking the pills (I note that [Ms A] drove her car shortly after taking the Largactil, and the outcome could have been disastrous).

Given other warning signs, he probably should have provided her with a small amount of printed Consumer Medicine Information (readily available from many sources such as Med+Info Information software or the Medsafe database).

3.5. [Ms A] noted that she normally took only one tablet when advised she was to take two tablets three times a day, and [Mr B] stated that he checked the prescription again. Given that the maximum strength of Largactil is 100mg, should a pharmacist of [Mr B's] experience have been alerted to the error by the number of tablets [Ms A] was required to take?

Given the circumstances, [Mr B] should have realised there was a problem. In fact, he *did* realise there was a problem, and re-checked the prescription — but still failed to notice the error.

However, it should be pointed out that PHARMAC, the medicines funding authority, does make regular changes to the schedule of funded medicines. This often leads unexpected changes in the appearance and nature of various medicines as different manufacturers are subsidised for the same drug formulation. This situation adds an extra element of risk in today's dispensing environment, and is an area where pharmacists must be eternally vigilant.

3.6. Should a pharmacist of [Mr B's] experience have been alerted to the dispensing error by the dosage of Largactil that he believed was prescribed?

Yes. Even if the prescription *was* for Largactil, the dose was large enough to cause significant concern. This is especially true considering that the patient had no Largactil in her prior dispensing history. [Mr B] should probably have referred to various drug resources about the suitability of the dose, and he certainly should have discussed his concerns with the patient and the prescribing doctor.

3.7. The sticker applied to the box of Largactil stated that the drug should not be taken with ferrous sulphate, which was also dispensed. Please comment.

Many medicines bear the standard warning, 'do not take with antacids, iron or calcium.' There are two reasons for such a warning. Firstly, antacids, iron and calcium can bind to many drugs in the stomach. Secondly, antacids, iron and calcium can alter the stomach's pH. In both situations, this can cause irregularities in the absorption of the patient's medicines.

The standard advice in such a situation is to take the medicines at different times throughout the day, usually by spacing doses by at least 2 hours.

In this case, it seems that the reaction between Largactil and iron is probably of limited clinical significance. Nevertheless, [Mr B] should have verbally counselled [Ms A] on how to take the Largactil. A sufficient explanation would have taken less than thirty seconds.

3.8. Should a pharmacist of [Mr B's] experience be aware of the cautions associated with prescribing Largactil for women who are breast-feeding?

According to the American Academy of Pediatrics, chlorpromazine (Largactil) is classified as 'an agent whose effect on the nursing infant is unknown but may be of concern because of isolated reports of drowsiness and lethargy in infants receiving breast-milk.'

Despite this classification, the evidence suggests that Largactil is *reasonably* safe to take while breast-feeding provided the benefits and risks are carefully considered, and provided appropriate precautions are taken. Largactil only transfers into breast milk in small quantities. (In one study, following a very large oral dose of 1200mg, only 0.29μg/mL could be detected in breast milk; with a 600mg oral dose, no Largactil could be detected at all.) Infants being breast-fed by mothers on chlorpromazine usually show no effects — but still should be monitored for signs of sedation or strange muscle movements.

Clearly, [Mr B] was not aware of these details when dispensing the Largactil. This is not surprising or concerning; it is unreasonable to expect a pharmacist to be a walking drug encyclopaedia. However, given the obvious signs that [Ms A] was nursing an infant, he should have confirmed that she was breast-feeding. He should have consulted appropriate resources to confirm the safety of the drug, and counselled her about safe nursing guidelines. Under the circumstances, he probably should have referred her to consult with her hospital obstetrician/paediatrician or family doctor for more advice.

Of course, by this point it should have been obvious that [Ms A] was not meant to be taking Largactil at all.

3.9. Should a pharmacist of [Mr B's] experience have been alerted to the dispensing of Largactil by [Ms A's] purchases of Lansinoh cream and dummies?

Speaking in general terms, the purchase of Lansinoh and dummies should alert any pharmacist (and indeed any pharmacy employee of any level of experience) that the purchaser is probably breastfeeding, or assisting someone who is.

As I have stated several times, the purchase of these items was one of many 'warning signs.' However, I must emphasise that pharmacists should not be expected to play 'Sherlock Holmes' with every customer. If we did that, every dispensing would take a very long time, and would probably result in many customers being annoyed or frustrated.

I am also mindful of the fact that [Mr B] was sick, tired and preoccupied with [Ms A's] question about the number of tablets she should take per dose. Again, this is no excuse, but is a context for the situation.

Overall, the evidence suggesting [Ms A] was breastfeeding was almost overwhelming, and [Mr B] should have been alerted to the fact.

3.10. Please comment on the adequacy and appropriateness of [Mr B's] actions following the discovery of the dispensing error. Was [the Pharmacy]'s standard operating procedure followed?

As previously discussed, [Mr B's] actions following the discovery of the dispensing error were clearly not appropriate. In fact, they fall well short of the required standards, and indeed fall short of the SOPs that [Mr B] himself helped to review.

The Pharmacy Defence Association spells out the appropriate steps to take in response to a medication error:

- if a patient notifies an error, the appropriate response is to express immediate concern;

- if the error is obvious, then the pharmacist should acknowledge the error and apologise;
- if the error is not obvious, the pharmacist should inform the patient they will investigate the situation and report back to the patient as quickly as possible;
- 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;
- if appropriate, the patient should be reassured that the symptoms experienced are side effects of the medication and advised when they are likely to abate;
- if necessary, the patient should be referred to the prescriber, and [the Pharmacy] should offer to pay for the visit;
- the pharmacist should notify the prescriber of the situation, how the patient is, and what actions have been taken to date; and
- all aspects of the incident should be documented.

Furthermore, the Standard Operating Procedures on errors, in effect at [the Pharmacy] at the time, state:

1. Your main concern is the patient — check if the patient is OK before anything else.
2. Re-assure the patient or patient's family that you are going to sort out the problem and help the patient over it.
3. Apologise (if appropriate).
4. Analyse what the error was (if appropriate).
5. Rectify the problems (if possible).
6. Contact Doctor concerned.
7. Contact Poisons Centre if required 0800 POISON 0800 764 766.
8. Contact the hospital to enquire on the patient's situation.
9. Use phone contacts list SOP 3.323 for serious incidents.
10. Fill out appropriate incident report forms
    3.321, 3.301 B, use incident book, 3.205B, 6.503 H1574

10B. Customer complaint form 4.102

11. De-briefing to be arranged as soon as possible with manager and/or proprietor and staff involved. At least within 2 weekdays.
12. Procedures put into place (changing SOPs) to reduce chance of incident occurring again — immediately.
13. Staff meeting to be arranged within 7 days for de-briefing and to present new SOPs or changes to existing SOPs.
14. Follow up letter to the patient/family concerned within a week. Informing them of steps taken to rectify the problem.
15. Phone call(s) to patient/family at regular intervals by management until situation has been resolved for all concerned.

Comparing these guidelines to [Mr B's] actual actions, one can only say that his behaviour was inappropriate and generally fell far short of what would be expected of a competent pharmacist. Aside from unsuccessfully "trying" to contact the patient a couple of times, [Mr B] did nothing to follow up on the error until contacted by regulatory authorities.

I should add that I am disappointed with the dismissive attitude that [Mr B] had to the error even when contacted by Medsafe, as evidenced in his comments made in a telephone conversation with [Ms I] on 25 August 2006:

[Mr B]: *The hospital rang on Sunday and I was working. They said the lady had gone back to hospital that night. The hospital confirmed the script was for labetalol but did not suggest any follow-up so I thought it was all resolved.*

[Ms I]: *So what follow up action have you taken?*

[Mr B]: *We have done nothing. I got the impression it was all sorted out. I thought she looked like a nervy person, and that she had gone back to the hospital to check it out.*

[Ms I]: *No, she was admitted to hospital.*

[Mr B]: *That's right, she went back to hospital to get it checked out.*

[Ms I]: *No, [Mr B], as I understand it she was actually admitted to hospital.*

[Mr B]: *Yes, she only took one dose and it is all sorted out now.*

I think these comments speak for themselves.

[Mr B's] failure to take responsibility and follow up the error is of particular concern to me.

3.11. Please comment on the relative responsibilities of the pharmacist and the technicians in the dispensing process.

In New Zealand, the relative levels of responsibility of pharmacists and pharmacy technicians are clearly spelled out under the Medicines Regulations 1984 (which exist pursuant to section 105 of the Medicines Act 1981); the Pharmacy Code of Ethics 2004 (especially obligations 6.4 and 6.5); the Pharmacy Competence Standards (especially sub-elements 4.1.1, 4.1.2 and 4.1.3); and the Pharmacy Practice Handbook 2003 (especially Part 3, Section 3.1.5; Part 4, Section 4.1 and Part 6, Section 6.1).

Medicines Regulations 1984

Part 7 r 42 — Dispensing of prescription medicines

(1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinary surgeon, pharmacist, pharmacy graduate, a pharmacy technician, a student, or dispensary technician may dispense a prescription medicine.

(1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:

(a) dispensary technicians;

(b) pharmacy graduates;

(c) pharmacy technicians;

(d) students.

Part 7 r 63 — Restriction on, and supervision of, compounding medicine

(1) A dispensary technician must not undertake any process of compounding a medicine.

(2) The following persons may compound a medicine, but only if under the direct personal supervision of a pharmacist:

(a) pharmacy graduates;

(b) pharmacy technicians;

(c) students;

(d) despite subclause (1), dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939.

Pharmacy Council of New Zealand Code of Ethics 2004

Obligation 3.6 — Delegation of duties

'The Charge Pharmacist must ensure that pharmaceutical services assigned or delegated to other personnel are commensurate with their qualifications, ability and experience.'

Obligation 3.18 — Supervision of medicines restricted to pharmacies

'The Charge Pharmacist must ensure that medicines restricted to sale from pharmacies are stored or displayed in such a way that the pharmacist can exert supervision over their sale.'

Obligation 3.19 — Control by pharmacist

'The pharmacist must exercise control over the sale or supply of any medicine, complementary therapy, herbal remedy or other healthcare product, which is sold or supplied from the Pharmacy.'

Obligation 6.4 — Supervision

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

Obligation 6.5 — Responsibility for professional activities

'The pharmacist must accept responsibility for their own professional activities and for all activities undertaken under their direct supervision.'

Pharmacy Council of New Zealand Competence Standards 2004

Sub-element 4.1.1 — Organises own work

'Examples of evidence: explains own work and responsibilities in work place; meets deadlines; prioritises work; decides what to do, plans to get it done and does it.'

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

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

Sub-element 4.1.3 — Supports the work of colleagues in the work place

'Examples of evidence: describes pharmacist's role and responsibilities in workplace; works in partnership with colleagues in work place, if applicable, to ensure safe practice.'

Pharmacy Practice Handbook 2003

Part 3, Section 3.1.5 (Supervision in Pharmacies)

'Section 41 of the Pharmacy Act 1970 requires that a registered pharmacist must always be present to supervise the activities going on in a pharmacy during opening hours.

The issue of supervision in pharmacies is a recurring one. Pharmacies are places where members of the public can go to receive informed, unbiased professional health advice and information. In order to maintain a professional image and retain the range of medicines able to be sold in a pharmacy it is essential that pharmacists continue to ensure appropriate supervision of all transactions occurring in a pharmacy. This is implicit in the act. Section 41 states "no person shall keep, or permit to be kept, or manage, any pharmacy which is not for the time-being under the immediate supervision and control of a pharmacist." Supervision is not defined in the act but it has been defined in the courts as existing only when the person supervising is in touch with transactions by sight and sound and is in a position to intervene if this is necessary. Clearly, supervision cannot operate without the physical presence of a pharmacist. Members of staff should be made aware of the effect of section 41 of the act.

The Council of the Pharmaceutical Society is convinced that it is in the interest not only of members of the public but of all pharmacists that there should be strict compliance with section 41. In the absence of a pharmacist, there is no apparent difference between a pharmacy and any other retail outlet.

…

Council expects close compliance with the provisions of section 41 and will continue to take a serious view of any contraventions.'

Part 4, Section 4.1, 4.1.1 (Dispensing)

'Pharmacy graduates, dispensary technicians, pharmacy technicians, pharmacy students and pharmacy technician students may only dispense under the direct personal supervision of a pharmacist …'

Part 6, Section 6.1 (Dispensary and Pharmacy Technicians)

'Dispensary and pharmacy technicians assist pharmacists with the dispensing of prescription medicines. They must always work under the direct personal supervision of a pharmacist (reg 63 of the Medicines Regulations 1984). Regulation 2 of the Medicines Regulations defines a Dispensary Technician and a Pharmacy Technician.

A Dispensary Technician (previously termed a Dispensary Assistant) has a Dispensary Assistant's Certificate issued by the Pharmaceutical Society following completion of a course of training prior to 1998.

A Pharmacy Technician has a National Certificate in Pharmacy (Technician) issued by the New Zealand Qualifications Authority, or has an overseas qualification recognised by the Pharmaceutical Society as equivalent.

In pharmacy, only pharmacists, pharmacy graduates actively taking steps towards registration as a pharmacist, pharmacy students, dispensary technicians, pharmacy technicians, pharmacy technician students and persons who served an apprenticeship under the Pharmacy Act 1939 are permitted to dispense prescription medicines (reg 42 Medicine Regs). All, except pharmacists, must work under the direct personal supervision of a pharmacist. Dispensary technicians are not permitted to compound medicines.'

Part 6, Section 6.1.1 — Roles of Dispensary and Pharmacy Technicians

Guidelines for the Pharmacist

'The functions performed by a pharmacist can be categorised as either non-judgemental product orientated or patient orientated. In developing the concept of comprehensive pharmaceutical care, it is essential that the pharmacist devolve responsibility for as many product orientated functions as possible so allowing time for patient orientated activities. However, technicians must be supervised by a pharmacist at all times when involved with the dispensing and supply of medicines.

Limitations of Role

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

The above standards are unanimous and very clear. They are repeatedly emphasised to pharmacists and pharmacy technicians throughout their training. There should be no ambiguity in the understanding of their respective roles. Pharmacy technicians must always work under the care of a pharmacist, who supervises their work and normally assumes full responsibility for each dispensing under their care.

Technicians have a greatly reduced degree of responsibility for their role in the dispensing process.[24] There is a very strong suggestion that whenever a pharmacy error occurs, it must be the responsibility of a pharmacist; as such, I am generally very hesitant to suggest that a technician has ever departed from an 'acceptable standard of care.'

However, despite the clear understanding that pharmacists are fully responsible for everything that occurs under their supervision, I am of the opinion that there are rare occasions when to apply this rule inflexibly and 'to the letter of the law' would violate common sense and natural justice. In those rare cases, it may be reasonable to hold a pharmacy technician directly responsible for an error, while *not* holding the supervising pharmacist responsible. Such determinations should not be made lightly, but only after an extremely thorough examination of all salient facts of the matter.

Examples of such situations might include:

1. Instances where a technician acts in bad faith or otherwise deliberately acts to harm patients;
2. Instances where a technician deceives a pharmacist or other authority about their actions;
3. Instances where a technician commits a serious error in dispensing, where the nature of the error is such that it would be unreasonable to expect even the most diligent supervising pharmacist to detect and amend the error prior to dispensing, and where there are no other relevant ameliorating or extenuating circumstances.

It should be emphasised that these three examples are merely hypothetical cases that I raise to illustrate my point; they should not be interpreted as necessarily applying to this nor any other case before the Commissioner.

[24] While there are some calls to expand the role and responsibility of technicians, these proposals are only at the stage of informal discussions, and any changes in this area will be years away — if they happen at all.

In the current case, although the actual error was committed by one technician and not detected by another technician, there are no exceptional circumstances extant. It is entirely reasonable to expect the supervising pharmacist, [Mr B], to have detected the error (especially given the numerous warning signs in the dispensing process). Thus, it is my opinion that in the current case, the full responsibility for the error rests with supervising pharmacist [Mr B].

As I already stated in section 3.2., 'In my opinion, [Mr B] clearly did not provide [Ms A] with an adequate standard of care. I believe pharmacy peers would regard the departure from care with moderate-to-severe disapproval.'

3.12. This dispensing error is the third from this pharmacy investigated by the Commissioner in 2006. Please give your views on whether there are any systemic or other causes for this number of dispensing errors. Please comment, if you are able, on whether the frequency of dispensing errors at this pharmacy is any higher than at a similar pharmacy.

General Comments

The fact that several errors have occurred at [the Pharmacy] this year is of considerable concern to me. The people [living in this city] need to know that they can visit [the Pharmacy] in confidence that their prescriptions will be dispensed with accuracy and professionalism.

I note that each of the three errors involved different members of [the Pharmacy] team. In each case, the responsibility for the error falls on a separate individual. No one person is an obvious "weak link" in the chain.

I have carefully reviewed all relevant aspects of the three errors that have occurred at [the Pharmacy]. In my opinion, there are no obvious problems with policies or procedures at [the Pharmacy]. I do not believe there are any systemic failures within [the Pharmacy]; rather, it seems that they have been hit by a run of terribly bad luck.

I do note that all three errors were committed by technicians, and missed by pharmacists during the final check. In my opinion, the nature of the first error meant it was unreasonable to hold the supervising pharmacist to account. However, the subsequent two errors could, and should, have been detected by the supervising pharmacists. These errors are a potential warning that the activities of technicians at [the Pharmacy] need closer attention and supervision.

I also note that in two of the cases, the errors that occurred were not followed up promptly. In one of those cases (HDC 06-09528), I believe that the follow-up was mostly adequate but aspects were delayed; whereas in the current case the follow-up was inadequate and did not occur until regulatory authorities intervened. This is a warning that the SOPs for responding to errors in [the Pharmacy] should be

reviewed and discussed with all staff, with individual responsibilities made completely clear. Any future errors at [the Pharmacy] must be followed up with extreme promptness and professionalism.

At this point, I need to make a very important qualification to all of my advice. I should point out that as an expert advisor, I can only comment on the printed documents I am given. I cannot make any comments on relevant "unwritten" issues such as the professional culture and working environment at [the Pharmacy]; nor can I consider how rigorously [the Pharmacy] team follow the SOPs in day-to-day practice. I can only assume, in good faith, that the entire team at [the Pharmacy] are professional and diligent. I have no reason to believe otherwise. I can make no further comment on this aspect, but I imagine that the team at Medsafe, who carry out physical audits of pharmacies, would be better equipped to guide the Commissioner on this question.

Statistics on Pharmacy Errors

I am not aware of any recent statistics on dispensing errors in New Zealand community pharmacies. However, I am familiar with the Ashcroft study,[25] a reasonably large survey of pharmacy errors in the United Kingdom. I think it is safe to assume that community pharmacies in New Zealand and the U.K. are similar. During the Ashcroft study period, 125,395 prescription items were dispensed and 330 incidents were recorded. Of these, 280 incidents were classified as a *near miss* while the remaining 50 incidents were classified as *dispensing errors*.

The most common errors were drug selection errors (199, 60.3%), followed by labelling (109, 33.0%) and bagging errors (22, 6.6%).

Most of the incidents were caused by misreading the prescription (90, 24.5%), confusingly similar drug names (62, 16.8%), selecting a previous drug or dose from the patient's medication record on [the Pharmacy] computer (42, 11.4%) or confusing drug packaging (28, 7.6%).

This study demonstrates that a range of medication errors can occur in community pharmacies, and I agree with its conclusion that on average, for every 10,000 items dispensed, there are around 22 near misses and four dispensing errors.

It is a safe assumption that [the Pharmacy] dispenses considerably more than 100,000 prescriptions and repeats every year. By the raw statistics of the Ashcroft

[25] Ashcroft, D.M., Quinlan, P. and Belinkinsopp, A. (2005). Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. *Pharmacoepidemiology and Drug Safety*. **14**: 327–332.

study, I would expect that any pharmacy of similar output to [the Pharmacy] would have at least 220 near misses and 40 actual dispensing errors annually.

While these statistics sound alarming, one should bear in mind that the total error rate they express is in the region of a quarter of one percent; many of these errors may be of limited significance; and the majority of these errors are detected and corrected before the medicine is given to the patient.

These statistics should not be interpreted as condoning any error, nor suggesting that there are a number of errors that each pharmacy should 'expect' to have. The goal should always be for perfect service and zero errors. *However, it must be understood that dispensing is a human process and errors, while regrettable, will happen from time to time.*

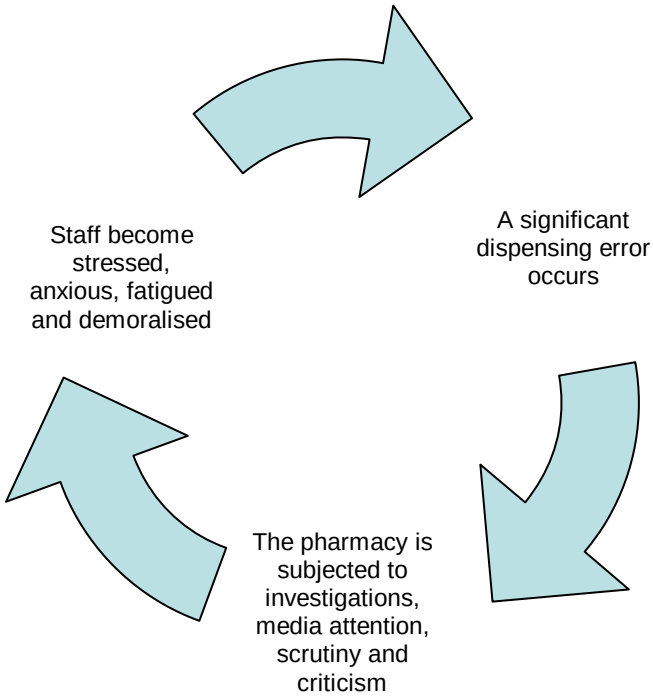
What is of concern to me about the errors at [the Pharmacy] is not that mistakes have occurred *per se*, but that they have been particularly significant ones. I am at pains to reiterate that pharmacists are diligent and hard-working professionals who work with robust error-control procedures.

Why so many errors?

The question remains, 'why have so many errors been reported at [the Pharmacy]?'

The primary reason [the Pharmacy] has had three reported errors this year may be simply due to a run of bad luck. Such statistical anomalies are not unheard of — for instance, in [other regions] it seems we have had several 'hundred year floods' in the past ten years!

Another aspect, which should not be downplayed, is the effect of stress and fatigue in [the Pharmacy]. I imagine that the following 'vicious circle' describes a process that occurred at [the Pharmacy] [below]:



The challenge to [the Pharmacy] is to break this cycle, look at their errors as constructive learning experiences, redouble their efforts to keep staff morale high and review their error-checking procedures.

Overall, on the basis of the information I have, I believe that [the Pharmacy] is a good, well-run pharmacy that has simply been hit by a run of bad luck.

3.13. Any other comments you wish to make.

Doctor's handwriting

In section 3.3, I mentioned that a doctor's handwriting can often present a challenge for dispensers. While I am satisfied that in this case the legibility of the prescription is acceptable, it is timely to remind all prescribers about the overwhelming importance of producing clear, unambiguous prescriptions.

Manufacturer's packaging

I have reviewed the manufacturer's packaging for Largactil and in my opinion there are no factors relating to the manufacturer's labelling that have any relevance to the current case.

Standard Operating Procedure

While [the Pharmacy's] SOP for responding to errors is perfectly adequate, I suggest that point 11 should be changed to *explicitly* include notification of the proprietor, and it should explicitly state that the supervising pharmacist involved in any error is responsible for coordinating the 'follow up' process. (Notwithstanding this suggestion for improvement, I still think the onus was clearly on [Mr B] to take responsibility for his error.)

4. Conclusion

It is obvious that [Ms A] and her family were deeply upset by this incident and the way it was handled. I am sure [the family] were very distressed to see [Ms A] readmitted to hospital so soon after giving birth.

It is also obvious that the team at [the Pharmacy] are terribly unhappy with the situation, and regret the way the error was dealt with. It is clear that [Mr E] and the management of [the Pharmacy] have a commitment to provide optimum care for their patients — a goal that can be difficult in the overworked and often hectic environment of modern pharmacies. While [the Pharmacy] dispenses tens of thousands of prescriptions professionally and correctly, three have 'slipped through the cracks.'

I would also like to refer specifically to [Mr B]. He is clearly a hard-working, intelligent and conscientious pharmacist. He knows he has done something wrong, and I am sure this incident is not typical of his character. While [Mr B] will no doubt have to face consequences for his actions, it would be a further tragedy if this lamentable incident has a permanent negative effect on his career.

I am confident that [the Pharmacy] now has redoubled their efforts to prevent dispensing errors, and I sincerely hope that the Commissioner will never again have reason to investigate any aspect of their service.

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."