

Pharmacist, Ms B

A Pharmacy

**A Report by the
Health and Disability Commissioner**

(Case 03HDC12256)



Health and Disability Commissioner
Te Toiāhu Hauora, Hauātanga

Parties involved

Ms A	Consumer
Ms B	Provider / Pharmacist
Mr C	Pharmacist
Ms D	Registered nurse at the rehabilitation service
Ms E	Caregiver at the rehabilitation service
Dr F	House surgeon
Mr G	Employer / Pharmacist
A Pharmacy	Provider

Complaint

On 18 August 2003 the Commissioner received a complaint from Ms A about the standard of service provided to her by Ms B, pharmacist. The following issues were identified for investigation:

Whether Ms B, pharmacist, provided services of an appropriate standard to Ms A. In particular:

- *the appropriateness and circumstances of dispensing morphine tablets to Ms A on 1 August 2003*
- *the appropriateness and circumstances of dispensing morphine tablets to Ms A on 7 August 2003*
- *the appropriateness and circumstances of dispensing morphine tablets to Ms A on 9 August 2003*
- *the adequacy of the information provided to Ms A, and the actions taken by the pharmacy on 9 August 2003.*

An investigation was commenced on 26 November 2003.

Information reviewed

- Information from:
 - Mr C, pharmacist
 - Ms D, registered nurse at the rehabilitation service
 - Ms A's caregiver at the rehabilitation service
 - Ms E, caregiver at the rehabilitation service
 - Mr G, employer/pharmacist
- Ms A's clinical records from the public hospital
- ACC file relating to Ms A's claim

Independent expert advice was obtained from Mr Alan Fraser, a pharmacist.

Information gathered during investigation

Hospital admission

On 29 July 2003, Ms A, aged 22 years, was admitted to a public hospital for surgical treatment for full thickness self-inflicted burns to the lateral and medial aspects of her mid left leg. The admission notes record:

“Multiple previous admissions for deliberate self harm with oven cleaner.
Last admission 6/52 [six weeks] ago.
6/7 [six days] ago put oven cleaner on lower leg as she was low in mood.
Seen in OPC [Out Patient Clinic] today and for OT [operating theatre].”

Ms A had debridement and split skin grafts to the burns under general anaesthetic later that day.

On 30 July Ms A was seen by a social worker, about arrangements for her discharge. The social worker noted that Ms A was “moving to [a residential psychiatric rehabilitation service] over the weekend where she will have contact with a case manager 3 x daily”.

On 31 July Dr F, house surgeon, recorded that Ms A was for discharge that day. She was given a prescription for antibiotics, codeine phosphate, panadol and morphine. An appointment was made for Ms A to return to the Outpatient Clinic on 3 August.

Ms A remained in hospital until 1 August for physiotherapy and occupational therapy.

Dispensing – 1 August

On her discharge on 1 August Ms A took her prescription to a pharmacy. The prescription, dated 31 July 2003 and signed by Dr F, noted:

“MORPHINE SULPHATE TEH
(MST) (10mg) (short acting)
One tab every 4 hours
(four)
05
(five).”

This prescription was crossed out and the following prescription written beneath.

“Morphine SULPHATE
ten (10) mg short acting
ONE tablet every four hours
5 (FIVE).”

Ms B, pharmacist, dispensed Ms A’s prescription at the pharmacy on 1 August 2003. She mistakenly dispensed long-acting morphine to Ms A instead of short-acting morphine.

Ms A experienced a lot of pain in her leg. She thought she had not been given enough morphine tablets, so rationed them and took only two pills a day. On 6 August she returned

to hospital for the dressings on her leg to be renewed. At that appointment Dr F gave her a further prescription for morphine.

The 6 August prescription, dated and signed by Dr F, noted:

“Morphine SULPHATE ten (10) mg
short acting
one tablet every four hours
tablet # 10)
(ten).”

Dispensing – 7 August

Ms A took the prescription to the pharmacy the following day, 7 August. Ms B informed me that when Ms A presented the second prescription on 7 August, the pharmacy had in stock only half the number of tablets required to fill the prescription. Ms B recalled that she went to the safe to get the morphine, saw the morphine sulphate 10mg on the shelf and took the container into the dispensary to generate the label on the computer. As only five tablets were in stock, they were dispensed. Again Ms B dispensed long-acting morphine to Ms A instead of the short-acting morphine prescribed by Dr F.

Ms B said that her usual practice when dispensing is to check the prescription for the patient’s name, address and date of birth. She checks the date of the prescription and whether a doctor has signed the prescription, and also the coding – whether it is A1 or A3.

(It is the doctor’s responsibility to fill in this information, which relates to the charge made to the patient. Patients with a Community Services Card will be coded A1 and their scripts will attract a \$3 basic charge, whereas A3 patients pay up to \$15 for each prescription item.)

Ms B stated that she looks at the contents of the prescription for the drug name, strength and formulation, as well as the instructions for administration. She checks the total amount of the drug required, for example, controlled drugs can only be prescribed for seven to ten days at a time.

Ms B said that when Ms A brought the prescription into the pharmacy she was working by herself and there was no one else available to check her dispensing.

Ms B asked Ms A to return to collect the outstanding tablets.

Dispensing – 9 August

Ms A returned to the pharmacy at 1pm on 9 August. Ms B gave her the five tablets owing, and again dispensed long-acting instead of short-acting morphine.

Ms B recalled:

“When I was checking the prescriptions at approximately 2.15pm on Saturday 9th August, I discovered that I had dispensed slow release morphine MST – as this was the

only morphine 10mg we had in stock, when the prescription called for morphine short-acting.

It was approximately 2.30pm – one and a half hours after [Ms A] collected her prescription before I was able to contact her as the phone number we had was incorrect.

When I spoke to [Ms A], I told her what had happened and instructed her to stop taking the morphine immediately (as the instructions on the medication were to take one every four hours).

I checked with [Ms A] how she had been taking the tablets and she informed me she had been taking them one twice daily in order to make them last longer. This information reassured me that she was taking the MST in the dosage regime that is recommended for this formulation and therefore no harm would result. As I had instructed her not to take any more tablets until I could replace them when I finished work, I was confident there would be no more harm to the patient.”

Ms B said that she was the sole pharmacist working that day. As she was going to be working until late that evening, which would delay her calling on Ms A, she arranged for one of her work colleagues, Mr C, to visit Ms A, uplift the incorrect morphine tablets and replace them with the prescribed long-acting morphine.

Follow-up

Ms D, registered nurse, was one of two clinical staff working at the residential psychiatric rehabilitation service (the rehabilitation service) on 9 August 2003. The other staff member was Ms E.

Ms D recalled:

“[Ms A] had been independently managing pain relief following a skin graft to her leg. She had been prescribed morphine sulphate, short acting, 1 tablet 4 hourly.

At 4.00pm on August 9th, I visited [Ms A’s] flat and she told me that [the] Pharmacist, [Ms B], had phoned her to inform her that a mistake had been made in dispensing the morphine and that [Ms A] had been given slow release morphine, instead of short-acting morphine. [Ms A] said that she told [Ms B] that she had taken two tablets. This was some time round 2.00pm. [Ms A] said [Ms B] had told her:

- Not to take any further tablets
- That she, [Ms B], would come to [Ms A’s] flat at around 6.00pm to collect the remainder of the slow release morphine and replace it with short-acting.

When I saw [Ms A] at 4.00pm she told me that she had taken 3 tablets. At that time she was looking pale and tired. I immediately phoned [Ms B] at [the pharmacy].

...

I told [Ms B] that [Ms A] told me that she had taken three tablets. [Ms B] sounded slightly surprised that [Ms A] reported taking three rather than two tablets. However, [she] was not alarmed. I queried the seriousness of [Ms A] taking this amount of medication and [Ms B's] viewpoint was 'that this was not an overdose'. [Ms B] gave no specific instruction for observing [Ms A] at this time and said that she would send [Mr C] around to collect the incorrect morphine and replace it with the correct morphine at about 6.00pm."

Ms E stated that Ms D told her of the incorrect dispensing of long-acting morphine to Ms A. Ms E visited Ms A at her flat. When Ms A opened the door she appeared unsteady on her feet and complained of feeling tired. Ms E tried to talk to Ms A about what had happened, but her responses were vague and confusing, particularly about how many tablets she had taken and when. Ms E recalled that Ms A told her that she had taken one or possibly two tablets after speaking with Ms B.

Ms E stated:

"[Ms A's] reason [for taking the additional tablet] being the extreme physical pain she was in and the need to dull the pain. As I had never met [Ms A] before this visit, I was unaware if the unsteady gait was due to the morphine, her leg pain, or if it was her usual gait."

Ms E returned to the rehabilitation service's office and received a telephone call from Mr C to say that he was on his way with the replacement tablets.

Mr C called at the rehabilitation service office at 6.30pm. He stated that Ms A was not to take any further medication until assessed by a doctor. He asked the staff to check Ms A's vital signs regularly. Ms E asked Mr C to write down what had happened as she needed written verification of his instructions, "particularly about not giving [Ms A] the tablets to hold herself, but for staff to hold them in the locked cabinet at the office".

Morphine overdose

Ms D and Ms E checked on Ms A at 7.45pm and found that she was sleeping very heavily and was barely rousable. Ms D noted that Ms A's breathing was "somewhat shallow" and her blood pressure was 90/64. An ambulance was called, and the paramedics administered the narcotic antidote, Narcan.

Ms A was admitted to the public hospital at 9.04pm. She was assessed in the Emergency Department of the hospital by a doctor, who noted a "working diagnosis" of "overdose morphine". The doctor recorded that Ms A was "drowsy but rousable, alert and orientated". He advised that although there was no indication of respiratory compromise the morphine should be discontinued, and Ms A should be observed until she was awake and alert. Ms A was discharged the following day.

Additional information

Ms B

Ms B stated that her usual practice when dispensing is first, to check the drug name on the prescription. She routinely checks the medication she is dispensing by leaving the sample bottle on top of the prescription just dispensed. She then moves onto the next prescription, and when she is free goes back to check the previously dispensed medications. She leaves the prescription flat on the table with the sample bottle on top, and that is how she identified her mistake on 9 August.

Ms B said that when she dispensed the morphine tablets to Ms A she checked the name of the drug, but she was not focussed on the formulation, although she is much more careful to check the formulation now. She then went to the safe to check that there was sufficient morphine in stock, returned to the dispensary, stamped the prescription and entered it into the computer.

Mr G

Mr G, pharmacist and owner of the pharmacy, informed me that when dispensing, the pharmacist should initially look at the prescription, enter the drug into the computer and then get the drug from the shelf or safe.

Mr G stated:

“I was informed by my employed pharmacist, [Ms B], M.P.S, as soon as she discovered her mistake and advised of the action she had taken to rectify her mistake. My pharmacy was not given any special instructions about dispensing to [Ms A] in this instance.

...

An informal review was conducted by myself after the incident and while it is acknowledged that the mistake was made, I would offer the explanation that we had never had a prescription for the short-acting Morphine tablets in the 13 years since this pharmacy was established.

I am satisfied that [Ms B] and her partner, [Mr C], M.P.S, acted promptly and in a professional manner as soon as the mistake was discovered. I have, however, impressed upon [Ms B] the importance of double-checking all prescriptions before release to the patient.

As a result of this incident we have re-enforced a checking system which assures that each prescription will be checked four times before issue. i.e. Upon presentation – while processing – while dispensing – and before issue.”

Mr G informed me that in August 2003 the pharmacy did not have in place a policy to enter short-acting morphine into the Controlled Drug Register, because they did not have any short-acting morphine in stock. He stated:

“It is acknowledged that on each occasion Morphine Sulphate 10mgm long-acting tablets were dispensed in error when the short-acting tablets should have been dispensed.

...

We have been very concerned over this incident and although I am satisfied that our procedures are correct, human error has led to a failure in this case. I give you my assurance that the importance of accuracy has been re-emphasised to staff as a result of this case.”

The pharmacy’s Dispensing Policy

Attached as Appendix 1.

ACC claim

ACC declined Ms A’s medical misadventure claim on the basis that, although a dispensing error occurred, there was no evidence that she suffered a physical injury as a result.

Independent advice to Commissioner

The following expert advice was obtained from Mr Alan Fraser, an independent pharmacist:

“Thank you for forwarding the relevant correspondence and case notes relating to the above file. Having reviewed the file I would make the following observations and comments.

[Ms A] aged 23 is a resident at [the rehabilitation service] in [a city]. [Ms A] suffers from a severe borderline personality disorder which includes frequent episodes of self harm. Other psychogenic symptoms include bulimia.

On 23 July 2003 [Ms A], by self mutilation with an oven cleaner, inflicted a burn injury to her left leg. On 29 July she was admitted to the Plastic Surgery Unit at [the public hospital]. Under the care of [a] consultant, [Ms A] underwent treatment which necessitated debridement of the injury site and a skin graft. [Ms A] was discharged from hospital to the care of the staff at [the community mental health residential care] on 1 August 2003. Her discharge medications charted by [the consultant] included the antibacterial Augmentin, the analgesic paracetamol, the opioid analgesics codeine phosphate and MST 10mg tablets. Copy of Discharge Notice attached appendix 1. Also attached is the [the rehabilitation service’s] Medication Prescribed Chart – appendix 2.

On 1 August 2003 [Ms A] presented her prescriptions for dispensing at the pharmacy. The prescriptions, dated 31 July 2003, were written by the registrar [Dr F]. The prescription in question namely Morphine Sulphate 10mg tablets, was initially written

for MST 10mg short-acting. As this is a contradiction in terms, MST being an abbreviation for MST Continus tablets (i.e. long-acting), the first attempt at writing the prescription was crossed out by [Dr F] and rewritten as morphine sulphate 10mg short-acting. The instructions were for one tablet every four hours. In my opinion, the prescription should have been written as morphine sulphate tablets immediate release 10mg. Attached New Zealand Pharmaceutical Schedules – appendix 3. If the prescriber had further endorsed the prescription with the brand name Sevredol this would have been helpful in eliminating all chance of error or confusion.

The Emergency Department notes from [the public hospital] written at the time of [Ms A's] admission on 9 August 2003 at 21.04 hrs show that the medical/nursing staff was also confused over the terminology used – attached appendix 4.

On 1 August 2003 the prescription for the morphine sulphate 10mg tablets was dispensed by the pharmacist, [Ms B], at the pharmacy. On 7 August 2003, a further prescription for morphine sulphate 10mg tablets was presented by [Ms A] and again dispensed by [Ms B]. On this occasion the prescription was only partially filled and [Ms A] was required to collect the balance of the prescription on 9 August. On all three occasions [Ms B] dispensed MST Continus 10mg tablets. Whilst the correct medication and the correct strength was dispensed, the formulation was not correct. [Ms B] had not clearly interpreted the prescriber's intentions when dispensing the MST Continus tablets. [Ms B] has acknowledged that she inadvertently dispensed the long-acting formulation rather than the immediate release formulation.

On discovering her error at 2.15pm on 9 August 2003, [Ms B] immediately made contact with [Ms A] to rectify the situation. In a telephone conversation with [Ms A] at approximately 3pm she ascertained that [Ms A] had taken only two tablets that day. [Ms A] was told by [Ms B] not to take any further tablets and that she would bring around the correct morphine tablets and uplift the incorrect tablets, as soon as she finished work at 6pm. At 4pm Ms D, the registered nurse at [the community mental health residential care], whilst making a routine check on [Ms A], was informed by [Ms A] of the dispensing error and further announced that she had ingested an additional tablet even though she had been told not to do so. [Ms D] telephoned [Ms B] who reiterated her earlier advice to [Ms A]. The nurse immediately removed the four remaining MST Continus 10mg tablets from [Ms A].

[Ms B] was required to work later than usual and arranged for her friend and pharmacist, [Mr C], to visit [the community mental health residential care] to deliver the correct tablets and collect the four incorrect ones. When [Mr C] arrived at approximately 6.15pm [Ms D's] shift had finished. [Mr C] was advised by [Ms D and Ms E], the caregivers on the evening shift, that [Ms A] was very drowsy. [Mr C], under [Ms B's] instructions, wrote the caregivers a note detailing the course of action to take to handle any adverse consequences from taking the extra MST Continus 10mg tablet. The caregivers were advised to monitor [Ms A] frequently and closely checking for any signs of difficulty in breathing, change of pulse and general alertness. They were told by

[Mr C] to contact the ambulance and send [Ms A] to hospital immediately if she showed any abnormal breathing, heart rhythm or lack of general alertness.

At 7.15pm when the caregivers checked on [Ms A] they found she was sleeping very heavily and was barely rousable. An ambulance was called and arrived at 8.30pm. As a precaution the ambulance officer administered intravenously 0.2mg of Narcan, an opioid antagonist. On arrival at the Emergency Department of [the public hospital] at 9.04pm [Ms A] was observed by [a] doctor as being drowsy, but able to be roused, alert and orientated with no respiratory compromise. She was nauseated but experienced no vomiting. She was observed overnight and discharged at 9.30am the following morning into the care of a staff member from [the community mental health residential care].

Morphine, a phenanthrene derivative, is a potent opioid analgesic. It is available as an immediate release tablet under the brand name Sevredol. This is available in tablet form in 10mg, 20mg, and 50mg strengths and is rapid acting. The onset of action is about 15-30 minutes after oral administration. The duration of action is three to four hours. The long-acting morphine is available in tablet and capsule form under the brand names of m-Eslon, MST, Kapanol and LA-Morph. Long-acting dosages are available in 10mg, 20mg, 30mg, 50mg, 60mg, 100mg and 200mg. The duration of action is eight to twelve hours. A suitable starting dose for chronic pain or following a painful procedure such as debridement of skin grafting is 10mg every four hours. It may be necessary to double the dose every twenty four hours until pain relief is achieved, although a slower dose escalation will often suffice. After control is achieved it is appropriate to change to an oral long-acting release formulation, which offers twice daily dosing.

In her letter to the Health and Disability Commissioner dated 12 August 2003 [Ms A] claims that she was taking a dose quadruple the maximum dosage. She expressed concern regarding the potential for a massive overdose. These statements from [Ms A] are highly inaccurate and grossly exaggerated. Whilst in the Plastic Unit recovering from her surgery [Ms A] was charted morphine elixir 5mg to 20mg every four hours. The adverse effects of opioids are nearly all dose related and tolerance develops to the majority with long term use. Maximum daily doses of up to 1000mg or 2000mg can be given if necessary but few patients require more than about 200mg daily.

Whilst a dispensing error has occurred, and this has been acknowledged by [Ms B], it did not as [Ms A] claims make her unconscious, effect her breathing, or cause respiratory complications that could have resulted in a fatal outcome. It must also be remembered it was [Ms A] who ingested the extra tablet after being clearly told not to take any more. Unfortunately [Ms B] knew little of [Ms A's] clinical history. [Ms A] has a history of overdosing and this is illustrated by her two subsequent admissions to hospital. On 23 August 2003 she overdosed on a combination of the atypical antipsychotic agent quetiapine and a lot higher dose of morphine sulphate 50mg, and on 9 September 2003 on the laxative coloxyl with senna.

In summary, [Ms B] has acknowledged her dispensing errors. She has not followed [the pharmacy's] Standard Operating Procedure 6.2 in verifying the legality of all prescription data. If she was unaware of the immediate release formulation of morphine

tablets she should have referred to New Ethicals Catalogue or the New Zealand Pharmaceutical Schedules. If she was unsure of the prescriber's intention regarding formulation it would have been prudent to ring and check.

Despite the fact that there existed a degree of confusion amongst other health professionals regarding the correct nomenclature of the morphine medication, I am of the opinion that [Ms B] has failed to observe a standard of care and skill reasonably to be expected in the dispensing of [Ms A's] prescriptions on the three occasions referred to. However, on discovery of her dispensing error, [Ms B] followed the procedures outlined in 6.9 Dispensing Errors Policy. Her handling of the event in contacting [Ms A], apologizing for the error and advising [Ms A] of the situation and telling her that she would come around in three hours and replace the tablets was carried out in a helpful and professional manner. In hindsight, [Ms B] should have contacted the caregiver at [the rehabilitation service] and advised her of the situation. I believe the caregiver, who would be all too familiar with [Ms A's] past clinical history, would have retrieved the remaining morphine tablets. The advice given by [Ms B] via [Mr C] regarding adverse effects and warning signs to watch for was exemplary. This advice was no doubt mainly responsible for calling the ambulance and the subsequent admission to hospital. [Ms B] again via [Mr C], who had been directly dealing with the caregivers, made a follow up call next day to [the rehabilitation service] to ascertain how [Ms A] was doing. In my opinion [Ms B] handled the situation competently. [Ms A], according to [Ms B] had visited the pharmacy on two occasions after this incident and no dissatisfaction was evident from [Ms A], with the way the incident had been dealt with.

I am perturbed that the caregivers at [the rehabilitation service] allow a high risk patient like [Ms A] to collect her prescriptions from the pharmacy, keep her medications in her flat and ingest the medications without supervision. Maybe the justification is based on the premise that [Ms A] has to learn to take responsibility for her own health needs.

This incident has been an unfortunate incident for all involved. Fortunately no harm came to [Ms A] as a result of this incident and I believe that [Ms B] has had a salutary lesson in the need to ensure accuracy in all her dispensing operations.”

Response to Provisional Opinion

Ms B responded to my provisional opinion stating:

“There is one comment that I would like to add to your report. This refers to page 6 of the report. I have, to the best of my knowledge, followed the standard operating procedure to its very last detail, and have consistently done so until now. In fact, because I am working completely on my own, particularly on the days that the errors occurred, I have added an additional step to the SOP, and so that is to leave the labels of every medication that I have dispensed so that I can again check the drugs during the course of the day. Also about the point that I only looked at the name of the drug and

not the formulation, this is not true. When I look at the drug details, I look for three things. They are the name, strength and formulation, all held in equal importance.

Overall, I acknowledge your opinion in this case and have undertaken careful steps in reviewing my dispensing standard operating procedure to ensure that in the future, I will dispense medications that are not only accurate, but also of high quality.”

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.*

RIGHT 6

Right to be Fully Informed

- 1) *Every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, would expect to receive ...*
-

Professional Standards

The Pharmaceutical Society of New Zealand’s *Code of Ethics* (June 2001) states:

“

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.

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.”

Opinion: Breach – Ms B

Dispensing errors

Ms B informed me that on three occasions, on 1, 7 and 9 August 2003, she received the wrong pills from the pharmacy, which resulted in her being hospitalised.

Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) state that every consumer has a right to have services provided with reasonable care and skill, and in compliance with professional standards.

On 1 August 2003 Ms A took the prescription, given to her by Dr F at the public hospital on 31 July for morphine sulphate tablets, to the pharmacy to be filled. The prescription specified five morphine sulphate 10mg short-acting tablets, one tablet to be taken every four hours. Ms B, pharmacist, dispensed five morphine sulphate 10mg long-acting tablets.

On 7 August Ms A returned to the pharmacy with a further prescription for morphine sulphate 10mg short-acting tablets, one tablet to be taken every four hours, this time for ten tablets. Dr F was again the prescribing doctor. Ms B dispensed the five morphine sulphate 10mg long-acting tablets she had in stock, and asked Ms A to return for the five tablets owing on the prescription.

When Ms A returned to the pharmacy at 1pm on 9 August to uplift the remaining five tablets, she was again given morphine sulphate 10mg long-acting tablets by Ms B.

At about 2.15pm when Ms B was checking the day's prescriptions she discovered her mistake in dispensing Ms A's medication. Ms B informed me that her usual practice when dispensing is to check the prescription for the patient's details, the date the prescription was written and whether a doctor had signed it. She then checks the contents of the prescription for the drug name, strength and formulation (in this case the prescription was for a short-acting formulation), as well as the instructions for administration, and the total amount of the drug required.

Ms B was unable to explain how the dispensing errors occurred on 1, 7 and 9 August. She was on duty by herself and there was no one to check her dispensing. Her recollection of the way she dispensed the morphine to Ms A on 7 August was that she went to the safe to get the morphine to make up Ms A's prescription, saw the morphine sulphate on the shelf, and took the container to the dispensary to generate the label.

Mr G, pharmacist and owner of the pharmacy, advised me that the pharmacist should initially look at the prescription, enter the drug into the computer and then get the drug from the shelf or safe. The pharmacy dispensing policy specifies (as the fifth step in the dispensing process) that the pharmacist should “Enter script into computer and generate label”, then “Select stock – check against prescription” before dispensing.

Mr G stated that in 13 years as owner of the pharmacy he had never had occasion to stock short-acting morphine sulphate.

My independent pharmacy advisor commented:

“The prescription in question namely, Morphine Sulphate 10mg tablets, was initially written for MST 10mg short-acting. As this is a contradiction in terms, MST being an abbreviation for MST Continus tablets (i.e. long-acting), the first attempt at writing the prescription was crossed out by [Dr F] and rewritten as morphine sulphate 10mg short-acting. ... In my opinion, the prescription should have been written as morphine sulphate tablets immediate release 10mg.

...

On all three occasions [Ms B] dispensed MST Continus 10mg tablets. Whilst the correct medication and the correct strength was dispensed, the formulation was not correct. [Ms B] had not clearly interpreted the prescriber’s intentions when she dispensing the MST Continus tablets.

[Ms B] has acknowledged that she inadvertently dispensed the long-acting formulation rather than the immediate release formulation. ... She has not followed [the pharmacy’s] Standard Operating Procedure 6.2 in verifying the legality of all prescription data. If she was unaware of the immediate release formulation of morphine tablets she should have referred to New Ethicals Catalogue or the New Zealand Pharmaceutical Schedules. If she was unsure of the prescriber’s intention regarding formulation it would have been prudent to ring and check. ... I am of the opinion that [Ms B] has failed to observe a standard of care and skill to be reasonably expected in the dispensing of [Ms A’s] prescriptions on the three occasions referred to.”

Based on my expert’s advice, in my opinion, in dispensing the prescriptions on 1, 7 and 9 August 2003, Ms B did not provide Ms A with a service with reasonable care and skill or that met the professional standards, and therefore breached Rights 4(1) and 4(2) of the Code.

Opinion: No breach – Ms B

Information provided after dispensing errors discovered

Ms A alleged that when the dispensing mistake was discovered, Ms B did not inform her that she could have overdosed or that she could be in any danger. She stated that she was not told any details.

Right 6(1)(b) of the Code states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. The right to information includes information about a dispensing error once it has been discovered by a health professional.

At 2.15pm on 9 August 2003 when Ms B discovered that she had mistakenly dispensed long-acting morphine sulphate 10mg to Ms A instead of the prescribed short-acting morphine, she immediately attempted to contact Ms A to tell her of the mistake.

Ms B was unable to contact Ms A until about 2.30pm as the telephone number recorded at the pharmacy was incorrect. (Ms A had recently moved to the residential service.) When Ms B spoke to Ms A, she told her what had happened and instructed her not to take any more tablets. She asked Ms A how many tablets she was taking daily. Ms A informed Ms B that in order to make them last, she had taken them twice daily. Ms A was reassured that Ms A was not at risk, as this is the recommended dosage regime for long-acting morphine sulphate. Ms B reiterated to Ms A that she should not take any more tablets. She explained to Ms B that she was the sole pharmacist that day and that she would call to see her after she closed the pharmacy that evening, to replace the long-acting tablets with the correct medication.

At 4pm Ms D, registered nurse at the rehabilitation service, checked on Ms A in her flat. The staff at the rehabilitation service were aware that Ms A had been independently managing her pain relief following her discharge from hospital after skin graft surgery to burns. Ms A informed Ms D that a mistake had been made her medication by the pharmacy. Ms A also told Ms D that she had taken three tablets, not two as she had told Ms B.

Ms D then telephoned Ms B to tell her that Ms A had taken an additional tablet and questioned the seriousness of her taking this amount of medication. Ms B advised that "this was not an overdose". Ms B did not give Ms D specific instructions about monitoring Ms A, but said that she would ask another pharmacist, Mr C, to call at the rehabilitation service to replace the tablets.

Ms A was checked again that afternoon by another of the rehabilitation service staff, Ms E. Ms E had not met Ms A previously but noted that she was unsteady on her feet and complaining of feeling tired. Ms E was under the impression that Ms A had taken one or possibly two tablets after speaking with Ms B.

Mr C arrived at the rehabilitation service at 6.30pm. He told the staff that Ms A was not to take any further tablets until she had been checked by a doctor, and advised that the tablets be removed from her possession and retained by staff in a locked cupboard. Mr C advised

the staff to check Ms A's vital signs regularly. He documented his instructions as requested.

When Ms D and Ms E checked on Ms A at 7.45pm they found her sleeping very heavily and barely rousable. An ambulance was called. As a precaution, the ambulance staff gave Ms A the opioid antagonist Narcan before transporting her to the public hospital where she was admitted overnight for observation.

My independent advisor stated:

“[O]n discovery of her dispensing error, [Ms B] followed the procedures outlined in 6.9 Dispensing Errors Policy. Her handling of the event in contacting [Ms A], apologising for the error and advising [Ms A] of the situation and telling her that she would come around in three hours and replace the tablets was carried out in a helpful manner. In hindsight [Ms B] should have contacted the caregiver at [the rehabilitation service] and advised her of the situation. ... The advice given by [Ms B], via [Mr C], regarding the adverse effects and warning signs to watch for was exemplary.

...

In my opinion, [Ms B] handled the situation competently.”

It appears that Ms A, after being advised by Ms B not to take any further tablets, took at least one more morphine tablet, which resulted in her admission to the public hospital on 9 August 2003. However, I am satisfied that the advice Ms B provided to Ms A was the information that a reasonable consumer in a similar situation would expect to receive. Accordingly, Ms B did not breach Right 6(1)(b) of the Code.

Opinion: No breach – The Pharmacy

Vicarious liability

Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) of the Health and Disability Commissioner Act 1994 it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee's breach of the Code.

The pharmacy had policies and procedures in place to ensure that dispensing pharmacists “maintain a methodical and disciplined approach to procedures which ensure the accuracy of all dispensing operations”. Ms B made independent decisions when dispensing Ms A's prescription and failed to take the proper steps to check that she was dispensing according to the prescriber's intention. Accordingly, the pharmacy is not vicariously liable for Ms B's breaches of the Code.

Actions taken

I note that Ms B has reviewed her practice as a result of this case. She informed me that she has amended the Standard Operating Procedures for the pharmacy, adding an additional checking step to ensure that a similar event does not recur.

Ms B provided a letter of apology, which has been forwarded to Ms A.

Follow-up actions

- A copy of this report will be sent to the Pharmaceutical Society of New Zealand.
- Copies of this report will be sent to Dr F and the rehabilitation service, drawing their attention to my advisor's comments about writing prescriptions for short-acting morphine tablets, and monitoring the medications of high risk residents, respectively.
- A copy of this report, with identifying details removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1 – The Pharmacy’s Dispensing Policy

6.2 DISPENSING

 The Pharmacist in charge of the dispensing operations of
 maintains a methodical and disciplined approach to procedures which ensure
 the accuracy of all dispensing operations, whether by him/herself or the
 Dispensary Technician under supervision.

DATE OR WRITING: 16th FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Pharmacist on duty

SIGNATURE OF AUTHOR

30 Aug 02

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 03

All dispensary operations meet the practice advice issued by the PSNZ in the
 Pharmacy Practice Handbook

When a prescription is received by a staff member from a patient the
 Pharmacist or Dispensary Technician shall:

- * Receive the Rx from the staff member or patient.
- * Ascertain
 - Verify the legality of all prescription data
 - Check patient details
 - Determine priority of the prescription
 - Advise patient of waiting time and stock availability
 - Enter script into computer and generate label
 - Select stock- check against prescription
 - Dispense as required
 - Attach label to container
 - Check, initial and prepare for issue to patient
 - Hand out prescription to patient at Dispensary after checking address
 etc to verify the correct patient is receiving the prescription
 - Counsel the patient as required at the dispensary so that such
 counselling is private and accompany patient to point- of sale to
 receive payment when appropriate.

* Rx processed by Pharmacist or Technician and medication history checked
 to ensure consistency of treatment and any evidence of misuse or non-
 compliance e.g. not collecting all eligible repeats at the appropriate time.

- hold Rx in collection area if patient not in pharmacy

* Annotate Rx and put in box with completed scripts

* If Rx cannot be filled completely, patient is advised and
 informed when balance will be available.

Process Rx as normal and write "owing" amount on Rx, then file in box for
 scripts awaiting completion.

Practitioners Supply Orders

Stock is ordered by Practitioner. Check all quantities are reasonable and signed and dated by the Practitioner

Bulk Supply Orders

Check quantities are a reasonable monthly allocation, meet schedule requirements and is signed and dated by the approved HFA institution.

6. 3 COMPOUNDING PROCEDURES

Routines to ensure that any compounding undertaken in the Dispensary complies with the standards expected of a modern pharmacy business

.....
DATE OF WRITING: 16th FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Pharmacist on duty

SIGNATURE OF AUTHOR

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 02
30 Aug 03

- * Compounding area is separate from other areas in the dispensary
- * Area is cleaned daily and kept free of extraneous items
- * All items required for compounding a prescription are assembled and checked by pharmacist responsible for the prescription.
- * Calculations are performed and checked if complicated
- * Product is prepared, packed, checked and labelled
- * No bulk compounding is undertaken in this pharmacy

6. 4 CHECKING OF STOCK FOR EXPIRATION

Routine procedure for a systematic procedure to check all stock for expiry

.....
DATE OF WRITING: 20th FEBRUARY, 2000

WRITTEN BY :

PERSON RESPONSIBLE:

Dispensary- Pharmacist

Shop - Assistant responsible for computerised inventory checks

SIGNATURE OF AUTHOR

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 02
30 Aug 03

Shop

Checking of stock is done daily using stock sheets generated by the retail computer so that the entire inventory is checked at the rate of 50 items per day.

Dispensary

Checking of dispensary stock is done on a regular basis at such a rate that the entire inventory is checked every six months.

- * Red spots are placed on stock which will expire before the next scheduled stock check.
- * Any expired stock is quarantined and placed in a designated area in the storeroom where it is held until destroyed.

6. 5 DISPOSAL OF RETURNED, EXPIRED OR DAMAGED STOCK

Procedure to ensure that stock identified as expired, damaged or returned from customers is disposed of safely

.....

DATE OF WRITING : 20th FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Manager on duty

SIGNATURE OF AUTHOR

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 02

30 Aug 03

- * All stock awaiting destruction is held in a specified area of the storeroom in quarantine.
- * Pharmacist is responsible for the safe disposal of unwanted products
- * Where incineration is deemed to be the best disposal option- the materials are collect by a contractor licensed to carry out the incineration of waste materials.

6. 6 RECALL PROCEDURES

Routines to ensure a consistent procedure to be followed when a recall notice is received for any stock item.

.....

DATE OF WRITING: 22nd FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Pharmacist on duty

SIGNATURE OF AUTHOR

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 02

30 Aug 03

- * Any stock affected by a recall notice is quarantined immediately and held in the storeroom.
- * Procedure for return or disposal as stated in the recall notice is followed.

- * Any documentation required is attended to, including a nil return if appropriate.
- * If a product recall is to patient level, every effort is made to contact patients who have been affected, using prescription records from the computer.

6.7 GENERIC SUBSTITUTION POLICY

DATE OF WRITING: 22nd FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Managing Director

SIGNATURE OF AUTHOR

REVIEW DATE: 28th FEBRUARY 02

30 Aug 03

A policy to ensure that any substitution which is necessary in order to supply a prescription is carried out in such a way that all requirements both ethical and legal, are complied with and the patient receives the medicine authorised by their practitioner.

.....

- * Any substitution of a medicine is done in accordance with Reg 42(4) of the Medicines Regulations which require a pharmacist to dispense the brand of medicine required. Any changes must be authorised by the prescriber.
- * Changes may be authorised by the prescriber for:
 - an individual prescription (may be done by phone and annotated on the prescription.
 - a particular medicine. This may be done as a general consent for each medicine and must be in writing.
 - all medicines in general. This must be in writing.
- * In an emergency when the prescriber cannot be contacted, the pharmacist may substitute if it is considered that the substitution is in the best interest of the patient. This action is authorised under the Society's Code of Ethics rule 2. 12. The pharmacist will inform the prescriber of the actions taken and the reason for it as soon as possible.
- * Any substitution is done in such a manner that it abides by the Preferred Supplier arrangements as set out in the Procedures Manual.
- * Written authorisations are reviewed at least every two years.

When a decision is taken to substitute a medicine for one prescribed the following actions are taken.

- Check if a valid authority to substitute applies
- Refer to current Interchangeable Multi-source Medicines List
- Seek authority from prescriber if no standing agreement is in place
- Advise patient that an approved substitution has been made

6.8 OWES POLICY

Routines to ensure that a consistent procedure is maintained in the handling of prescriptions which are not able to filled in full at the time of the initial dispensing.

DATE OF WRITING: 22nd FEBRUARY, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Pharmacist on duty

SIGNATURE OF AUTHOR

REVIEW DATE: ~~28th February, 2001~~ 30 Aug 02
30 Aug 03

- * When all of a medicine cannot be supplied at the time of dispensing, the pharmacist will advise the patient and take action to ensure that the balance will be available for collection as soon as possible.
- * The procedure followed is as follows
 - The patient is advised that we are unable to supply the prescription in full
 - The expected time of the availability of the balance is told to the patient and an arrangement to collect the balance is agreed
 - The prescription is annotated with a red spot with the amount owing noted on it and the prescription filed separately from the completed scripts
 - The label on the supply handed to the patient includes advice of the amount owing
 - The amount owing is recorded on the computer
- * When prescriptions are submitted for pricing:
 - Either the original prescription is held back until the amount owing is collected, or a "Certified True Copy" is made and submitted when the balance is collected
 - For pricing purposes scripts are annotated "medicine owed" and indicate that there is a repeat still to be submitted on the prescription, which may be for a changed quantity
 - The repeat portion of the uncompleted script with "owes outstanding" is filed separately from the completed scripts.
 - When the balance owing has been dispensed, the Certified True Copy is submitted nad the balance only of the medicine claimed
- * Every effort is made by the pharmacist to ensure that "owings" are collected by the patient.
- * The pharmacist will ensure that no claims are made for scripts which have not been collected. within one month of the original dispensing date.

MANAGEMENT OF PHARMACEUTICALS

A system to note and grade by their significance any interventions by the pharmacist in the provision of improved patient care

DATE OF WRITING: 1st MARCH, 2000

WRITTEN BY:

PERSON RESPONSIBLE: Pharmacist on duty

6.9 DISPENSING ERRORS POLICY

Routines to ensure that a consistent procedure is maintained in the handling of dispensing errors when detected.

.....
DATE OF WRITING: 29th JANUARY, 2004.

WRITTEN BY:

SIGNATURE OF AUTHOR

REVIEW DATE: 31st January, 2005

- * If, during the checking process after a prescription has been dispensed, a mistake is detected, the following procedure will be undertaken.
 - The patient will be contacted without delay and advised of the situation.
 - An apology will be offered for the mistake.
 - The pharmacist will check whether the patient has taken any of the medicine.
 - The patient's doctor will be advised of the situation. If the doctor required to see the patient, the consultation will be paid for by the pharmacy.
 - A follow up call will be made to the patient to check that all is well after a suitable interval.
 - If the review of the incident identifies any system failure, the Dispensing S.O.P will be reviewed and re-written.