A Pharmacy Registered Nurse, Ms C Trainee Technician, Ms D Pharmacist, Ms E Dispensary Manager, Ms F A Rest Home

A Report by the Health and Disability Commissioner

(Case 02HDC04619)



Parties involved

Mrs A Complainant / Consumer's daughter

Mrs B Consumer

Ms C Provider / Registered Nurse Ms D Provider / Trainee Technician

Ms E Provider / Pharmacist

Ms F Provider / Dispensary Manager

Ms G Caregiver

Dr H General Practitioner Mr I Pharmacy owner

A pharmacy Provider
A rest home Provider

Complaint

On 5 April 2002 the Commissioner received a complaint from Mrs A about services provided to her mother, Mrs B. The complaint is that:

A rest home nursing staff did not provide services of an appropriate standard to Mrs B as follows:

• In the morning and evening of 27 March 2002, nursing staff did not check Mrs B's blister pack medication. Incorrect medication was dispensed to her.

A pharmacy did not provide services of an appropriate standard to Mrs B as follows:

- The pharmacy dispensed Mrs B's blister pack with incorrect medication.
- When advised of the error, on 27 March 2002, the pharmacy recalled the blister packs and corrected the morning doses. However, the evening doses were not corrected.

An investigation was commenced on 26 August 2002. On 4 February 2003 the following individual providers were notified:

Ms C

Registered nurse Ms C did not provide services of an appropriate standard to Mrs B. In particular:

- On the morning of 27 March 2002 registered nurse Ms C did not ensure that Mrs B's blister pack medication was correct. Incorrect medication was dispensed to Mrs B.
- Following discovery of the error Mrs B's morning dose was corrected. However, Ms C did not ensure that the evening dose was corrected.

Ms D

In March 2002 Ms D, trainee technician, did not provide services of an appropriate standard to Mrs B. Ms D prepared Mrs B's blister pack with incorrect medication.

Ms E

In March 2002 Ms E, pharmacist, did not provide services of an appropriate standard to Mrs B. Ms E dispensed Mrs B's blister pack with incorrect medication.

Ms F

On 27 March 2002 Ms F, dispensary manager, recalled the blister pack and corrected the morning dose. However, she did not ensure that the evening dose was corrected and Mrs B received incorrect medication that evening.

Information reviewed

- Complaint letter from Mrs A
- Response, relevant records and policies from the rest home
- Response from Ms C
- Information from Ms G
- Information from Dr H
- Response and relevant policies from Mr I of the pharmacy
- Response from Ms F
- Response from Ms E
- Response from Ms D

Independent expert advice was obtained from Ms Andrea Shirtcliffe, a pharmacist, and Ms Wendy Rowe, a registered nurse.

Information gathered during investigation

Overview

Mrs B, a resident at the rest home, had her medications prepared into blister packs by the pharmacy. On the morning of 27 March 2002 Mrs B discovered a different (green) tablet in her blister pack. She queried the tablet with a staff member, who assured her that it was appropriate to take the medication. However, soon after swallowing the green tablet Mrs B vomited. Her general practitioner, Dr H, visited and treated her for side effects of taking pergolide (a treatment for Parkinson's disease), which had been dispensed into her blister pack instead of perhexiline (treatment for angina).

The blister pack was corrected by Ms F, pharmacy manager, that same morning. However, that evening Mrs B was given her evening blister pack, which again contained the incorrect

medication (pergolide). She recognised that it was incorrect and did not take it. Mrs B did not alert the staff to this error, but the next morning spoke about it to her daughter, who telephoned the rest home.

Although Mrs B has medical conditions that affect her health and mobility, she is an alert woman who independently manages her medications, which are prepared for her in a Medico blister pack.

Blister pack preparation

Medico blister packs are in common use within the rest home and private hospital sector, as well as in the community. Medication is prepared in the pharmacy and dispensed from a doctor's prescription. Each individual dose of medication is placed into a tray checked by the pharmacist (against the doctor's prescription and medication dispensed). The pack is then sealed with a foil overlay. The medications contained in each blister are listed on the back of the pack.

The advantage of this type of system in a rest home and private hospital setting is that it potentially minimises medication errors in a busy working environment, with multiple medications being administered to large numbers of patients. Furthermore, it enables medication to be given by staff who are not registered nurses, and provides a level of safe autonomy for residents who prefer to self-medicate.

Dispensing error

Ms D, a trainee pharmacy technician, was responsible for preparing Mrs B's blister packs. Ms D incorrectly placed pergolide, a green tablet, instead of perhexiline, a white tablet, in Mrs B's tray. Ms D is unable to recall making the error. She stated that the only explanation she could offer was that the two names of the drugs were similar and were not often dispensed. At the time of this incident Ms D had completed two years of a four-year National Pharmacy Technician course. As a trainee technician Ms D was permitted to prepare medication for dispensing. However, she worked under the supervision of a pharmacist, who was responsible for checking her work.

Mrs B's blister packs were checked by pharmacist Ms E. Ms E explained that her normal checking procedure involved referring to the patient's medication chart and the stock bottles used, and matching them up with the trays and the tablets. She is unable to explain why she did not pick up the error. However, as the tablets involved have similar names, Ms E believes that she mistook the tablets involved.

Mr I, owner of the pharmacy, explained that all medications are double-checked before leaving the pharmacy. He advised that the same checking process existed for blister pack preparation, and provided a copy of the policy for dispensing blister packs. Mr I advised that following this incident the pharmacy's dispensing systems had been reviewed. A new policy has been developed for managing dispensing errors in blister packs. It specifies that all blister packs must be identified and checked.

The pharmacy no longer prepares blister packs for the rest home.

Blister pack delivery

Like many of the rest home's residents, Mrs B's medication was organised into two packs – a morning pack and an evening pack. These packs are kept in two separate areas in the nurses' station at the rest home so that only the medication required to be administered at the time is carried on the medication trolley (minimising bulk and the potential for confusion).

Blister packs were delivered to the rest home once a month, on a Tuesday night, by a staff member from the pharmacy. Accompanying the blister packs is a Medication Administration Record. This is a signing sheet for the rest home staff who administer medications. Listed on this sheet are the prescribed medications, a description of their appearance and their purpose. Perhexiline is described as "med[medium] wh[white] rd[round] 'PEXSIG'".

On the evening of 26 March 2002 (a Tuesday) a delivery of blister packs was made to the rest home. The rest home advised me that as a registered nurse is not on duty on the Tuesday evening it is Wednesday morning before the blister packs are checked (and administered from). The rest home's policy requires the registered nurse to ensure that the medication listed on the blister pack matches the medication prescribed by the general practitioner (as recorded on the medication chart).

A second check is performed immediately prior to the medication being given to the resident (and may be performed by the caregiver). This involves counting the number of tablets in the blister pack and checking that it matches the number of tablets that have been prescribed.

Morning of 27 March 2002

The registered nurse on duty on the morning of Wednesday 27 March was Ms C. Ms C came on duty at 7am and, following the handover from the night staff, checked blood sugar levels and administered insulin to the diabetic patients who reside in the serviced apartments (which form part of the rest home complex) before commencing her medication round in the rest home. Ms C's lawyer advised that Ms C was responsible for up to 120 residents in the complex living in the rest home, serviced apartments or units. Between 7.30am and 8am Ms C had to administer blister packs to 40–45 rest home residents.

Ms C stated that the medication round in the rest home typically finishes at approximately 9.30am, "with a lot of interruptions". On Wednesday morning, as usual, Ms C gave Mrs B her medication, which was still sealed in the blister pack, and moved onto the next resident. The rest home advised me that because Mrs B was able to self-medicate it was not necessary for staff to remain in the room to observe her swallowing her tablets.

Mrs B noticed that one of the tablets in the blister pack was green, which was different from what she normally took. She alerted a staff member, who said she would check. When the staff member returned to Mrs B's room, Mrs B was assured that it would be all right to take. Mrs B cannot recall the identity of the staff member she alerted and, when describing these events, interchanged the titles "the nurse" and "the caregiver".

Approximately half an hour after taking the medication Mrs B started vomiting. She alerted the caregiver on duty, Ms G. Ms G was unable to recall the events, but her written record in Mrs B's notes states that she brought Mrs B's illness to the attention of Ms C.

Ms C confirmed that she was told by a caregiver that Mrs B was vomiting. She attended Mrs B, who told her that she had taken the wrong medication (a green tablet). Ms C took Mrs B's blood pressure and pulse and reassured her. She returned to the nurses' station to check the medications Mrs B was meant to be taking. Mrs B telephoned her daughter, Mrs A, and told her that she was sick because she had been given the wrong medication.

Ms C told Dr H that Mrs B was vomiting and that a green tablet had been put in Mrs B's blister pack. Dr H telephoned the pharmacy and spoke to Ms F, alerting her to the error.

Dr H visited Mrs B that morning. He noted that she was pale and complaining of nausea. Her pulse was 70 and regular and her blood pressure was within normal limits at 120/70. He concluded that Mrs B was experiencing some of the listed side effects of pergolide, nausea and vomiting (but not hypotension). Dr H prescribed Maxolon to relieve Mrs B's nausea.

Dr H stated:

"The medication she was given was pergolide mesylate otherwise known as Permax 0.25 half a tablet. This is a dopaminergic agent (Dopamine Receptor Agonist) used for the treatment of Parkinson's Disease and usually prescribed in a very small does of 0.05mg for two days, then increasing slowly. ... The potential consequences of the medication error for [Mrs B], had she continued to take the wrong medication and the problems had gone unnoticed, are the listed adverse effects which are:

Orthostatic hypotension. This would have been potentially detrimental to her ischaemic heart disease, but appears not to have happened.

Dyskinesia. This refers to involuntary repetitive occasionally stereotypical movements effecting distal proximal and axial musculature and varying combinations.

Hallucinations

Somnolence

Insomnia

Gastrointestinal upset which she had as she did vomit.

Rhinitis

Cardiac dysrhythmias. Given her cardiac history that was maybe a very small potential possibility.

Pergolide is not listed as a drug that could have caused interaction problems with her current medications. I feel given the fact that she did vomit on the first dose and had noticed that the tablet was the wrong colour, there was virtually no possibility for the error to continue. She would not have continued taking the same medication."

Ms F's response to error

Following Dr H's telephone call, Ms F drove to the rest home. She stated that she was unable to find any of the regular nursing staff on duty, aside from an "agency nurse", who she said appeared to be very busy and left her to deal with the problem.

Ms F advised that the pharmacy dispenses only one green rectangular tablet. The description matched the appearance of pergolide so she consulted a *New Ethicals* to check for the side effects. As hypotension was listed as a side effect, she asked for Mrs B's blood pressure to be taken. Ms F recalls that the result was within the normal range (for Mrs B). Ms F completed an incident report at the rest home and asked whether she should visit Mrs B to apologise, but was told that it would be best to discuss the matter with her daughter, Mrs A.

Ms F advised me that no one alerted her to the fact that Mrs B received the same medication at night-time. The breakfast and evening packs are kept in separate places at the rest home, and only the breakfast tray had been left out for her to correct, so it was not immediately obvious to her that there was an evening pack. Ms F stated that she was so concerned with correcting the tray and ensuring that Mrs B was all right that she did not notice on Mrs B's medication chart that she had the same medication in the evening.

Ms F returned to the pharmacy with the pack containing Mrs B's breakfast medication. She telephoned Mrs A and apologised for the error, explained the steps she had taken to rectify the error, and offered to cover any costs incurred as a result of Dr H's visit. Ms F corrected Mrs B's morning blister pack and returned it to the rest home.

Evening dose – 27 March 2002

Later that evening Mrs B was given her blister pack evening dose of medication as usual. The caregiver who gave Mrs B this medication worked the 3pm to 11pm shift. Once again, Mrs B noticed that there was a green tablet in her blister pack. Realising this was incorrect Mrs B did not take it, but she did not alert the caregiver to the error. The caregiver confirmed that she was unaware that Mrs B had received the incorrect medication that evening as she had not brought it to her attention. Accordingly there is no record, or incident report, of this error.

Morning of 28 March 2002

The next morning Mrs B telephoned Mrs A, and told her that the same error had happened again. Mrs A telephoned the rest home, who contacted the pharmacy and told them that the error had occurred again the previous evening. Ms F again collected Mrs B's evening blister packs, corrected them, and returned them to the rest home. She telephoned Mrs B's daughter, and apologised again. Ms F wrote another report on the incident.

Ms F submitted the following as factors that compounded the matter:

- 1. Mrs B had "alerted the duty nurse" in the morning that the medication was incorrect, but the nurse did not check.
- 2. It was not until late morning that the pharmacy was advised of the error, and Mrs B and Mrs A were distressed at the lack of explanation.

3. There had been a large number of staff changes at the rest home and it is "very likely" that the regular staff would have alerted the pharmacy to the fact that there were two packs to be corrected.

Nurse Ms C

At the time of these events Ms C was a registered nurse with a current practising certificate. She advised that when she does her medication rounds in the morning, she puts on the trolley the current medication sheets listing the medications being taken by residents. The medication list is handwritten by the doctor and lists the drugs by name, but does not describe what the tablet looks like (ie, colour or shape). She was not sufficiently familiar with Mrs B's medications to recognise that the colour of one of her tablets was different.

Ms C explained that when she gave Mrs B the blister pack in the morning, she did so "knowing it had been checked by at least two people within the pharmacy". Ms C's lawyer stated:

"[Ms C] acknowledges she omitted to recheck the items in the blister pack to ensure the items were in accordance with the doctor's prescription and that they were specifically for [Mrs B]. She administered what was contained in the blister Pack, as packaged by the pharmacy. Due to the number of residents and patients overseen by [Ms C] and the brief handover period in the morning, the comparison of the items contained in the Blister Pack with the items as listed on the medication chart was not made. ... She was required to complete the round of medication in a limited timeframe and was under tight constraint. ... [Ms C] has been given a shock reminder of the need for constant vigilance. Any recurrence is not likely."

Ms C could not recall whether Mrs B alerted her to the fact that the medication was incorrect prior to it being administered. However, "she suspects not because if it had been mentioned then it would have been checked". Ms C stated that it was not until she attended Mrs B (when she was vomiting) that she was aware that a mistake had been made with her medication.

Independent advice to Commissioner

Pharmacy advice

The following expert advice was obtained from an independent pharmacist, Ms Andrea Shirtcliffe:

"Conclusion:

[The pharmacy] appears to have appropriately formatted written standard operating procedures. If the dispensing procedure is carried out in accordance with the documentation this would be regarded as acceptable standard of practice.

[The pharmacy] appears to have procedures in place to enable identification of both the dispenser and checker which is acceptable standard of practice.

[The pharmacy] appears to have a documented procedure which identifies who should deal with a dispensing error which is acceptable standard practice. Pharmacies are not required to identify exactly what steps should be taken upon identification of an error. This is deemed to be impractical as every situation would be different. It is not regarded as essential to have a specific procedure that deals with checking blister packs and dealing with dispensing errors in blister packs in particular. [The pharmacy] now has such a procedure which would be regarded as very good practice.

[The pharmacy] appears to review their standard operating procedures annually which is in line with acceptable standards of practice.

[Ms F] appears to have acted quickly and in a patient focused manner. However, she appears to have overlooked the need to check all blister packs that were current for [Mrs B]. It would be acceptable professional practice to check all blister packs in the event of a dispensing mistake.

Adverse effects of pergolide are thought to be similar to bromocriptine. Bromocriptine's side effects tend to be dose related, occur at the higher doses, and often diminish or resolve with dose reduction. Although there are a number of rare side effects that may not be reversible, a good number of the adverse effects noted for both pergolide and bromocriptine are documented in patients who have either Parkinson's, acromegaly or are postpartum females. It is not necessarily correct to assume that adverse effects experienced by these patient groups are the same as would be experienced by the population at large.

These factors make it difficult to quantify the potential effects on [Mrs B's] health of long term administration of pergolide. However, I would like to concur with [Dr H's] comments; given that [Mrs B] did vomit on the first dose and had noticed the tablet was the wrong color, there was very little potential for the error to continue.

The other potential health risk associated with the long term administration of pergolide is the concomitant risk of NOT receiving perhexiline treatment for [Mrs B's] angina. Given that [Mrs B] is also taking Duride®, diltiazem and atenolol for angina it may be difficult to quantify this risk. The fact that multiple antianginal medications are being administered may decrease the risk associated with inadvertent omission of one such agent. It would be more appropriate for [Mrs B's] general practitioner to advise on this aspect.

It appears that [Ms E] has made a mistake in the packing of [Mrs B's] blister packs. So long as [Ms E] carried out her duties according to appropriate standard operating procedures held in the pharmacy she could be considered to have carried out her duties to an acceptable level of professional practice. Code of Ethics guidelines indicate that a high standard of accuracy is expected of a pharmacist. They also imply that even in the presence of good systems human error is possible.

It is appropriate for a dispensary technician in training to be working in the dispensary in the preparation of blister packs so long as they are acting under the direct supervision of a pharmacist and in accordance with written standard operating procedures that correspond to the packing of blister packs (and all other relevant standard operating procedures relating to work in the dispensary).

According to principle 3.9 of the Pharmaceutical Society of New Zealand Code of Ethics 2001 [Ms E] is responsible for all dispensing for which she has dispensed with the help of a technician.

Questions asked:

1 Please comment on the appropriateness of the steps taken by [Ms F] to rectify the matter.

Professional standard of practice expected by PDA (Pharmacy Defence Association) when a dispensing mistake occurs:¹

- i Verbal apology
- ii Change medicine for correct one
- iii Check if patient has taken any
- iv Check with doctor that patient is OK
- v If patient has had to see the doctor, it is expected that the pharmacist would pay for the doctor's visit
- vi Follow up with a written apology to the patient
- vii Check the pharmacy's SOP to check if it's a system error (if so, what can be done to ensure it doesn't happen again), or if there are good systems in place but it was a human error

[Ms F] rang [Mrs B's] daughter to apologize instead of apologizing directly to [Mrs B]. This was done on the advice of a staff member from the rest home. Although it is ideal to apologize to the patient directly, it is reasonable to assume that rest home staff have accurate information as to whether a resident should be visited/contacted or whether their next of kin/guardian should be contacted. Given that it was [Mrs B's] daughter who contacted health professional staff in this instance I feel it is appropriate practice for [Ms F] to contact the daughter instead of [Mrs B].

[Ms F] removed the morning blister pack and replaced it with a new one with correct contents. However, [Ms F] did not check all of [Mrs B's] blister packs. It is acceptable professional practice to check the entire prescription (i.e. all blister packs) when following up on a potential dispensing error.

It would appear to have been obvious that [Mrs B] had taken some of the incorrect medication so I would not expect [Ms F] to have to check if the patient had taken any medicine.

Point iv can also be disregarded as [Ms F] was alerted to the fact that there was a problem by a phone call from [Mrs B's] general practitioner and a phone call from the nursing home. It is therefore reasonable to assume that the doctor has assessed the situation.

[Ms F] offered to cover any costs incurred with [Dr H] which was appropriate.

I cannot find any reference to [Ms F] offering a written apology.

It would appear that as a result of this incident that [Ms F] wrote a Standard Operating Procedure to deal with errors in Medico packs, basically ensuring that all packs for a patient are checked if an error is discovered. It is not clear whether a standard operating procedure for checking blister pack errors was in place before this incident or whether an existing procedure was modified to ensure that all packs are checked in the event of an error. It is acceptable standard of practice to review processes and written operating procedures in the event of an error – in particular to identify any methods of avoiding such errors in the future.

[Ms F] documented the incident at the rest home, wrote a report to be sent to Pharmacy Defence and also documented this incident in the dispensary log. This is all acceptable professional practice.

[Ms F] 'researched the likely effects on [Mrs B]', identified that the most likely side effect could be hypotension and put in place steps to ensure [Mrs B's] blood pressure was checked. This is regarded as acceptable professional practice.

2 Should the evening blister pack have been checked also?

Perhexiline has a relatively long half life, and the manufacturers seem to suggest that doses at the upper end of the dose range should be given as divided doses.² So it would not necessarily be a natural assumption that the low dose of 100mg daily would be given as a twice daily regime. Administration of perhexiline 100mg daily would not in itself alert a pharmacist to the fact that there would be two blister packs containing this medicine.

However, it is acceptable professional practice to check all blister packs for a given patient if a dispensing error is identified. When blister packs for a given patient are dispensed they tend to be packed at the same time. So, if an incorrect stock bottle is used to pack (for example) the morning pack for a patient, there is a chance the same incorrect stock bottle could be used to dispense packs for the other times of the day (e.g. lunch, dinner etc). This means that when a dispensing error is identified it is reasonable to assume that all packs for that patient will be checked.

The printed information on Medico® blister packs refer to ALL medicines being taken by a given patient. That is, all medicines meant for a given patient are referred to on all blister packs for that patient. So if checking processes are carried out accurately, it is

obvious to the checker that more than one blister pack is on the premises for that patient.

3 What would have been the effects of [Mrs B] had she taken the incorrect medication long term?

Adverse effects as documented by pergolide's manufacturer.²

Adverse Effects

Nervous System

Confusion; Dizziness; Dyskinesia; Hallucinations; Insomnia; Somnolence

Gastrointestinal

Constipation; Diarrhoea; Nausea; Vomiting

Cardiovascular

Palpitation; Orthostatic hypotension; Syncope

Respiratory

Dyspnoea

Skin and Appendages

Rash

Other Uncommon or Rare Undesirable Effects

Fever; Liver function tests abnormal; Pericarditis; Pericardial effusion; Pleuritis; Pleural effusion; Pleural fibrosis; Retroperitoneal fibrosis; Neuroleptic malignant syndrome (with rapid de-titration of pergolide); Sudden onset of sleep; Cardiac valvulopathy.

Martindale suggests that adverse effects to pergolide are similar to Bromocriptine.³

Bromocriptine side effects are generally dose-related and may therefore be more frequent with the higher doses that have been used in the treatment of parkinsonism and acromegaly. Reduction of the dosage of bromocriptine, followed in a few days by a more gradual increase, may alleviate many side-effects.³

Bromocriptine is well absorbed orally, and peak concentrations occur after two hours. It is metabolized in the liver and excreted in the bile. Unwanted reactions include nausea and vomiting, which may be ameliorated by taking the drug with meals. Dizziness, constipation and postural hypotension may also occur.⁴

There have been several reports of cerebrovascular events (hypertension, seizures, stroke and myocardial infarction) in women taking bromocriptine in particular for postpartum milk suppression. This may be due to vasospasm of cerebral blood vessels and may be associated with pre-existing hypertension and use in association with other ergot derivatives. Blood pressure should be carefully monitored in postpartum women taking bromocriptine, and particular care should be taken in those also on antihypertensives.^{3,5} However, it should be noted that a causal relationship between these effects and bromocriptine is not clear.

Asymptomatic hypotension occurs in many subjects given bromocriptine. However, faintness and dizziness, sometimes accompanied by nausea and vomiting, are common at the start of treatment with bromocriptine and these symptoms rather than an anaphylactic type of reaction are likely to account for the collapse that occurs in a few sensitive patients.³

Bromocriptine is a vasoconstrictor; digital vasospasm, induced by cold, and leg cramps have been reported. Other cardiovascular effects have included erythromelalgia, prolonged severe hypotension, arrhythmias and mental disorders have been reported in postpartum women given bromocriptine.³

Psychotic reactions to high doses of bromocriptine are well known in patients with parkinsonism. Bromocriptine produces a severe psychosis in which the patient is violent and aggressive, suffering from intense delusions which are often hostile and violent. Complete withdrawal of bromocriptine may still leave a residue of severe psychotic illness persisting for 1 to 3 weeks.³

Other side effects reported include headache, nasal congestion, drowsiness, dry mouth, constipation, diarrhoea, and altered liver-function tests. Dyskinesias have occurred in patients suffering from parkinsonism. Gastro-intestinal bleeding has been reported in acromegalic patients.³

Audiometric evidence of bilateral sensorineural hearing loss has been reported. Blurred vision, diplopia and reversible myopia have also been reported. There have been isolated reports of severe hyponatraemia, and cerebrospinal-fluid rhinorrhoea.³

Hypersexuality has been reported with bromocriptine. Constant dribbling urinary incontinence has also been reported, which appears to resolve on withdrawal of the drug. There have also been case reports of oedema and a withdrawal syndrome (transient galactorrhoea and hyperprolactinaemia).³

There have been case reports of pergolide causing pleural effusion. However this may be more likely at the higher end of the dose range, and after some period of treatment (one case exhibited this side effect after 1000–2,250 mcg/day for eleven years). Pulmonary fibrosis has also been reported, but is reported to be rare.⁵ Interstitial lung disease and other functional respiratory symptoms have been reported with bromocriptine. However, these appear to largely resolve on withdrawal of the drug, although problems can persist for up to six months after withdrawal.³

Martindale implies that hallucinations and confusion may occur on abrupt withdrawal of pergolide, so this agent should be withdrawn gradually. If a patient was given pergolide long term, it is likely that the risk of this adverse effect could be minimized by slow withdrawal. It has been suggested that Neuroleptic malignant syndrome may also result from pergolide administration, in particular from rapid dose reduction/withdrawal.

It has been suggested that the risk of this can be decreased by slow withdrawal.³

Lieberman et al report that the adverse effects that they observed with pergolide namely mental changes, dyskinesias, orthostatic hypotension and nausea, were reversible when pergolide was decreased or discontinued.⁶

Lieberman et al report that pergolide was discontinued in 18 patients because of the following adverse effects: organic confusional syndrome, dyskinesias and cardiovascular abnormalities.⁶

In summary:

- bromocriptine's side effects tend to be dose related, tend to occur at the higher doses and often diminish or resolve with dose reduction
- it is not clear whether there is a causal relationship between bromocriptine and cardiovascular events (these adverse effects have also been reported with pergolide but the same uncertainty about causality may apply). These may be more common in postpartum women.
- asymptomatic hypotension, faintness, dizziness, nausea and vomiting are common at the start of bromocriptine treatment
- psychotic reactions with bromocriptine can be severe but are reversible
- reversible urinary incontinence has been reported with bromocriptine
- pulmonary fibrosis and pleural effusion has been reported with pergolide. These appear to occur with bromocriptine as well, and in the case of bromocriptine they appear to largely resolve on drug withdrawal. This may also be the case with pergolide, this appears to be unclear.
- pergolide induced mental changes, dyskinesias, orthostatic hypotension and nausea have been reported to be reversible
- abrupt withdrawal of pergolide may cause a withdrawal syndrome and/or neuroleptic malignant syndrome. The risk of these adverse effects can be diminished by slow withdrawal.
- Other side effects reported include headache, nasal congestion, drowsiness, dry
 mouth, constipation, diarrhoea, altered liver-function tests. Gastro-intestinal
 bleeding in acromegalic patients, hearing and visual disturbances, hypersexuality and
 oedema. My initial investigations did not identify if these adverse effects are
 reversible.

It is important to note several factors when assessing the above information:

- although pergolide's adverse effects are thought to be similar to bromocriptine, it is not good practice to assume that all of bromocriptine's adverse effects are possible with pergolide
- a good number of the adverse effects noted for both pergolide and bromocriptine are experienced in patients who have either Parkinson's, acromegaly or are post partum. It is not necessarily correct to assume that adverse effects experienced by these patients groups, would be the same as those likely to be suffered by [Mrs B]. [I am making the assumption that [Mrs B] does not have any of these conditions]

These factors make it difficult to quantify the potential effects on [Mrs B's] health of long term administration of pergolide.

I would like to concur with [Dr H's] comments. Given that [Mrs B] did vomit on the first dose and had noticed that the tablet was the wrong colour, there was very little potential for the error to continue. Despite the rather extensive list of adverse effects *possible* with pergolide (as is the case with most medications), the large majority are dose related or reversible. Many of the others that may not fit into these categories are rare.

The other area of potential health risk associated with long term administration of the incorrect drug relates to NOT receiving perhexiline treatment. Given that [Mrs B] is also taking Duride®, diltiazem and atenolol for angina it may be difficult to quantify this risk. It would be more appropriate for [Mrs B's] general practitioner to advise on this aspect.

4 Please comment on the appropriateness of the dispensing procedures of [the pharmacy]

The information provided by the rest home contains standard operating procedures for the nursing home. These do not cover the dispensing procedures of [the pharmacy]. The additional information that is provided to [the rest home] by [the pharmacy] appears to be standardized reference material provided by Dispensary First®. However, this information is quite extensive, relevant and would be useful to [the rest home] staff in their care for their residents.

[The pharmacy] has not provided copies of their initial dispensing procedures, however they have included their standard operating procedure for handling dispensing errors in Medico® packs. According to the Pharmacy Quality Audit II⁷ pharmacies are not required to have a standard operating procedure that specifically identifies how to deal with dispensing errors in Medico® packs (or equivalent). Pharmacies *are* required to have a standard operating procedure for dealing with dispensing errors in general, in particular they are required to identify who is responsible for dealing with such errors. They are not required to detail exactly what steps should be followed upon identification of the error as this will vary from case to case. It would be impractical to document this procedure to this level of detail.

A general dispensing standard operating procedure should include a summary of the checking process that is required for any given prescription. As a prescription for a blister pack includes all packs (eg for a bd medication regime on a prescription – this may include a morning and evening pack), the checking process should include the checking of all packs. This may or may not be specifically spelt out in an operating procedure. Even if it isn't spelt out it would be regarded as acceptable professional practice to do so.

Having a standard operating procedure for dispensing errors in Medico® packs that specifically identifies that all trays are to be checked is therefore not required but is very good practice.

Pharmaceutical Society of New Zealand Code of Ethics 2001 Standard 3.9

The Charge Pharmacist must ensure that the identity of the pharmacist who has taken final responsibility for a dispensed prescription is able to be determined. For example, if there is a paper copy of a prescription, then the Charge Pharmacist must ensure that it bears an annotation or code that identified the pharmacist who has taken final responsibility for the dispensed medicine. For good practice, the pharmacist may also choose to have a record of others such as technicians who have been involved in the dispensing process. However, from a discipline perspective, only pharmacists can be considered in breach of the Code of Ethics.⁸

[The pharmacy] appears to have procedures in place to ensure the identification of the dispenser and checker of prescriptions. This is good professional practice.

It would appear that [the pharmacy] is reviewing these procedures annually which is regarded as acceptable professional practice.

5 Please comment on the appropriateness of a trainee technician preparing blister packs for dispensing

It is appropriate for a trainee technician to prepare blister packs for dispensing. 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.⁹

In a 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 in pharmacy under the Pharmacy Act 1939 are permitted to dispense prescription medicines (reg 42 Medicines Regs). All, except pharmacists, must work under the direct personal supervision of a pharmacist. Dispensary technicians are not permitted to compound medicines.⁹

Limitations of role: 9

The technician:

- Will not deal with Controlled Drugs or prescriptions for such
- Will not decide the brand to be dispensed when filling a generic prescription
- Will not receive prescriptions by telephone. Taking the reference number of a prescription due for a repeat is permissible
- Under no circumstances will a technician give a prescription to a patient unless it has been checked and initialled by the pharmacist.

Pharmacy technicians with the National Certificate are permitted to take full part in the dispensing process. This includes compounding medicines. Dispensary technicians are only permitted to 'count and pour' and are not permitted to compound pharmaceutical preparations or counsel patients.⁹

The following tasks may be performed by **all** technicians in a pharmacy (regardless of their qualification) according to procedures established by a pharmacist:⁹

Assisting the pharmacist dispense medicines

- receive a written prescription from the patient or representative
- check with the pharmacist as to the accuracy and completeness of the prescription
- stamp, number and annotate the prescription
- perform necessary calculations for checking by the pharmacist
- computer entry for generation of prescription labels
- retrieve, count or pour medicines under the supervision of the pharmacist
- select appropriate container for dispensed medicine
- affix prescription and auxiliary labels to prescription container
- price prescriptions
- file prescriptions
- establish and maintain prescription records
- repackage and label medicines for OTC sale or dispensing

The various technician training courses that are available cover unit standards that are on the national qualifications framework. Some of these units specifically cover handling of hazardous good, dispensing and legislation. There is currently no requirement that these units be covered/studied before a technician in training is allowed to assist in the dispensing process. It is up to the course provider to determine the order that the unit standards are covered. Therefore it is appropriate for a trainee technician to take part in the dispensing process and the preparation of blister packs is regarded to be part of this process. This is also regarded as acceptable professional practice so long as the technician is operating under the direct personal supervision of a pharmacist.

6 Please comment on the role of the checking pharmacist, [Ms E], in respect to the dispensing of [Mrs B's] blister pack

The New Zealand pharmacist's code of ethics and professional standards outlines the following requirements of pharmacists with respect to dispensing.

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.⁸

It is the checking pharmacist's role to ensure that the work of the dispensary technician is accurate. Even if it is a technician who is doing the actual dispensing, the checking pharmacist must still comply with section 2.6 of the pharmacist's code of ethics as outlined above. This role should be performed in a manner that is outlined in written standard operating procedures held by the pharmacy. Pharmacies are audited by Medsafe with respect to these operating procedures (amongst others) as [Mr I] mentions. [Mr I] states that [the pharmacy] has completed this audit. So long as [Ms E] carried out her duties in accordance with the written operating procedures in the pharmacy she would be fulfilling her duties to an acceptable level of professional practice.

These comments do not take account of the possibility of human error. No amount of standard operating procedures is going to totally eliminate the possibility of human error. The occurrence of a dispensing mistake is not in itself evidence of unprofessional conduct.

- 7 Please comment on any other matters relating to professional or ethical standards, which [Mrs B] believes are relevant to this complaint.
- [HDC's] file note of a phone call to [Mrs B] on 15 April 2003 states that when [Mrs B] queried the different coloured tablet with the caregiver, that the caregiver went and got the nurse. The nurse looked at the tablet and went away and when she returned [Mrs B] was told that the doctor had said that it was alright to take it.
- [Mrs A's] letter dated 4 April 2002 states that 'the caregiver called the Nurse who told [Mrs B] that she would check it out. The Nurse returned saying that the Doctor must have prescribed it although [Mrs B] said he made no mention of changing her medication.'

I cannot see any confirmation of this in any of the other documentation. I am not qualified to comment on acceptable standards of practice for nursing staff, and am not contracted to decide which pieces of documentation best reflect the true course of events. However, I hope that this has been assessed in other parts of this investigation. These statements seem to imply that either the doctor contacted suggested going ahead with administering a medication that appeared to have changed OR that the nursing staff did not in fact check with either the pharmacy or doctor before administering a medication that appeared to have changed.

Documents provided:

- 1 Letter of complaint from [Mrs A], [Mrs B's] daughter marked 'A'
- 2 Response from [Ms D] marked 'B'
- 3 Response from [Ms E] marked 'C'
- 4 Response from [Ms F] marked 'D'
- 5 Response from [Mr I] marked 'E'
- 6 Response from [[Ms C]] marked 'F'
- 7 Response from [the rest home] marked 'G'
- 8 Record of action note of conversation with [Mrs B] dated 15 April 2003 marked 'H'
- 9 Information from [Dr H], general practitioner marked 'I'

References

- 1 Conversation held with Carolyn Hooper at Pharmacy Defence Association, 24-02-03
- 2 Information for Health Professionals. Permax data sheet http://www.medsafe.govt.nz/profs/Datasheet/p/permaxtab.htm http://www.medsafe.govt.nz/permaxtab.htm <a href="http://www.medsaf
- 3 Brayfield A, Cadart C, Eager K, Funnell S, Gotecha P, Handy S et al, editors. Martindale The Complete Drug Reference 32nd ed. United Kingdom: Pharmaceutical Press; 1999
- 4 Rang HP, Dale MM, Ritter JM. Pharmacology. 4th ed. Edinburgh, Scotland: Churchill Livingstone 1999
- 5 Lee A, editor. Adverse Drug Reactions. United Kingdom: Pharmaceutical Press; 2001
- 6 Lieberman AN. Goldstein M. Gopinathan G. Neophytides A. D-1 and D-2 agonists in Parkinson's disease [Review] Canadian Journal of Neurological Sciences. 1987;14(3 Suppl):466-73 [Abstract]
- 7 Pharmacy Quality Audit II (PQAII) Version 2.01 Integrated Requirements of Medsafe the District Health Boards (Pharmacy Services Agreement) and the Pharmaceutical Society of New Zealand. www.psnz.org.nz accessed 7/7/03>
- 8 Pharmaceutical Society of New Zealand Code of Ethics 2001
- 9 Pharmaceutical Society of New Zealand. Pharmacy Practice Handbook 2003. Pharmaceutical Society of New Zealand 2003."

Nursing advice

The following verbal expert advice was obtained from an independent registered nurse, Ms Wendy Rowe:

- Rest homes should have a policy that states that all blister pack medication should be checked by a registered nurse on delivery to the rest home.
- This check involves comparing what is listed on the blister pack against the
 medications listed on the medication chart. However, if the medication is correctly
 described on the blister pack, but incorrectly dispensed, then it is not reasonable to
 expect the nurse to identify an error unless it is an obviously inappropriate

medication for the patient, such as frusemide (its size and shape makes it easily identifiable).

- Checking blister pack medication is an essential step because medications are often administered by caregivers who can not be expected to recognise tablets.
- Counting tablets is a secondary check performed at the time of administration. However, in this situation, because the number of tablets was not incorrect, the administrator would not have been alerted to the error.

Responses to Provisional Opinion

The pharmacy

The lawyer responded as follows:

"…

[Ms F] and [Ms E] would like to clarify the statement in paragraph 3 on page 11 of the Opinion that 'if checking processes are carried out accurately it is obvious to the checker that more than one blister pack is on the premises for that patient'.

Each Medico tray lists all medicines contained within that particular tray for the patient and limited details of dosage due to software space constraints. Therefore 'all medicines meant for a given patient' are not necessarily referred to on all blister packs for that patient.

For this reason although the foil is checked against the patient medication chart for accuracy, because the foil is not necessarily a complete record, the patient medication chart rather than the foil should be used to check the correct medicines are contained in a tray."

Mr I, pharmacy proprietor, submitted the following comments:

"...

Overall, I feel the report accurately reflects the events that occurred and that Ms Shirtcliffe's expert comments were valid and fair.

I would, however, like to add some further comments and submissions in support of [Ms D], [Ms F] and [Ms E] for your consideration. Some have already been made but need further reinforcing as I believe that they are a most professional, caring and accurate team of Health Professionals.

. . .

[Ms F], although not directly involved in the original error, immediately sought to take responsibility for the identification of risk, correction and communication in her role as Dispensary Manager to ensure [Mrs B'] health. This was the overwhelming priority.

In her report Ms Shirtcliffe stated:

'[Ms F] appears to have acted quickly and in a patient focussed manner ...'

In her genuine efforts to ensure [Mrs B's] health, she omitted to check the second tray which she was not aware of at the time.

[Ms F] has been a Senior Pharmacist in this pharmacy for ten years, two of those as Dispensary Manager. We originally employed her knowing her professionalism and highest integrity. In the time that she has been here, I have respected her as one of the most professional and quality-focused pharmacists I have met. This experience has been devastating for her, as she prides herself on the highest standards in her work.

[Ms D], has just completed her training period as a Dispensary Technician, and at the time of the incident was still a trainee. Her studies, assessment results and her work habits have been exceptional as she has always maintained the highest levels of professionalism.

Her record of accuracy, before and after this incident has been impeccable. Obviously, this has been a very traumatic time for her and she has learnt a lot from it. I stand by the fact that she is an exceptional young technician for whom I have the highest regard.

[Ms E] has worked as a pharmacist in this Pharmacy for seven years. In this time, she has always worked to the highest levels of accuracy and has an unblemished record. I would recommend her as the most capable, competent pharmacist who is a valued part of the dispensing team.

While acknowledging that my opinion is biased to some degree, I have the highest professional and private regard for these members of our team. At no stage have they tried to shirk their responsibilities and have acted in the most professional way to ensure [Mrs B's] health and to co-operate with your Office in your investigation.

As already stated, this investigation has taken a huge toll on all of us and while in no way belittling the seriousness of the incident, I would ask that no further action be taken by your Office. We have learnt much from this experience; we have reviewed our procedures and improved our systems.

Hopefully, the professional record of those concerned over a long period of time may influence your recommendations."

The rest home

The General Manager Operations at the rest home responded as follows:

"

We are satisfied with your findings regarding [the rest home]. We support the advice provided by your Nursing Advisor, Wendy Rowe regarding the importance of correct dispensing by the pharmacy. Providing quality services in the aged care sector is a complex undertaking in the current social and political environment. As you are aware we have comprehensive policies in place and continually monitor industry best practice to ensure the continuation of high quality service delivery.

However we are reliant on our contractual partners to meet their professional and legal obligations regarding the services they provide. Without knowing your opinion regarding the Pharmacy involved we are unsure if there are changes we will need to make in the current arrangements we have with our pharmacy suppliers.

We will await your final report to determine if there is anything further [the rest home] needs to implement to minimise the risk of a similar event occurring in the future."

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

Rule 2.11 of the Pharmaceutical Society's Code of Ethics (2001) states:

"A pharmacist must be responsible for maintaining and supervising a disciplined dispensing procedure that ensures the highest standard is achieved."

Standard 3.9 states:

"... For good practice, the pharmacist may also choose to have a record of others such as technicians who have been involved in the dispensing process. However, from a discipline perspective, only pharmacists can be considered in breach of the Code of Ethics."

Standard 2.6 dispensing 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."

The Nursing Council of New Zealand's Guidelines for Competence Based Practising Certificates for Registered Nurses (June 1999) states:

"4.8 Administers and monitors the effect of prescribed interventions, treatments and medications within a framework of current nursing knowledge and knowledge of pharmacology, physiology, pathophysiology, pharmacodynamics and pharmacokinetics.

. . .

4.10 Evaluates the effectiveness of the client's response to prescribed interventions, treatments and medications and monitors prescribing, takes remedial action and/or refers accordingly.

. . .

6.0 Legal Responsibility

The applicant practices nursing in accord with relevant legislation and upholds client rights derived from that legislation.

. . .

6.6 Administers interventions, treatments and medications within legislation, codes, scope of practice and according to authorised prescription, established policy and guidelines."

Opinion: Breach – Ms D

Preparation of blister pack

Ms D was a trainee technician working under the direct supervision of a pharmacist, who was responsible for checking her work. Ms D accepts that she placed incorrect medication (pergolide) in Mrs B's blister pack. She cannot recall making the error.

My advisor stated:

"It is appropriate for a dispensary technician in training to be working in the dispensary in the preparation of blister packs so long as they are acting under the direct supervision of a pharmacist and in accordance with written standard operating procedures that correspond to the packing of blister packs (and all other relevant standard operating procedures relating to work in the dispensary)."

The fact that Ms D was working under the supervision of a pharmacist does not excuse her from being held accountable for her actions. A serious medication error was made when Ms D mistook pergolide for perhexiline. It is important that all staff, whether they are qualified pharmacists or not, follow professional standards for correctly preparing medication. In particular, Ms D should have been alert to the fact that pergolide is a medication that is not frequently prescribed. It would have been prudent of her to draw this to the attention to the checking pharmacist.

In my opinion, Ms D breached Rights 4(1) and (2) of the Code when she placed incorrect medication into Mrs B's blister pack.

Opinion: Breach – Ms E

bear no relationship to the person's actual name.

Dispensing of pergolide

As I have discussed above, Ms D made up Mrs B's blister pack. Ms E, as the dispensing pharmacist, was responsible for checking that the contents were correct.

Ms E does not have any recollection of the events. However, she states that she was the responsible dispensing pharmacist for Mrs B's blister pack. My advisor stated:

"It is the checking pharmacist's role to ensure that the work of the dispensary technician is accurate. Even if it is a technician who is doing the actual dispensing, the checking pharmacist must still comply with section 2.6 of the pharmacist's code of ethics as outlined above. This role should be performed in a manner that is outlined in written standard operating procedures held by the pharmacy."

The medication error had an adverse effect on Mrs B, and meant that she did not receive the medication for her angina symptoms (perhexiline). Had Mrs B inadvertently continued taking the wrong medication, her health would almost certainly have been compromised.

Fortunately Mrs B is an alert consumer and was able to recognise that the medication was different to what she normally took.

Ms E failed to adequately check Mrs B's blister pack medications, which resulted in a serious medication error. Standard 2.6 of the Pharmacy Code of Ethics states that it is the responsibility of the pharmacist to ensure that medication being dispensed is correct. Accordingly, in my opinion Ms E breached Rights 4(1) and (2) of the Code.

Opinion: Breach - Ms F

Rectifying the error

Ms F, dispensary manager, acted promptly when advised of the error and, in most respects, fulfilled her professional responsibilities. However, Ms F failed to ascertain whether all of Mrs B's blister packs were correct.

I do not accept Ms F's explanation that the reason she did not check for other blister packs was because the rest home staff did not alert her to the existence of more than one blister pack. I consider that it was her responsibility to ensure that all of Mrs B's blister packs were correct.

My advisor stated:

"... [I]t is acceptable professional practice to check all blister packs for a given patient if a dispensing error is identified. When blister packs for a given patient are dispensed they tend to be packed at the same time. So, if an incorrect stock bottle is used to pack (for example) the morning pack for a patient, there is a chance the same incorrect stock bottle could be used to dispense packs for the other times of the day (e.g. lunch, dinner etc). This means that when a dispensing error is identified it is reasonable to assume that all packs for that patient will be checked. The printed information on Medico® blister packs refer to ALL medicines being taken by a given patient. That is, all medicines meant for a given patient are referred to on all blister packs for that patient. So if checking processes are carried out accurately, it is obvious to the checker that more than one blister pack is on the premises for that patient."

Furthermore, I note that it is not unusual for residents to have more than one blister pack.

Pharmacists must always maintain the highest level of vigilance when dispensing medications, given the potential risks that may follow from an error. In relation to blister pack medication, this is even more critical as rest homes, private hospitals, and the community at large, must be able to rely on the accuracy of bulk dispensing.

In my opinion Ms F breached Rights 4(1) and (2) of the Code when she failed to ensure that all the blister packs were checked for incorrect medication. Her failure to do so

compounded the error made in the checking/dispensing process and, in my view, is an aggravating feature of this complaint.

Opinion: Breach – Ms C

Administration of morning medication 27 March 2002

As discussed above, incorrect medication, namely pergolide, was dispensed in Mrs B's morning and evening blister and administered by Ms C.

Ms C was the registered nurse on duty who was responsible for checking that the blister pack medication, which had arrived the evening before, was correct. Making this check involves ensuring that the medication listed on the blister pack matches the medication prescribed by the general practitioner (as recorded on the medication chart). This check must be made by a registered nurse. A further check is made at the time of administering the medication (when the medications are counted).

Ms C has admitted that she did not perform a check of the medications; instead, she relied on the integrity of the checking process within the pharmacy. This was not in accordance with the rest home's policy or good nursing practice.

I accept that it is not possible to be familiar with the individual medications that all residents are prescribed, particularly in a large rest home. Indeed, that is why blister packs are commonly used in rest homes and private hospitals. While Ms C could have been expected to be alert to a greater or smaller number of tablets (as the rest home's policy states), in Mrs B's case the number was the same as one tablet had been substituted for the other. Therefore, had she compared the number of tablets with the amount listed on the medication chart, it would not have assisted her with recognising that there was an error.

In relation to the first check, Ms C stated that the medication chart does not have a corresponding description of the tablets to assist with this checking process (although there is a description on the signing sheet). Nor was she familiar with Mrs B's medications. Ms C advised that the medication chart is taken on the medication rounds; however, as noted above, there is no description of the medication on the form.

My nurse advisor commented that comparing the medications listed on the back of the blister pack with the medications listed on the medication chart was an appropriate check for a registered nurse to take when blister pack medication is delivered. However, if the medication is correctly described on the blister pack, it is unlikely that the nurse would recognise an error, unless it was an obviously inappropriate medication such as frusemide, which stands out because of its size. My nurse advisor further commented that this first check was the most essential one to make, especially since caregivers (who are not expected to recognise medications) also administer medication.

It is not known whether the medications were correctly listed on the blister pack, although I note that they are correctly listed on the signing sheet that accompanied the blister pack. Assuming the medications were correctly listed on the blister pack, it is possible that even if Ms C had performed her check she would not have detected the error. However, in my view, that is no excuse.

Ms C has submitted that she was very busy with a high workload. While I do not doubt this, in my view, it is not appropriate for a registered nurse to abdicate his or her professional responsibility for performing mandatory checks and rely on the checking process of other providers. As this situation clearly demonstrates, if the pharmacy checking system fails, then the checking system at the rest home is critical.

I note that Ms C is a registered nurse holding a current practising certificate and is obliged to adhere to the competency framework for registered nurses. Criteria 6.6 states that registered nurses must administer medication in accordance with "authorised prescription, established policy and guidelines".

In my opinion Ms C breached Rights 4(1) and 4(2) of the Code when she failed to check Mrs B's blister pack medication.

Opinion: No breach – Ms C

Incorrect evening medication 27 March 2002

Mrs B was given incorrect medication again in the evening of 27 March by the caregiver. Mrs B fortunately recognised this and did not take it. She decided not to bring this second error to the attention of the rest home staff at the time.

The second error was not made by the rest home or their staff. My expert nurse advisor stated that the responsibility for correcting the medication error rested with the pharmacy and not with the rest home staff. Accordingly, in my opinion, Ms C did not breach the Code in relation to the incorrect medication being administered to Mrs B in the evening.

Opinion: No breach – The Pharmacy

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

My advisor has identified that there were appropriate standards in place in the pharmacy. Although there was not a specific policy in place for managing blister pack errors, she advised that it is not necessary or practicable for pharmacies to have a policy that covers every step following identification of an error. My advisor commented:

"[The pharmacy] appears to have a documented procedure which identifies who should deal with a dispensing error which is acceptable standard practice. Pharmacies are not required to identify exactly what steps should be taken upon identification of an error. This is deemed to be impractical as every situation would be different. It is not regarded as essential to have a specific procedure that deals with checking blister packs and dealing with dispensing errors in blister packs in particular. [The pharmacy] now has such a procedure which would be regarded as very good practice."

In my view it was reasonable for the pharmacy to expect its employees Ms D and Ms E to adhere to the policy for safely dispensing medication. Accordingly, in my opinion the pharmacy is not vicariously liable for the breaches of its employees.

Opinion: No breach – The Rest Home

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

I am satisfied that the rest home's policy for checking of blister packs was appropriate, and that Ms C was aware of the policy for checking blister packs and understood her responsibilities. Accordingly, in my opinion the rest home is not vicariously liable for Ms C's breach of the Code.

Other comment

Response to consumer query

My investigation was unable to identify the staff member who Mrs B told about the incorrect medication, as she cannot recall the individual's name. However, it is clear that she told somebody. Ms C is adamant that she was only alerted to the medication being incorrect after Mrs B started vomiting. She stated that had it been brought to her attention, she would not have given Mrs B the medication and would have made further checks. The caregiver, Ms G, is unable to recall any of the relevant events.

I am concerned that a staff member assured Mrs B that it was all right to take medication she had recognised was different, without first making the appropriate checks. In my view, this highlights a need for improved education of the rest home staff about responding appropriately to residents who raise such serious concerns.

Non-referral to Director of Proceedings

I have been persuaded by Mr I's response to my provisional opinion not to refer this complaint to the Director of Proceedings. In doing so, I have taken into account the length of time my investigation has taken and the toll this has had had on all concerned. Furthermore, I am satisfied that adequate measures have been taken by the pharmacy to ensure that such an incident does not occur again. I believe that a valuable lesson has been learned by Ms F, Ms E and Ms D and that there is little likelihood of them making a similar mistake in the future.

Follow-up actions

- A copy of this report will be sent to the Pharmaceutical Society of New Zealand, the Nursing Council of New Zealand, and Quality Health New Zealand.
- A copy of this report, with details identifying the parties removed, will be sent to the Pharmaceutical Society of New Zealand and the Nursing Council of New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.