A Pharmacy

Manager of the Pharmacy, Mr B

Pharmacist, Mrs C

A Report by the

Health and Disability Commissioner

(Case 01HDC11910)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Mr B	Manager at the pharmacy
Mrs C	Pharmacist at the pharmacy
Dr D	General Practitioner
Dr E	Rheumatologist
Ms F	Staff member at the pharmacy
Mrs G	Pharmacist at the pharmacy
Dr H	General Practitioner

Complaint

On 16 October 2001 the Commissioner received a complaint from Mrs A about a pharmacy. The complaint was summarised as follows:

The pharmacy did not provide services of an appropriate standard to Mrs A. In particular:

- *On 27 March 2001 staff at the pharmacy dispensed Mrs A's prescription for 5mg folic acid with the incorrect instruction that she take one tablet daily. The prescription stated that it was to be taken in the dosage of one tablet per week.*
- *On 27 March 2001 staff at the pharmacy also dispensed methotrexate 2.5mg with the incorrect instruction that she take one tablet per week. The prescription stated that it was to be taken in the dosage of four tablets per week.*
- *Surgam 300mg was dispensed by staff at the pharmacy with the instructions "one tablet twice daily". The prescription stated "two tablets daily".*
- *On 2 October 2001 staff at the pharmacy incorrectly dispensed Premarin 0.625mg, instead of the prescribed Premarin 1.25 mg.*

An investigation was commenced on 14 December 2001.

Information reviewed

- Complaint material from Mrs A
- Information from Mr B
- Information from Mrs C
- Medical records and information provided by Dr D, general practitioner
- Medical records and information provided by Dr E, rheumatologist
- Prescription records provided by Healthpac, Ministry of Health

Independent expert advice was obtained from Ms Andrea Shirtcliffe, pharmacist.

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Information gathered during investigation

Background
The pharmacy is registered as a limited liability company and Mr B is listed as the director and a joint shareholder with his wife. Mr B responded to the complaint in his capacity as pharmacist, and manager of the pharmacy. The complaint also involved another pharmacist, Mrs C, who at the time of the complaint was employed to work in the pharmacy. There is some dispute as to the respective roles and responsibilities of the two pharmacists involved in this complaint.

Dispensing of folic acid
On Tuesday 27 March 2001 rheumatologist Dr E prescribed Mrs A 5mg folic acid, to be taken once a week, and 2.5mg methotrexate, 10mg to be taken once weekly at night (four 2.5mg tablets) for her arthritis. By letter dated 29 March Dr E advised Mrs A's general practitioner, Dr D: "At this stage the plan is to try her on low dose methotrexate 10mg once weekly with folic acid 5mg once weekly."

On 27 March, Mrs A took the prescriptions to the pharmacy, where the medications were dispensed.

Two pharmacists were present at the relevant time, Mrs C (the only full-time pharmacist) and Mr B. Mr B advised that the dispensing occurred at 1.06pm. (Mrs C advised that her hours of work were usually from 9.00am until 6pm.) Ms F and two other staff were present.

HealthPac provided a copy of the original prescriptions. The prescriptions stated:

> "Folic acid
> 5mg once weekly po 3/12
> Methotrexate 2.5mg
> Take 10mg po once weekly nocte."

Both prescriptions are stamped with a pharmacy stamp (dated 27 March), but have not been signed by the dispensing pharmacist.

On arrival home on 27 March Mrs A observed that her prescription for 5mg folic acid was dispensed with the incorrect instruction that she take one tablet daily, not one tablet per week. She returned to the pharmacy the next day. Mrs A stated:

> "[I] returned to the pharmacy, who corrected it and apologised for the mistake, and gave me a refund for the extra tablets I had been given."

The pharmacy computer records for the folic acid prescription show the dispensing date as 27 March; the "staff" field records the staff member as "Mrs C", with the comment that the script was re-priced from $8.60 to $6.50 by Mrs C on 28 March. Mrs C advised she was not present on 28 March when Mrs A returned to discuss the error and that Mrs A spoke to Mrs G, who was the only pharmacist on duty at that time.

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Mrs G was employed as a part-time pharmacist at the pharmacy. On Wednesday 28 March 2001 she worked from 10am until 8.30pm. Mrs G recalled Mrs A coming into the pharmacy during that evening and advised that she must have re-priced the prescription (although she has no specific recall of doing so). Mrs G does not remember any specific details in relation to the incident itself. She stated:

> "I left written notification on [Mr B's] desk informing him of the details of the incident, as is standard practice."

Mrs G also advised:

> "On a Wednesday the pharmacist identification on the computer is not changed throughout the day as sometimes both pharmacists are involved in the dispensing of a prescription."

Mr B stated that after he reviewed Mrs G's report the following day, he discussed the matter with Mrs G (by telephone), and with Mrs C and Ms F. He then completed a full incident report. Mr B advised that at the time of these discussions, Mrs C admitted to making the error. Mrs C denied this, and stated she was not made aware of the incident at the time.

Mr B provided the incident report that was written in relation to this dispensing error. The report states:

> "Date:
> 27/3/01
>
> Complainant (patient):
> [Mrs A]
>
> Pharmacist who dispensed:
> [Mrs C]
>
> Incident Description:
> Script 307995. Given correct medication, wrong dose. Given 1 daily, should be 1 weekly. Folic acid 5mg.
>
> Solution/Action Taken:
> Patient returned 28/3/01 having noticed error. Script corrected, refund issued for over supply of tablets, apology offered to [Mrs A].
>
> General Comment/Changes to Future Policy ETC,
> [Mr B] discussed with [Mrs C] nature of error: more care required checking scripts, although no previous dispensing problems. Good staffing levels O.K. at the time (2 pharmacists available and shop staff).
>
> Person/pharmacist dealing with complaint: [Mrs C]/[Mr B]."

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The report is not signed by either "Mrs C" or "Mr B".

Dr E advised that he did not anticipate any ill effects from taking 5mg of folic acid daily instead of weekly. Folic acid is used to reduce the toxicity of methotrexate and Mrs A received more than that required. Dr E stated:

> "There has been conjecture that higher dosages of folic acid might in some ways reduce the effectiveness of methotrexate but that is not proven. Certainly no ill health would follow from this mistake."

Dispensing of methotrexate

Mrs A next consulted Dr E on 6 June 2001. At this visit she discovered that another error had been made with her prescription on 27 March, which she had not noticed at the time. Staff at the pharmacy had dispensed methotrexate 2.5mg with the incorrect instruction that she take one tablet per week. Dr E stated in his letter of 7 June to Dr D:

> "She [Mrs A] has been taking one tablet once a week which is not what I intended and upon returning home she has determined that this is a 2.5 strength rather than 10mg. If this is true then she is going to be very sensitive to methotrexate and can instead of going up to 12.5mg as I suggested to her look to going to 7.5mg once a week and seeing how she gets on."

Dr E advised that the incorrect dispensing of methotrexate is "more important" than the folic acid error. However, in this case, as the error in the instructions led to a lower than intended dosage, there was no real danger to Mrs A and the only noticeable ill effect would have been delay in the impact of treatment.

Mr B stated:

> "The second error with the methotrexate was amended on Friday, the 8/6/01. A meeting was held with [Mrs A] on this day, where I offered her a full apology and reassured her extra measures would be put in place to prevent a repeat of the errors, particularly the addition of a warning that would flash up on the screen whenever her name was entered the pharmacists to 'Double check all dispensings'."

The incident report in relation to this error states:

> "Date:
> 27/3/01
>
> Complainant (patient):
> [Mrs A]
>
> Pharmacist who dispensed:
> [Mrs C]

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> Incident description:
> Methotrexate dispensed 1 weekly, should have been 4 once weekly. Patient returned to pharmacy to discuss 8/6/01. [This report also makes reference to [Mrs A's] Surgam script, see *Labelling of Surgam*, below.]
>
> Solution/Action Taken:
> Medicine (Methotrexate) correctly labelled and extra tablets given. Discussion held with [Mrs A] re errors. Message to be put on computer 'Please double check all prescriptions – special care required' under [Mrs A's] patient comments.
>
> General Comment/Changes to Future Policy ETC
> Assured [Mrs A] extra attention would be actioned when dispensing her scripts. Gave her full apology.
>
> Meeting held with dispensing staff, [Mrs C] and [Ms F]. Discussed staffing levels, dispensary organisation, etc. Concluded that these errors were extremely rare and unfortunate 1 person was subject to more than 1 error. We agreed that more care required at final checking stage of prescription dispensing.
>
> Person/pharmacist dealing with complaint: [Mr B] /[Mrs C]."

As with the folic acid report, this incident report was not signed by either Mr B or Mrs C, or by "Ms F" (pharmacy technician) who also attended the meeting held with dispensing staff.

The pharmacy computer records for the methotrexate prescription state that the date of dispensing was 27 March 2001, the staff member was Mrs C, and the script was re-priced from $14.90 to $15.85 by Mrs C on 8 June. A further screen with Mrs A's patient information states, "!Please Double Check All Dispensings!"

Dispensing pharmacist on 27 March 2001
Mr B stated that he was not personally involved with dispensing Mrs A's medication, although he "spent much time with staff reviewing procedure to help ensure a repeat of these errors did not happen". He said:

> "The doses incorrectly given were, in fact, the more normal doses used, with these drugs. The pharmacist concerned simply did not check the dispensing sufficiently. In my 25 years as a pharmacist, I have never seen a situation like this, where 2 errors were made on one prescription. Our dispensing procedure is sound, and has passed health department audits. We dispense about 100,000 prescriptions annually, and have a near zero error rate. The pharmacist concerned is employed full time and is generally very competent."

Mr B advised that the pharmacist who dispensed Mrs A's medication was Mrs C. He stated that there was no difficulty in identifying her as the dispensing pharmacist. This is because "the incident reports filed at the time confirm this beyond doubt. The computer records also confirm this."

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Mr B provided a copy of the pharmacy's standard operating procedures on the subject of dispensing (see Appendix 1) which he considered to be most relevant to Mrs A's complaint.

Mr B commented that generally (80% of the time) there is only one pharmacist dispensing at the pharmacy. He stated:

> "Initialling of prescriptions is part of dispensing procedure that should always be done by the checking pharmacist prior to giving out the medicines. However, since we only have one pharmacist on most of the time (and a pharmacy technician), and the computer keeps a record, it is normally obvious who the responsible pharmacist is … Since the advent of computerised prescription pricing, annotation of prescriptions in general is far less of a requirement. However, this does not take away the responsibility of the checking pharmacist to sign."

Mr B explained (in relation to the quote above) that annotation of prescriptions is a separate function to signing. In this context, annotation refers to the additions made to the prescription by a pharmacist, to assist the person pricing to understand the details of the prescription.

In contrast, Mrs C alleged that the pharmacy records are unclear as to who dispensed for Mrs A, as Mr B and a pharmacy technician were also on duty at that time. She stated:

> "Unfortunately, the scripts were not initialled and therefore the dispensing pharmacist is unknown. When an error was detected by [Mrs A] it was dealt with by [Mr B], as I was on holidays overseas. Discussions between the three of us since that date, have been unable to reveal who may have made the error."

Mrs C stated that the pharmacy's standard operating procedures had never been shown to her: "It was certainly never enforced by [Mr B] and as a result prescriptions were not signed."

Mrs C stated that the dispensing pharmacist works alongside the technician and other pharmacist: "All aspects of dispensing are shared and the pharmacist does not always do the loading of labels into the computer."

In relation to the incident reports which were provided to me as part of the investigation, Mr B stated:

> "The Incident Report Forms filled out at the time, are the written evidence showing [Mrs C] to be the pharmacist on duty at this time. The only other pharmacist present at this time was myself, and I know I was not involved in dispensing this prescription. I did very little dispensing when [Mrs C] was present, as I was usually involved in managerial matters re the pharmacy. When [Mrs C] left at 6.00pm I was the sole pharmacist until 8.30pm. Furthermore, the computer record for this dispensing of [Mrs A's] prescription, has [Mrs C] as the dispensing pharmacist. [Ms F and two other staff were present.] However, none of these people can recall any event on this day, almost one and a half years ago."

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Mrs C stated:

> "I was not aware such incident reports written by [Mr B] existed and I had certainly never been shown them, until now. I was overseas during the discussions between [Mrs A] and [Mr B] regarding the methotrexate but was told of the error on my return to work. Whilst it is true [Mr B] would often involve himself in managerial duties it was normal for me to leave the premises for a lunch break some time between 12.00pm and 2.00pm on Tuesdays. [Mr B] was the sole pharmacist on duty during this time."

Mrs C said that as the error was said to have occurred at 1.06pm, it was at a time when it was highly unlikely that she was actually on the premises. She stated that in the course of the discussions that followed between Ms F, Mr B and herself, it was not possible to determine the identity of the dispensing pharmacist. She therefore believes that the incident reports written by Mr B are inaccurate.

Incident reports

Mr B commented that the incident reports (set out above) were "filled in at the time" [after Mrs A reported the errors to the pharmacy] and that the discussions with staff occurred "within one to two days … of the incidents". In contrast, Mrs C questioned whether the incident reports were filled in at the time of the incident and commented that she was not made aware of them until notified as a result of the complaint.

Mrs C also commented that it was not a requirement for staff to write incident reports at that time. Mrs C stated that Mrs G, the pharmacist on duty when Mrs A returned the next day, did not complete an incident report. Mrs C doubted that Mr B was aware of the incident with the folic acid until 8 June; "he certainly never discussed it with me". (As mentioned previously, Mrs G in fact provided written notification of the incident to Mr B on 28 March 2001.)

Mr B stated:

> "When [Mrs A] alerted us to this error, a message was put on her records to do extra checks on future prescriptions to prevent any further errors. Furthermore, dispensing procedure was discussed with the pharmacist concerned at length, again with the purpose of preventing any future errors.
>
> …
>
> The dispensary staff were summoned by myself to discuss the errors, and all possible solutions to prevent future problems. A thorough written record is also kept. A discussion was also held with [Mrs A], and it was decided to put in her comments in her patient history computer records a message indicating all future dispensings must be given extra checking attention."

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Mrs C stated that there was no formal meeting – there was only a discussion and they could not determine who was at fault. She commented:

> "However, aside from a note on [Mrs A's] file to pay careful attention, no review of procedures occurred or were recommended by [Mr B]. I was told the matter did not require any further attention."

Labelling of Surgam medication

Mrs A was also taking Surgam for osteoarthritic pain. Mrs A's general practitioner, Dr D, first prescribed Surgam to Mrs A for osteoarthritic pain in the left knee, on 5 May 2000. Dr D prescribed a dosage of two tablets daily of 300mg of Surgam, which has remained unaltered since.

On 8 June 2001, Mrs A discussed with Mr B an error in instructions for Surgam that had been dispensed at the pharmacy. The discussion occurred when Mrs A returned to the pharmacy to discuss the methotrexate error:

> "He [Mr B] explained this was caused by the Dr prescribing it that way at some previous time, and now the computer automatically prints the labels that way. I was not happy with that and we agreed in future to write the label on the bottle/packet the way the script reads."

The incident report stated (in part):

> "Explained with Surgam that her Dr had changed the way Surgam was prescribed, but she was still effectively taking two daily."

Mrs A did not specify which particular Surgam prescription was the subject of her complaint, but indicated that she became aware, following a consultation with Dr D on 8 June 2001, that the pharmacy labels had incorrectly instructed her to take Surgam as a split dosage, ie, twice daily rather than as a single daily dosage.

The available pharmacy label records (which are a copy of the labels that appeared on Mrs A's medication) are as follows:

- 29 May 2000, prescribed by Dr D. 300mg Surgam "take two capsules daily with food for knee pain". No repeats remaining.

- 26 July 2000, prescribed by Dr H. 300 mg Surgam "take one capsule twice daily with food for arthritis" (with two repeats prescriptions of this amount before 24 October 2000 dispensed on 30 August and 21 September 2000).

- 27 October 2000, prescribed by Dr D. 300mg of Surgam "take one capsule twice daily with food for arthritis".

- 17 Nov 2000, prescribed by Dr D. 300mg of Surgam "take one capsule twice daily with food for arthritis" (with two repeats before 15 February 2001, dispensed on 24 December 2000 and 16 January 2001).

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- 20 April 2001, prescribed by Dr D. 300mg of Surgam "take two capsules daily after food" (with three repeats before 20 July 2001, dispensed on 7 May, 29 May and 23 June 2001).

- 13 July 2001, prescribed by Dr D. 300mg of Surgam "take two capsules daily after food" (with two repeats before 11 October 2001, dispensed on 18 August 2001).

- 7 September 2001, prescribed by Dr D. 300mg of Surgam "take two capsules once daily as directed" (with two repeats before 6 December 2001, dispensed on 23 September 2001).

- 15 October 2001, prescribed by Dr D. 300mg of Surgam "take two capsules once daily as directed" (with one repeat before 6 December 2001, dispensed on 8 November 2001).

The label records reveal that instructions were given by the pharmacy for a split dosage of Surgam from 26 July 2000 until 20 April 2001. The prescription records confirm Dr D's statement that he initially prescribed Surgam with instructions to take a single daily dosage of two tablets.

Mr B accepted that the Surgam 300mg prescription was given to Mrs A with the incorrect instruction of one tablet twice daily, rather than two daily. He commented that "[Mrs A's] previous prescription" had stated "one tablet twice daily", and the dispensing pharmacist assumed this dosage regime was to continue. He stated:

> "This is a reasonable assumption, although [Mrs A] or the prescribing Doctor should have been consulted. Once again, the matter was discussed with the pharmacist concerned. This does not constitute a dispensing error, but procedural oversight."

Mr B commented that checking with the prescribing doctor and/or the patient is a common sense step that any careful pharmacist should have performed.

Mr B advised me: "Please note that as indicated earlier, Surgam was prescribed originally One twice daily, not 2 daily." (This is incorrect; see label record above.)

Mr B further commented: "It would appear that the doctor changed the Surgam dose over time. The daily dose is constant throughout however, being 600mg. This is the important factor."

The original copies of the handwritten scripts, as written by Dr D, were requested from HealthPac, Ministry of Health. HealthPac provided the following information:

- 5 May 2000, original prescription of Surgam by Dr D, handwritten instructions state two capsules to be taken once daily (as per the final repeat label of 29 May 2000 supplied by the pharmacy).

- 26 July 2000, prescription by Dr H, handwritten instructions state one capsule twice daily (as per the label supplied by the pharmacy).

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- 27 October 2000, prescription by Dr D. HealthPac was not able to provide this script. Instruction on label was one capsule twice daily.

- 17 Nov 2000, prescription by Dr D, handwritten instructions state two capsules once daily (in contrast the pharmacy label states one capsule twice daily).

- 20 April 2001, prescription by Dr D, handwritten instructions state two capsules daily (as per the label supplied by the pharmacy).

In summary, there was an error in the label instructions provided to Mrs A on 17 November 2000. The prescription read "Surgam, two capsules once daily". The pharmacy dispensed the medication with label instructions for it to be taken as a split dosage, one capsule twice daily. The original copy of the prescription for 17 November 2000 is not initialled, and therefore the identity of the dispensing pharmacist cannot be established.

It is unclear whether a similar error also occurred on the 27 October prescription as neither HealthPac nor the pharmacy was able to provide me with a copy of this prescription. The instruction on the pharmacy label was "one capsule twice daily", which is inconsistent with the manner in which Dr D advised he prescribed Surgam. The identity of the dispensing pharmacist for this prescription is also not identifiable.

(I note that the original prescriptions confirm that Dr H prescribed a split dosage on 26 July 2000.)

Comments regarding Mrs A's concern about the Surgam instructions are written on the methotrexate incident report. The report notes that Surgam was not dispensed according to the prescription instructions, as two daily. Surgam was relabelled "two daily" and Mr B explained to Mrs A that "her doctor had changed the way Surgam was prescribed, but she was still effectively taking two daily".

Dr E commented that he usually prescribes Surgam as two tablets once a day but that it is common practice for many doctors to divide the dosage. The Surgam being dispensed twice a day "can make little difference to efficacy and certainly it is not a toxicity issue. However, the manufacturers of the drug have always intended that the dose be given once a day."

Mr B stated that Mrs C was clearly responsible for the dispensing of Mrs A's Surgam at the relevant times (Friday 27 October 2000 and Friday 17 November 2000). He noted that her name appears on the computer record for these dispensings, which both occurred at approximately 2.30pm. (Mr B provided a copy of the relevant computer records.) Mr B commented that Mrs C was normally the only pharmacist on duty at that time. In response, Mrs C agreed that, on the basis of the information available, it was likely that she was responsible for those dispensings.

Dispensing of Premarin

Dr D prescribed Premarin for Mrs A from 20 June 1995, to relieve menopausal flushing. He explained that, in the meantime, Mrs A had developed rheumatoid arthritis, and Premarin can also assist in long-term reduction of osteoporosis.

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Dr D provided a copy of his records, which confirm that Premarin was prescribed for Mrs A on 2 October 2001 at a dosage of 1.25mg, once daily. Mrs A collected the medication from the pharmacy that day.

Mrs A advised that several days later, when she took the Premarin, she discovered that the "tablet box" clearly stated 0.625mg, but the label stated that they were 1.25mg. She stated:

> "I again saw the manager who could offer no explanation, although he apologised as did the pharmacist who made the error, they were unable to offer any remedy to prevent future mistakes. I feel this is not acceptable. I realise there will always be a margin for errors, which is why I let it go the first time. But three errors in six months does seem to be excessive."

Mr B provided a copy of the pharmacy label record for the medication dispensed, which confirms that Mrs A's medication was labelled, as prescribed by Dr D, at a dosage of 1.25mg.

A copy of the original Premarin prescription was requested from HealthPac. However, HealthPac was not able to provide a copy of the prescription and advised that this prescription was not supplied by the pharmacy. (Mr B commented that he was unable to verify whether Mrs A's Premarin prescription was signed by the dispensing pharmacist, as HealthPac had been unable to locate it.)

Mr B advised that the pharmacist who dispensed this prescription was, as with the other reported dispensing errors, Mrs C. He provided the Premarin incident report of 2 October 2001:

> "Solution/action taken:
>
> Changed medicine to correct strength. Spoke to [Mrs A] about, and assured her this was such an unlikely event for her to receive yet another error. Could only offer full apologies.
>
> General comments, changes to future policy etc
>
> Spoke to [Mrs C] again – she could offer me no explanation. Again, we discussed the issue of more care required. However, other errors by [Mrs C] were absent, and seemed to be confined to [Mrs A]!"

Mr B stated:

> "The prescription concerning incorrect Premarin dose was being given for a repeat of the original prescription. The original was dispensed correctly but the incorrect strength was dispensed on the repeat. The pharmacist concerned was unable to offer an explanation and it was particularly unfortunate that [Mrs A] was again involved in a dispensing error.

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> I can only once again apologise to [Mrs A] for these errors. It seems inconceivable and statistically impossible that one person should receive multiple dispensing errors. It seems equally unlikely that the same pharmacist should be involved in the dispensing errors."

Mrs C confirmed that she was the pharmacist who dispensed Mrs A's Premarin incorrectly on 2 October 2001, and stated: "I accept full responsibility for incorrectly dispensing Mrs A's Premarin on 2 October 2001." She commented:

> "When dispensing [Mrs A's] medication I labelled the medication correctly however supplied the incorrect strength. This was because I retrieved the wrong strength from the shelf. I recall [Mrs A] returned to the pharmacy the next day and although it was [Mr B] she confronted, I approached her and apologised sincerely for the error.
>
> …
>
> I believe the error that occurred on the 2 October 2001 was the result of a momentary lapse in concentration where I failed to correctly check the work I had done. While this can only be cold comfort for [Mrs A], as a result of the aforementioned incident I have reviewed my checking procedures and in my new place of work all scripts are now initialled and double-checked by another pharmacist/technician."

Mrs C subsequently forwarded to my Office a letter of apology addressed to Mrs A, in which she stated:

> "I cannot offer any firm explanation for these errors however, I can reassure you that I have taken all possible measures to ensure such incidents are not repeated. My own personal dispensing procedures along with standard operating procedures at my new place of employment ensure the highest levels of accuracy in dispensing and customer service."

Dr D advised me that the most common effect of a reduced dose of Premarin would be the return of flushing or migraine headaches. Dr D noted that Mrs A was suffering from particularly severe flushing and sweats before starting Premarin in 1995, but had not reported a return of these symptoms following the dispensing error.

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Independent advice to Commissioner

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

"Conclusion:

1 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. There is no evidence to suggest that there was a problem with the overall accuracy of the dispensing at [the pharmacy]. However, because the dispenser cannot be identified then I would have to state that the dispensing of [Mrs A's] medication was not dispensed in accordance with professional standards.

2 There is some discrepancy in the reports of what happened after these dispensing errors; however whether an informal discussion or formal meeting was [held] is not so relevant. It is acceptable standard of practice to review procedures annually which is what appears to happen at [the pharmacy] anyway. However, there does not appear to be conclusive evidence that steps were taken to ensure that all prescriptions were signed after this date. Therefore I cannot state that *all* appropriate steps were taken to ensure further errors would not occur.

3 The standards relating to this complaint involve the practice of pharmacy in a professional and ethical manner i.e. complying with the various excerpts from the Codes of Ethics that applied at the time, and the requirement for a pharmacist to dispense to a high level of accuracy. Quality in Pharmacy Audit procedures require pharmacies to have written operating procedures and for the practice of pharmacy in that pharmacy to reflect those procedures. Because the dispenser cannot be identified in the methotrexate and folic acid dispensings then I would have to state that [the pharmacy] has not met all of the standards relating to this complaint.

4 I have some concerns about the manner in which the incident reporting system at [the pharmacy] is carried out. It is not clear when they are written, who is present when the reports are written and who has access to them.

There has been some inconsistency in labelling for [Mrs A's] Surgam®. However, it would appear that inconsistency in the way the two prescribers have written their prescriptions has added to this.

It was acceptable standard of practice at the time of these dispensing errors to write incident reports. [Mrs C's] comments that the pharmacy did not is of concern.

The evidence provided by [Mr B] and [Mrs C] does not conclusively prove who the dispenser of the methotrexate and folic acid was. In this type of scenario, according to the Pharmaceutical Society Disciplinary precedent, it is more likely that the owner/manager of the pharmacy would be held responsible for the dispensing error itself.

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It is the responsibility of an individual pharmacist to practise pharmacy in a professional and ethical manner. It seems apparent to me, that both [Mr B] and [Mrs C] have not acted in this manner in these instances as they have not ensured that they were initialling their work and hence making the identity of the dispenser clear. In the absence of such behaviour they have failed to ensure that it is clear who was in sole charge at any given time.

Questions asked:

1 From the information available, did [the pharmacy] dispense [Mrs A's] medication in accordance with professional standards?

Prior to April 2001 (old code of ethics):[1]

2.11 'A pharmacist must be responsible for maintaining and supervising a disciplined dispensing procedure that ensures a high standard is achieved.'

3.1 'A pharmacist must act in a manner that is consistent with the good reputation of the profession and must refrain from any conduct that might bring the profession into disrepute or impair the public's confidence in the pharmacy profession.'

3.2 'A pharmacist must maintain high professional standards at all times.'

After April 2001 ('new' code of ethics):

7.1 'The pharmacist must uphold reasonably accepted standards of behaviour both within and outside their professional practice and must refrain from any conduct that might bring the profession into disrepute or impair the public's confidence in the pharmacy profession.'

2.6 'The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly.'

(Excerpt from Pharmaceutical Society of New Zealand Code of Ethics that was in existence prior to June 2001.)

The pharmacist responsible for a dispensed product must always be readily identifiable. Unless there is only one pharmacist on duty at one time and a diary record is sufficient to identify that pharmacist, each prescription must be annotated with the initials of the person dispensing the prescription and the initials of the pharmacist responsible for the finished product.[2]

Prior to the introduction of the 2001 Code of Ethics, in the event of a dispensing mistake and a corresponding inability to identify the dispenser – the owner or manager was likely to be held responsible.[3]

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– [Mr B] states that since they only have one pharmacist on *most* of the time, and the computer keeps a record, it is *normally* obvious who the responsible pharmacist is. It is clear from quotes from the Codes of Ethics that applied at the time of these incidents that it is expected that the dispenser should *always* be identifiable.

– [Mr B] states in his letter dated 15-8-02 that 'the only other pharmacist present at this time was myself, and I know I was not involved in dispensing this prescription. I did very little dispensing when [Mrs C] was present, as I was usually involved in managerial matters re the pharmacy.' This statement does not provide conclusive evidence that [Mrs C] was the dispensing pharmacist.

– [Mr B] has provided a roster to state when [Mrs C] was working. The only time that he has stated that either himself or [Mrs C] were the *only* pharmacist on duty was from 6-8:30pm which was when he was the sole pharmacist present. This does not provide *evidence* of any particular time that [Mrs C] was the only pharmacist present.

It is clear from the excerpts from the Codes of Ethics that applied to the period in which these incidents took place, that the identity of the dispenser should be clear. This statement from [Mr B] does not imply that this is *always* the case in [the pharmacy].

[Mrs C] states in her letter dated 10 October 2002 that it was *normal* for her to leave the premises for a lunch break some time between 12pm and 2pm on Tuesdays and that [Mr B] was the sole pharmacist on duty during this time. The dispensing error is thought to have taken place at 1:06pm and [Mrs C] states that 'this is a time when it is highly unlikely I was on the premises'. These statements do not prove conclusively one way or the other that [Mrs C] was not the dispensing pharmacist.

– [Mr B] states in his letter dated 29 October 2002 that the computer records confirm [Mrs C] to be the dispensing pharmacist. This may not be the case. In many pharmacies it is common practice to enter one person's initials at the beginning of the dispensing day and not change this for each prescription. In addition to this, the person who puts the prescription through the computer is not necessarily the person who does the actual dispensing.

– [Mr B] states that 'since the advent of computerized prescription pricing, annotation of prescriptions in general is far less a requirement.' This has no bearing on whether a prescription should be signed/initialled to identify the dispenser.

– *incident reports indicate that there had been no previous dispensing problems with [Mrs C's] work*

– *incident reports also indicate that staffing levels at the time were good (two pharmacists available plus shop staff)*

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2 From the information available, did [the pharmacy] take appropriate steps to ensure further errors would not occur?

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

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

Steps taken by [the pharmacy]:

– put message in computer to be extra careful in dispensing future scripts "Please double check all prescriptions – special care required" (wording according to incident report dated 27-3-01). This would be in line with acceptable standards of practice.

– [Mr B] states that he held meetings with staff and discussed the dispensing procedure 'with the pharmacist concerned at length'. This would be in line with acceptable standards of practice.

– It would be an acceptable standard of practice to review the dispensing/prescription checking SOP. This SOP appears to be reviewed annually, which is acceptable practice. Also, this SOP is of a relatively standard format and content – if what [the pharmacy does] in practice is accurately reflected in the content of this SOP, then this would be acceptable standard of practice.

NB: [Mrs C] states that in her new place of employment all scripts are now initialled and double-checked. [Mrs C] states that she has reviewed her dispensing and checking procedures and that she is not aware of any other dispensing mistakes since these incidents. This manner of review and 'self audit' would be in line with acceptable standards of practice.

3 What are the relevant standards relating to this complaint and did [the pharmacy] comply with those?

– practise pharmacy in a professional and ethical manner and complying with the requirements of the quality in pharmacy audit.
– dispensing accurately – there is no evidence provided of any previous problems with the quality of dispensing from [the pharmacy]. [Mr B] has documented that there has not been any previous problems with the accuracy of [Mrs C's]

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dispensing. [The pharmacy's] SOP includes suitable requirements for checking of dispensing.
- ensuring that the dispenser is identifiable. The pharmacy's SOP includes the requirements for the dispenser to initial the prescription.
- [The pharmacy's] SOP for dispensing and checking of prescriptions appear to be reviewed annually which is in line with current acceptable standards of practice.

4 Are there any other matters relating to professional standards which you believe to be relevant to this complaint?

- The incident reports from [the pharmacy] are dated 27-3-01, but they refer to incidents that happened after that date e.g. patient returned 28-3-01, patient returned to pharmacy to discuss 8-6-01. It would be more normal practice to date the incident report with the date that it is written.
- All of the incident reports are written in one person's handwriting. It might have been a good idea to get both [Mr B] and [Mrs C] to sign.
- [Mr B] states in his letter dated 16-7-02 that the original dispensing was for 'one capsule twice a day'. If the dispensing labels provided to me cover all of [Mrs A's] Surgam® prescriptions, then this statement is not correct. It would appear that the first label provided to [Mrs A] in actual fact reads 'two capsules daily'.
- It would appear from the information provided that the original prescription for Surgam® was written 'two capsules daily', and the Surgam® manufacturers' data sheet states that the SA caps should be taken as 'one to two capsules daily, to be taken once daily'.[4] It would also appear that the directions on the pharmacy label changed to 'one capsule twice a day' in July 2000, and reverted back to 'two capsules daily' in April 2001. [Mrs A's] GP notes indicate that there has been some variation in the manner in which these prescriptions have been written, with some of the prescriber's notes indicating that on at least two occasions this has been prescribed as 'one capsule twice a day'. Any change in the way that this medicine should be taken should be picked up when the pharmacy counsels the patient – however, as the rheumatologist has pointed out, this is unlikely to cause any toxicity issues for the patient.

[Mrs C] states in her letter dated 10 October 2002 that it was not a requirement for staff of [the pharmacy] to write incident reports when she worked there during 2001. This is not in line with acceptable standards of practice. The first round of 'pharmacy quality audits' had been completed by approximately June 2000. Part of this audit required pharmacies to write incident reports. It is reasonable to assume that [the pharmacy] had been audited and should have had procedures in place to cover this by June 2001.

The Pharmaceutical Society of New Zealand's Code of Ethics 2001 was passed by the Council of the Society on 28th November 2000 and took effect from 1st June 2001. Being a Rule of Council, under section 12(c) of the Pharmacy Act, a wilful breach of any obligation of the Code may form the basis of disciplinary action. Aspects of the Code will also be audited in the Pharmacy Quality Audit of each pharmacy, as compliance with the Code is a requirement of the Pharmacy Services Contract.[5]

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[Mrs C] states that there was no formal meeting to discuss the dispensing error, rather informal discussion. The nature of such a meeting is not so relevant, as in small work places often meetings are of a rather informal nature. However the outcome of this meeting is of concern – or rather the conflicting reports of this outcome. [Mr B] states that [Mrs C] was spoken with at length, and [Mrs C] states that staff could not determine who was at fault. This is of significant importance: before the 2001 Code of Ethics i.e. for the methotrexate and Surgam® dispensings the manager or owner would be likely to be held responsible if the dispenser could not be identified, and if it was not possible to be *sure* exactly who was on the premises at the time.

It is considered to be the responsibility of the owner or manager to ensure that SOPs that outline acceptable standards of practice are in place and that they are *followed* in practice. It seems apparent to me that [Mr B] has not fulfilled his responsibilities in this instance.

It is the responsibility of an individual pharmacist to practise pharmacy in a professional and ethical manner. It seems apparent to me, that both [Mr B] and [Mrs C] have not acted in this manner in these instances as they have not ensured that they were initialling their work and hence making the identity of the dispenser clear.

References

1 Pharmaceutical Society of New Zealand Code of Ethics 2001
2 Pharmaceutical Society of New Zealand Pharmacy Practice Handbook August 1999 Update. Page 20 Section 2.13
3 Conversation held with Carolyn Hooper at Pharmacy Defence Association, 24-02-03
4 Surgam® data sheet Medsafe website http://www.medsafe.govt.nz/DatasheetPage.htm <accessed Jan 03>
5 Interactions. Pharmaceutical Society of New Zealand April 2001

Documents provided:

- HDC background document
- Letter of complaint of 11 October 2001 from [Mrs A] to the Commissioner, marked 'A'
- Investigation letter to [the pharmacy] (dated 14 December 2001) together with investigation letter to pharmacist [Mrs C] (dated 26 March 2002), marked 'B'
- Letters from [Mr B] to the Commissioner dated 13 December 2001, and 25 February, 30 April, 16 July, 15 August, 29 October 2002, marked 'C'
- Letters from [Mrs C] to the Commissioner dated 4 March and 16 October 2002, marked 'D'
- Letter and medical records forwarded by [Dr D], [Mrs A's] general practitioner dated 2 March 2002, marked 'E'
- Letter and medical records from [Dr E], [Mrs A's] rheumatologist, dated 21 December 2001, marked 'F'

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– Letters and dispensing records forwarded by HealthPac dated 18 March and 23 September 2002, marked 'G'."

Response to Provisional Opinion

Mr B and Mrs C both made submissions to my provisional opinion. Their submissions focused on (1) Mrs C's role in the pharmacy; (2) the identity of the dispensing pharmacist; (3) standard operating procedures; and (4) incident reporting systems.

Mrs C's role
Mr B advised that Mrs C was employed as the Dispensary Manager. Mr B was not able to provide a copy of Mrs C's employment contract or position description. Mr B enclosed a copy of the position requirements that were provided to the recruitment agency when Mrs C was employed. The position requirements are for a qualified Dispensary Manager, with a few years' experience. He advised:

> "… [H]er responsibilities were clearly greater than that of a person employed purely as a pharmacist. She was responsible for the day to day operation of the dispensary. Her duties included preparing of prescription batches and electronic claims, stock control, ordering, overseeing the Methadone programme, communicating information to part-time pharmacists, general organization and functioning of the dispensary … including knowledge and application of standard operating procedures and systems that were in place."

Mr B provided further documentation concerning Mrs C's role. In particular, he provided a copy of information outlining pharmacy organisation, which he stated was included in the quality assurance manual at the relevant time (undated). Particularly relevant are the description of the responsibilities of the "Manager/Owner", and the "Pharmacist Dispensary Manager".

> "Manager/Owner
>
> Responsibilities:
>
> *Eg Overall financial planning, marketing, staffing, business plan, staff rosters, wages etc*
>
> Pharmacist Dispensary Manager
>
> Responsibilities:
>
> *Eg Dispensing services, healthcare advice, stock control, methadone programme, general management of dispensary including communication with the other pharmacists/staff, prescription batches, familiarity with quality assurance procedures*

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> *and their implementation, general quality control in the dispensary etc. Responsible to the owner.*"

Mr B stated that Mrs C made sure the other staff knew she was the dispensary manager, actively managed the pharmacy, and made changes as required. Mr B advised that Mrs C had responsibility for quality control in the dispensary, as dispensary manager. Mr B also described Mrs C as the "Pharmacy Manager".

Mr B stated that incidents involving dispensing by pharmacists were primarily investigated by himself. He described his role as "proprietor, and overall management", as well as occasionally dispensing. He stated, "Staff reported either to myself or [Mrs C] depending on the nature of the matter." (The pharmacy organisation document shows that the "Pharmacist Dispensary Manager" and the "Dispensary Technician" are both responsible to the owner. The "Shop Senior" reports to the owner, or in his/her absence to the pharmacist in charge.)

In contrast, Mrs C stated that she was employed as a pharmacist:

> "A job description other than standard pharmacist responsibilities was neither discussed at the interview or commencement of employment. I was employed as pharmacist (often sole pharmacist) but not as a manager with the responsibilities [Mr B] now claims I had, such as quality control and dealing with problems. [Mr B] took this role upon himself, as shown by many scenarios including his dealings with [Mrs A] and handling of the pharmacy audit process."

Mrs C stated that she was not specifically designated as the "charge pharmacist", but that being the only full-time pharmacist at times meant that she was involved in coordinating basic pharmacy tasks. Although Mr B may have viewed her as "managing the dispensary", this was not made clear to other staff. Mrs C considered other pharmacy staff, Mrs G and Ms …, to be just as senior as herself:

> "If managing the dispensary means taking care of basic dispensary functions such as dispensing of prescriptions, ordering and electronic claims, then I did take an active role. However, I did not and was never requested to take responsibility for quality control, standard operating procedures, or managing staff."

Mrs C commented that she had no role in relation to improvements and quality control in the pharmacy, except in relation to her own personal performance. Mr B took responsibility for Mrs A's complaints as Manager.

Dispensing pharmacist on 27 March 2001

The identity of the pharmacist who dispensed Mrs A's folic acid and methotrexate prescriptions on 27 March 2001 is a matter of dispute. Mr B commented that as the methotrexate error was made on the same prescription as the folic acid error it was obvious that the error was made by the same pharmacist, Mrs C. Mrs C agreed that it was likely that the same pharmacist dispensed the entire prescription.

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Mr B disputed Mrs C's comment that it was highly unlikely that she was on the premises at the relevant time (1.06pm), as she was accustomed to take a lunch break around midday. He stated:

> "To the contrary, it was highly likely. [Mrs C] generally only took about 15 minutes break only, and this was most often between 12 and 12.30pm."

In contrast, Mrs C stated that she always took a minimum 30-minute lunch break. She also stated that she rarely took her lunch break so early in the day.

Mr B commented that Ms F always helped him with dispensing when Mrs C was on her lunch break, and that Ms F does not recall this dispensing. (Ms F confirmed in writing that she does not recall dispensing to Mrs A.)

Mrs C confirmed that Mr B primarily confined himself to managerial tasks while she was working, and that there was usually only one pharmacist dispensing. (Mr B stated that 80% of the time there was only one pharmacist on duty.) She stated, "[He] rarely dispensed while I was present", and that Mr B was in practice available only for dispensing as required, such as when she was on her lunch break.

Mrs C also commented that the pharmacy identification was not changed after she had logged onto the pharmacy computer in the morning, and that the person who the computer identifies as the dispensing pharmacist was not necessarily responsible for that dispensing.

Identity of dispensing pharmacist – Surgam
Mr B stated that Mrs C "most definitely dispensed" Mrs A's Surgam at the relevant times (Friday 27 October 2000 and Friday 17 November 2000). He advised that her name appears on the computer record for these dispensings, which both occurred at approximately 2.30pm. He stated that this was not a time at which Mrs C was able to take a break. Mr B stated, "I did not dispense at this time and was usually gone home for the day. Another pharmacist, …, started on Fridays at 3.30pm."

Mrs C agreed that it is likely that she was responsible for the dispensing of Mrs A's Surgam. (Her hours of work were 9am until 6pm.) She stated:

> "Another pharmacist would have started in the afternoon sometime to carry on until 8pm but I cannot recall what time that would have been. It is likely I was responsible for those dispensings."

Standard operating procedures
Mr B emphasised that the pharmacy's standard operating procedures in place at the pharmacy in 2000-2001 stated that the initialling of prescriptions is a requirement. As Dispensary Manager, Mrs C had an obligation to be aware of this requirement. Mr B submitted that Mrs C was responsible for the implementation of the pharmacy's standard operating procedures in her capacity as the Dispensary Manager (as well as being responsible for the errors she made as an individual pharmacist). Mr B stated:

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> "I accept [Mrs C] failed to sign some of the prescriptions under scrutiny. This was a requirement of our dispensary SOP, which she clearly ignored, at least in these incidents. I should have scrutinized her work more closely. She was however, dispensary manager, with previous managerial experience."

In contrast, Mrs C stated that the standard operating procedures were "never shown to me or enforced". Mrs C stated that, to her knowledge, no staff at the pharmacy ever signed prescriptions:

> "As far as I am aware, no staff ever signed prescriptions …. At the time of my employment at the pharmacy it was not my practice to sign prescriptions. In hindsight, I should have and now do sign my prescriptions. [Mr B] was aware of this and never had any complaints, despite this apparently being a requirement in his SOP's."

Mr B stated that the written manuals were "readily available". He also stated that he took proactive steps, at the time of consideration of the errors, to ensure that standard operating procedures were implemented and that prescriptions were signed.

In contrast, Mrs C stated that Mr B was "perfectly aware" of procedures used by staff; if they had not been satisfactory, Mrs C assumed that he would have rectified them.

Incident reporting systems

As previously noted, Mrs C stated that she was unaware of the folic acid incident until 8 June 2001. Mrs C was also not at work when Mrs A returned to discuss the error with her methotrexate on 8 June 2001, and was made aware of the matter the next week on her return. Mrs C advised that at that point there was "informal discussion" about the matter, and no conclusions were drawn as to who was at fault. No review of procedure was recommended.

Mr B refuted Mrs C's comment that no review of procedures occurred following the errors and stated that following the error with the methotrexate he spent considerable time reviewing errors and procedures. Mr B submitted that the incident report represents only a brief summation of the discussions that occurred. He stated that where the incident report records "more care required at final stage of prescription checking" the discussion included reference to the signing of prescriptions according to Standard Operating Procedure requirements.

Mr B commented that discussions about these errors were largely confined to himself and Mrs C. He stated that he did not want to make a "big issue" of the errors as Mrs C was "quite embarrassed by her errors". He stated that as dispensary manager, he "naturally assumed" that Mrs C would take steps herself to correct/address any problems. Mr B stated that "she generally seemed competent in the work place, and preferred to have me at a distance".

Mr B also commented that Mrs C had full access to the reports as they were stored in the working documents manual "which she could have consulted at any time". He stated that he "would be surprised if [Mrs C] had not seen them".

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Mrs C advised that there was no requirement for staff to write incident reports, and that she was "not aware of any staff member making it standard practice to do so". Mrs C also stated that while it was not stipulated as a requirement, "it is an obvious thing to do and I did so as situations arose".

Mr B advised that while it was not a requirement of staff to write full incident reports at that time, it was a requirement for incidents to be reported. Mr B provided a written statement from pharmacist Mrs G. Mrs G advised:

> "I left written notification on [Mr B's] desk informing him of the details of the incident, as is standard practice."

Mr B submitted that the incident reporting process was a relatively recent audit requirement, and that modification was inevitable. Mr B conceded that the reports should have been dated to indicate when they were written, and signed by the parties involved. He noted that the process in place at the time was sufficient to pass audit requirement. Mr B advised that incident reporting procedures have since been improved, with staff now required to write their own reports following incidents, and relevant parties required to date and sign forms.

Mrs A also responded to my provisional opinion. She stated that she did not recall Mr B being involved in the dispensing of her folic acid and methotrexate (but does not know for sure that he was not present that day). Mrs A stated that the first time she met Mr B was when she returned to the pharmacy to discuss the errors on 8 June 2001. She now recalls that previously she had dealt with a female pharmacist, and is "fairly sure" the same person was on duty when she returned in the evening for her folic acid refund.

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.*

Professional Standards

The Pharmaceutical Society Code of Ethics and Professional Standards 1996 (the Code of Ethics) state:

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2.6:

> *"The pharmacist who is responsible for the dispensing of a prescription must verify its authenticity, interpret and evaluate the prescription, ensure that it is correct and complete, assess its suitability for the patient within the limitations of available information, and dispense it correctly."*

2.11:

> *"The pharmacist's responsibilities include:*
>
> *...*
>
> *Ensuring that the label is accurate, unambiguous and clear, contains the relevant information required by the consumer and complies with all the relevant statutory requirements; ..."*

Rule 2.13:

> *"The pharmacist responsible for a dispensed product must always be readily identifiable. Unless there is only one pharmacist on duty at one time and a diary record is sufficient to identify that pharmacist, each prescription must be annotated with the initials of the person dispensing the prescription and the initials of the pharmacist responsible for the finished product."*

Opinion: Breach – Mr B

Dispensing of folic acid and methotrexate
Mrs A was concerned that on 27 March 2001 staff at the pharmacy made two errors with her prescriptions. Mrs A's prescription for 5mg folic acid stated "one tablet daily" instead of "one tablet per week". The pharmacy also dispensed methotrexate 2.5mg as one tablet per week instead of four tablets per week. I am satisfied that, as is agreed by the parties, one pharmacist was responsible for both errors, which occurred on the same prescription.

Under Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) every consumer has the right to have services provided with appropriate care and skill, and in accordance with legal, professional, ethical and other relevant standards. The standards relating to this complaint include the Pharmaceutical Society Code of Ethics and Professional Standards (1996) and the standard operating procedures for the pharmacy.

These inter-linking professional standards state that the identity of the dispenser must be ascertainable. The underlying rationale is that root cause analysis of any pharmacy error will be significantly impeded without identification of the dispensing pharmacist.

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The Code of Ethics and Professional Standards 1996 (the Code of Ethics 1996) was applicable in 2000 and early 2001 (superseded by the new Code of Ethics from 1 June 2001). Rule 2.13 of the Code of Ethics (1996) stated:

> "The pharmacist responsible for a dispensed product must always be readily identifiable. Unless there is only one pharmacist on duty at one time and a diary record is sufficient to identify that pharmacist, each prescription must be annotated with the initials of the person dispensing the prescription and the initials of the pharmacist responsible for the finished product."

Standard operating procedures are required to comply with the Code of Ethics (1996). The pharmacy's standard operating procedure stated:

> "When dispensing the prescription the pharmacist shall:
> Annotate prescription in accordance with contract requirements, initial prescription and assemble prescription items, with receipt, check against prescription and store in alphabetical order on the shelf to await collection."[1]

Identity of dispensing pharmacist

The pharmacist who bears overall responsibility for the dispensing of medication is the dispensing pharmacist. It is unclear who dispensed Mrs A's folic acid and methotrexate prescriptions on 27 March 2001 as the prescriptions were not signed. It is not disputed that the prescriptions were dispensed by either Mr B or Mrs C.

Pharmacy records, including incident reports and computer records, show that the dispensing pharmacist was Mrs C. However, Mrs C disputes that she was the dispensing pharmacist. Mrs C, Mr B and a pharmacy technician were available for dispensing, if required, at that time. Mrs C stated that the dispensing pharmacist is not always responsible for the initial loading of data and labels into the computer. Further, she commented that subsequent discussion (after the errors were identified) did not determine the identity of the dispensing pharmacist. She submits that the incident reports written by Mr B are inaccurate and that she had not seen the reports until recently.

Although the incident reports state that the dispensing pharmacist was Mrs C, I am not satisfied that they provide conclusive evidence as to who dispensed the medication. The lack of detail, including a report date and annotation, significantly reduces their reliability. Mr B commented that Mrs C had full access to the reports, as they were stored in the working documents manual "which she could have consulted at any time". He stated that he "would be surprised if [Mrs C] had not seen them". Mrs C's statement that she did not see the reports is credible, owing to the lack of signature. In these circumstances, I accept that the reports may not be accurate. Furthermore, I note that the discussion content of the methotrexate report does not identify responsibility, although Mrs C is recorded as the dispensing pharmacist in the heading.

[1] Refer Appendix 1

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My advisor considered that the computer records do not provide conclusive evidence of the identity of the dispensing pharmacist. She commented:

> "In many pharmacies it is common practice to enter one person's initials at the beginning of the dispensing day and not change this for each prescription. In addition to this, the person who puts the prescription through the computer is not necessarily the person who does the actual dispensing."

It is common ground, therefore, that the computer records do not accurately record involvement of staff in the transaction. In particular, I note Mrs G's comment that the pharmacist's identification is not changed throughout the day (on a Wednesday). Mrs C also commented that the pharmacy identification was not changed after she had logged onto the pharmacy computer in the morning. In my opinion, although the computer records state that Mrs C was the staff member responsible for the transaction, they do not provide conclusive evidence that she was the dispensing pharmacist. Mr B was also on the premises and available to dispense.

Mr B stated that he did very little dispensing when Mrs C was present, as he was usually involved in managerial matters. Mrs C confirmed that Mr B rarely dispensed when she was present (she was a full-time employee), and usually only one pharmacist dispensed at any time.

I note this particular dispensing occurred at 1.06pm. The information provided shows that Mrs C usually had her lunch break some time after midday, but did not have a set time for a break. I therefore accept Mrs C's submission that the dispensing *may* have occurred when she was on a lunch break. I do not consider Ms F's statement that she does not recall dispensing to Mrs A to have any particular evidential value, more than two years after the incident at issue.

Similarly, I do not consider that Mrs A's general recollection that she dealt with a female pharmacist provides useful clarification, in circumstances when Mrs C was clearly not the only female staff member who Mrs A may have dealt with that day.

Although it is clear that Mrs C was responsible for the majority of dispensing that day, I am not able to establish that she dispensed Mrs A's methotrexate and folic acid prescription.

Accordingly, I am unable to resolve the conflict of evidence as to the identity of the dispensing pharmacist. Neither the incident reports nor the computer records provide conclusive evidence. It is regrettable that the prescriptions were not signed by the dispensing pharmacist, as is required, as this would have removed any doubt as to the identity of the dispenser.

Dispensing error accountability

In the absence of an identified dispenser, the core issue to be determined in this case is how the dispensing error may have occurred. This involves consideration of whether there were appropriate systems in place to prevent the errors occurring. It is therefore necessary to establish what systems were in place, and the scope of accountability for those systems.

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The specific issues that arise in this case are (1) accountability when the dispensing pharmacist has not been identified; (2) individual responsibility in relation to systems; (3) the adequacy of the implementation of those systems; and (4) the incident reporting system.

Responsibility when dispensing pharmacist not identified
Mrs A's folic acid and methotrexate prescriptions were not signed by the dispensing pharmacist. Mrs C stated that it was not her practice at that time to sign prescriptions. I note that the information provided tends to support this conclusion. Mrs C also stated that, as far as she is aware, no staff ever signed prescriptions.

Professional standards, as stipulated by Quality Standards for Pharmacy in New Zealand, the Code of Ethics, and the standard operating procedure for the pharmacy, state that prescriptions must be signed by the dispensing pharmacist or otherwise be identifiable.

Rule 2.13 of the applicable Code of Ethics 1996 stated that the dispensing pharmacist must be identifiable. The exception to signing of prescriptions is when only one pharmacist is on duty, *and* where a diary entry (for example, staff roster) is sufficient to identify that person. This exception does not apply when the dispenser is not otherwise identifiable.

My advisor commented:

> "It is the responsibility of an individual pharmacist to practise pharmacy in a professional and ethical manner. It seems apparent to me, that both [Mr B] and [Mrs C] have not acted in this manner in these instances as they have not ensured that they were initialling their work and hence making the identity of the dispenser clear."

My advisor commented that prior to the introduction of the 2001 Code of Ethics, in the event of a dispensing mistake and a corresponding inability to identify the dispenser, the owner or manager was likely to be held responsible:

> "It is considered to be the responsibility of the owner or manager to ensure that SOPs (standard operating procedures) that outline acceptable standards of practice are in place and that they are *followed* in practice. It seems apparent to me that [Mr B] has not fulfilled his responsibilities in this instance."

Quality Standards for Pharmacy in New Zealand state:

> "1.1d The owner/manager ensures that all regulations covering the operation of the pharmacy are complied with."

Mr B has confirmed that he is the owner (as well as the director and joint shareholder) of the pharmacy.

Responsibility for systems
There is a conflict of evidence concerning the respective roles of Mr B and Mrs C within the pharmacy. Mr B claimed that Mrs C was the "Dispensary Manager". In his final submission, Mr B also referred to her as the "Pharmacy Manager".

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Mr B submitted that responsibility for dispensing systems lay with Mrs C. He accepted that he had primary responsibility for the investigation of incidents.

In my opinion, Mrs C had full responsibility for the implementation of standard operating procedures in her own practice, and as a senior pharmacist. I do not accept Mr B's submission that Mrs C had a pharmacy managerial role, which included complete responsibility for the implementation of standard operating procedures at the pharmacy. This submission is not supported by the information provided. Mrs C was the only full-time pharmacist, and has confirmed that she undertook responsibilities in relation to basic dispensary functions. I do not consider that the pharmacy organisation documentation supplied by Mr B provides sufficient clarification of the respective roles or necessarily reflects the pharmacy's practice at that time. I accept Mrs C's submission that her role is better defined as "pharmacist", rather than "manager". In particular, responsibility for the investigation of incidents and staff reporting primarily lay with Mr B.

My advisor emphasised that under the Code of Ethics at the time, the identity of the dispenser should always be clear. This was not the case at the pharmacy. Although Mrs C was the only full-time pharmacist at the pharmacy, there were many other occasions when other staff may have been responsible for dispensing. The pharmacy's Operating Systems required that prescriptions were signed. This did not occur on any of the prescriptions under scrutiny, and Mrs C has admitted that she did not sign her prescriptions. As owner, Mr B had an obligation, to the best of his abilities, to ensure that staff were aware of, and followed, the pharmacy operating systems.

Implementation of systems
Mr B provided no evidence that he took proactive steps at the time to ensure scripts were signed, or that the standard operating systems were implemented, before or after the errors occurred. Mr B stated that he assumed that Mrs C would take steps herself to address any concerns arising from the incident:

> "I accept [Mrs C] failed to sign some of the prescriptions under scrutiny. This was a requirement of our dispensary SOP, which she clearly ignored, at least in these incidents. I should have scrutinized her work more closely. She was however, dispensary manager, with previous managerial experience."

Mrs C stated that the standard operating procedures were "never shown to me or enforced". Mr B was "perfectly aware" that staff did not sign prescriptions "despite this apparently being a requirement in his SOP's".

These two statements indicate that Mr B did not proactively implement the standard operating procedures in relation to Mrs C's work. While Mr B was entitled to expect a high standard of dispensing from Mrs C, he also had a specific obligation to draw the standard operating procedure requirements to Mrs C's attention and to ensure that she was implementing those requirements in practice, particularly when concerns arose over her dispensing.

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Incident reporting system
My advisor stated that it was acceptable practice at the time of these dispensing errors to hold meetings with staff, to write incident reports, and to place a message in computer records requesting staff to be extra careful in dispensing future scripts. My advisor was concerned at the quality of the incident reports, which are not dated or signed. The reports are headed 27 March but they refer to the incidents reported when Mrs A returned to the pharmacy on 28 March and 8 June.

Mr B advised that he has since stressed to pharmacists the need to sign prescriptions, particularly when more than one person is involved in dispensing. Mr B submitted that the incident report represents only a brief summation of the discussions and that the discussion included reference to the signing of prescriptions according to Standard Operating Procedure requirements, as indicated by "prescription checking". However, at the time of the reporting of the errors, there is no clear documentation that shows discussion of the lack of signing of Mrs A's scripts. Therefore, I am not able to conclude that such discussion occurred.

It was Mr B's responsibility as pharmacy manager to take steps to analyse the errors and ensure that pharmacy systems were reviewed to avoid a repetition of the errors. This should have involved accurate incident reporting and relevant, timely discussions with staff. There is some dispute as to whether this took place. There is no indication that Mrs C changed her practice with regard to signing of prescriptions as a result of the incident reporting process, or that any particular measures (such as an audit of her prescriptions) were put in place to check or ensure that Mrs C did indeed sign her prescriptions.

In my opinion, Mr B breached Rights 4(1) and (2) of the Code by not ensuring that there was a means of establishing the identity of the dispensing pharmacist for Mrs A's prescriptions, through the signing of the prescriptions by dispensing staff, and by failing to take appropriate steps to minimise the risk of repetition of the errors.

Opinion: Breach – Mrs C

Dispensing of Premarin
Under Rights 4(1) and 4(2) of the Code every consumer has the right to have services provided with reasonable care and skill, and in accordance with legal, professional, ethical and other relevant standards.

The Code of Ethics and Professional Standards 2001 at 2.6 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."

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The standard operating procedure at the pharmacy states that the dispensing pharmacist shall "check the strength and quantity of the medication against the prescription, and check the expiring date". Signing of the prescription provides verification that the checking process has occurred.

Mrs C admitted full responsibility for the error in dispensing Mrs A's Premarin on 2 October 2001. Mrs C labelled the medication correctly but she supplied the incorrect strength. The error apparently occurred because Mrs C did not check her dispensing correctly, and was the result of a momentary lapse of concentration.

Mrs C advised me that she did not sign her prescriptions at that time. Therefore, I conclude, on the balance of probabilities, that Mrs C did not sign Mrs A's Premarin prescription.

Mrs C assured me that since this incident she has reviewed her checking procedures, and is not aware of any other dispensing mistakes. Mrs C forwarded to my Office a letter of apology addressed to Mrs A.

My advisor considered the steps taken by Mrs C to review her practice and commented that her "self-audit" was in accordance with acceptable standards of practice. Nonetheless, in incorrectly dispensing and not signing Mrs A's medication on 2 October 2001, Mrs C breached Rights 4(1) and (2) of the Code.

Labelling/dispensing of Surgam
A dispensing pharmacist is required to demonstrate a high standard of accuracy when dispensing medication. This includes the correct labelling of prescription instructions.

In relation to the labelling of prescriptions, the standard operating procedure at the pharmacy stated:

> "… Labels should be prepared in accordance with the recommendations of the pharmaceutical society council, and [the dispensing pharmacist] should ensure that labels are prepared with the intentions of the prescriber properly represented.
>
> …
>
> [The pharmacist shall] check the labeling against the prescription."

The requirements of the Pharmaceutical Society are stated in the Code of Ethics (1996), which stated, at 2.11:

> "The pharmacist's responsibilities include:
>
> …
>
> Ensuring that the label is accurate, unambiguous and clear, contains the relevant information required by the consumer and complies with all the relevant statutory requirements; …"

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In my opinion, an important component of accurate and responsible dispensing is checking the label instructions on each new prescription, even if a patient has previously been prescribed the medication. Mr B commented that checking with the prescribing doctor and/or the patient to obtain clarification in these circumstances is a "common sense step which any careful pharmacist should have performed".

This error highlights the need for staff to adhere to the pharmacy's standard operating procedure requirements of ensuring the prescriber's instructions are properly represented, including instructions on how a medicine should be taken. Checks must occur with each new prescription received by a pharmacy, even if the medicine has been previously prescribed. This is particularly important when prescriptions are presented as repeats. Repeats are generated automatically and the opportunity to check may be reduced. If there is any doubt, the prescription should be checked directly with the prescriber.

My advisor stated:

> "Any change in the way that this medicine should be taken should be picked up when the pharmacy counsels the patient – however, as the rheumatologist has pointed out, this is unlikely to cause any toxicity issues for the patient."

While the evidence suggests Mr B may not have taken the opportunity to draw pharmacy operating procedures to Mrs C's attention, the correct labelling of prescriptions is a matter of elementary pharmacist competence.

There was an error in the label instructions provided to Mrs A on 17 November 2000. The prescription read "Surgam, two capsules once daily". The pharmacy provided the prescription to be taken as a split dosage, one capsule twice daily.

It is unclear whether a similar error also occurred on the 27 October prescription, as the original script has been mislaid. The instruction on the pharmacy label was "one capsule twice daily", which is inconsistent with how Dr D said he prescribed Surgam.

Mrs A's Surgam script of 17 November 2000 was not initialled. Mrs C has advised that it was not practice to initial prescriptions at that time. I consider it most likely that the other Surgam script under consideration was also not initialled.

Mr B stated that Mrs C was clearly responsible for the dispensing of Mrs A's Surgam at the relevant times (Friday 27 October 2000 and Friday 17 November 2000). Her name appears on the computer record. Both dispensings occurred at approximately 2.30pm. Mr B stated:

> "I did not dispense at this time and was usually gone home for the day. Another pharmacist, …, started on Fridays at 3.30pm."

Mrs C agreed that it is likely that she was responsible for the dispensing of Mrs A's Surgam. (Her hours of work that day would have been 9am until 6pm.) She stated:

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> "Another pharmacist would have started in the afternoon sometime to carry on until 8pm but I cannot recall what time that would have been. It is likely I was responsible for those dispensings."

In these circumstances, I consider it established, on the balance of probabilities, that Mrs C dispensed Mrs A's Surgam on Friday 27 October 2000 and Friday 17 November 2000.

Accordingly, in my opinion, Mrs C breached Rights 4(1) and (2) of the Code by failing to initial, and in failing to correctly label, Mrs A's Surgam prescriptions.

Signing of prescriptions
Under Rights 4(1) and 4(2) of the Code every consumer has the right to have services provided with appropriate care and skill, and in accordance with legal, professional, ethical and other relevant standards. The standards relating to this complaint include the Pharmaceutical Society Code of Ethics and Professional Standards (1996); standard operating procedures for the pharmacy; and Quality Standards for Pharmacy in New Zealand.

The Code of Ethics and Professional Standards 1996 (the Code of Ethics) was applicable in 2000 and early 2001 (superseded by the new Code of Ethics from 1 June 2001). Rule 2.13 of the Code of Ethics stated:

> "The pharmacist responsible for a dispensed product must always be readily identifiable. Unless there is only one pharmacist on duty at one time and a diary record is sufficient to identify that pharmacist, each prescription must be annotated with the initials of the person dispensing the prescription and the initials of the pharmacist responsible for the finished product."

The current Code of Ethics (which became effective after 1 June 2001) also stipulates that the dispenser must be identifiable. The Code states:

> "Rule 3.9 Identifiers. The charge pharmacist must ensure that the identity of the pharmacist who has taken final responsibility for a dispensed prescription is able to be determined."

The standard operating procedures at the pharmacy stated:

> "When dispensing the medication the pharmacist shall:
>
> Annotate the prescription in accordance with contract requirement, initial prescription and assemble prescription items, with receipt, check against prescription and store in alphabetical order on the shelf to await collection."

Mrs A's prescription for 5mg folic acid stated "one tablet daily" instead of "one tablet per week". The pharmacy also dispensed methotrexate 2.5mg as one tablet per week instead of four tablets per week. Neither of these was signed.

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An error also occurred with the labelling of Mrs A's Surgam medication (on 17 November 2000 and 27 October 2000), and her Premarin medication of 2 October 2001 was dispensed incorrectly. The prescription obtained was not signed.

The dispenser for each of these prescriptions has not been clearly identified except for the Premarin, which Mrs C recalled dispensing. Mrs C has stated that she was likely to have dispensed the Surgam, due to the time of day and date of dispensing. Mrs C may also have been responsible for the incorrect dispensing of folic acid and methotrexate.

Under the Codes of Ethics, a pharmacist must be identifiable as the dispenser. This generally requires the signing of prescriptions. the pharmacy standard operating procedures also required pharmacists to sign prescriptions.

While Mrs C was often the sole charge pharmacist, there were other pharmacists, including Mr B and Mrs G, who may have dispensed at any given time. In my view, the most effective way of meeting the obligations of the applicable standards was to sign prescriptions. Mrs C stated that, at the time of her employment, she did not sign her prescriptions, nor did other staff, to her knowledge. This created a situation whereby the dispenser could not be accurately identified.

Mr B, as manager, had an obligation to ensure his staff were aware of, and followed, the standard operating procedures of the pharmacy. In my opinion Mrs C had a corresponding obligation to inform herself about the relevant standard operating procedures at the pharmacy, particularly in circumstances where the dispenser was not always clear. (Mrs C was aware that the computer record did not provide a reliable identification.) It is not sufficient to state that these procedures were not drawn to her attention.

Therefore, in failing to ascertain the relevant standard operating procedures, and not signing her prescriptions, Mrs C breached Rights 4(1) and (2) of the Code.

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Opinion: Breach – The Pharmacy

My investigation highlighted three systems failures at the pharmacy: (1) failure to identify dispensing staff; (2) checking of labels on prescriptions; and (3) lack of consistency and accuracy in the reporting and investigation of incidents.

Identity of dispensing staff
There was a failure to properly identify the dispensing pharmacist for the prescriptions under scrutiny in my investigation. Mrs C has since advised that it was not her practice to sign prescriptions. She stated that she was not certain that other staff signed prescriptions.

The only script for which the dispensing pharmacist could be readily identified was the Premarin script of 2 October 2001, as Mrs C recalled this error. It is not clear whether other pharmacy staff signed their prescriptions when dispensing. There is no specific evidence to suggest that at the time of the errors, or subsequently, any steps were put in place to ensure future prescriptions would be correctly signed by Mrs C, or other pharmacy staff. However, the signing of prescriptions was a requirement of the pharmacy standard operating procedure.

In addition, there was a conflict of evidence as to who was responsible for management of the dispensary, and thus for minimising the risk of future errors. It appears that the lack of clarity of roles and responsibilities contributed to these errors.

Labelling checks
My investigation also showed that Mrs C failed to carefully check the instructions on Mrs A's 17 November 2000 Surgam script, and may also not have checked the prescription of 27 October 2000.

Mrs A was informed by Mr B that the error had occurred because her doctor had changed the way the medication was prescribed. However, my investigation showed that the dosage regime at that time was, in fact, incorrect. It appears likely that Dr D did not change the way it was prescribed but that it was prescribed in a different manner once only, by Dr H on 26 July 2000, although there was insufficient evidence to make a conclusive determination.

While the error was one that did not cause Mrs A any harm, this was fortuitous. Mr B advised me that the dispensing pharmacist should have checked with the prescribing doctor or with Mrs A, rather than assuming the dosage regime would continue. It is also important to conduct the required checks for all prescriptions. In these circumstances, I concluded that Mr B did not have a specific obligation as manager to ensure Mrs C was carrying out labelling requirements, prior to any errors being detected. Nevertheless, the information gathered suggests there may have been a systems failure in relation to the checking of labelling.

Incident reporting
The pharmacy is required to have systems in place that enable dispensing staff to fulfil their duty of care, and to take appropriate action when a labelling error occurs, to minimise the risk of future errors. This requires careful analysis of errors and review of the

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pharmacy system. There needs to be accurate incident reporting and relevant, timely discussions with staff.

My investigation revealed that the quality of the incident reports, and the investigation into the incidents, was poor. It is essential that incident reports are dated and accurately set out specific actions taken to ensure that the risk of repeat incidents is minimised. It may be advisable to collate a more detailed report following the initial report. Mr B has since stated that this did in fact occur. However, the incident reports he provided do not show this level of detail.

I do not accept Mr B's submission, made at a late stage, that detailed discussion in fact occurred, but was not fully recorded in the report. Furthermore, I consider an incident report that does not record the details of a particular incident is of little use to other staff not directly involved in an incident, or even to those involved, when time has passed and memory of the detail discussed has faded. It appears that the key issue of the lack of signing by the dispensing pharmacist, and the checking of labels, was not considered as part of the incident reporting process.

Furthermore, and crucial to this investigation, the incident reports cannot be verified. Mr B was not present when Mrs A returned to the pharmacy to report the error with the folic acid. In the absence of a date for the reports it is not clear when they were written, nor whether they were seen by Mrs C. Mrs C denies having seen the incident reports. Mr B has stated that he "would be surprised if Mrs C had not seen them". I accept that Mrs C may not have seen them.

Mrs C stated that, at the time, there was no requirement for staff to individually fill out incident reports. She further commented that although it was not a requirement, "however it is an obvious thing to do and I did so as situations arose". I note that written notification of the folic acid incident was provided to Mr B by Mrs G.

Mr B submitted that the incident reporting process was a relatively recent audit requirement, and that modification was inevitable. Mr B conceded that the reports should have been dated, to indicate when they were written, and signed by the parties involved. He noted that the process in place at the time was sufficient to pass audit requirement. Mr B advised that incident reporting procedures have since been improved, with staff now required to write their own reports following incidents, with forms dated and signed by the relevant parties.

However, while I note that improvements have since occurred, it remains my view that the quality of the incident reports, and the investigation into the incidents, was inadequate in this case.

I accept that the pharmacy's standard operating procedures were adequate, as indicated by my advisor. However, the number of errors with Mrs A's prescriptions should have alerted the pharmacy that, although adequate operating procedures were in place, they were not functioning effectively. This should have prompted a review. There should have been a thorough incident analysis followed by a review of dispensing practice, with particular emphasis on signing of scripts and the checking of prescription labels. Unfortunately, the

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quality of incident reporting and investigation of these incidents was such that the full extent of the systemic failures was not highlighted.

In my opinion, the pharmacy Limited breached Rights 4(1) and 4(2) of the Code by failing to ensure that the systems in place were operating effectively to minimise the risk of repeat errors.

Actions

I recommend that the pharmacy and Mr B take the following actions:

- Apologise to Mrs A for their breaches of the Code. The apology is to be sent to the Commissioner's Office and will be forwarded to Mrs A.
- Review standard operating procedures requirements in relation to the dispensing of prescriptions and ensure that the dispensary manager is identified and that all staff are aware of the standard operating procedures, with particular reference to the prescription checking process, the labelling of prescriptions, and the signing of prescriptions.
- Review incident reporting procedures.

I recommend that Mrs C take the following actions:

- Review her dispensing practice, with particular reference to the requirement for the signing of prescriptions and the checking of labels.

Further actions

- A copy of this report will be forwarded to the Pharmaceutical Society of New Zealand.
- A copy of this report will be forwarded to Medsafe, Ministry of Health, to assist with the next audit of the pharmacy.
- A copy of this report, with all identifying details removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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APPENDIX 1

8.25 STANDARD OPERATING PROCEDURE [THE PHARMACY]

SUBJECT: DISPENSING

PURPOSE: ACCURATE AND EFFICIENT PRESCRIPTION PROVISION IN COMPLIANCE WITH THE HFA CONTRACT

PROCEDURE:

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

- Ensure its completeness regarding patient details, legibility, contact requirements (looking at medicine availability etc), legal requirements.
- Determine its priority for dispensing

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

- Mentally review the suitability of the prescribed medicine with regard to its therapeutic use, adverse effects, contraindications, dosage and possible interactions with other medication or food.
- Check acquired medication history for consistency of treatment, interactions and evidence of misuse e.g. calling for repeats too early or too late. Check also for compliance with HBL prescription controls and requirements.
- Select a product which best serves the interest of the patient ie. maintains continuity of treatment and bioavailability and complies with the Preferred Supplier Brand scheme of Pharmac/HFA – see SOP 8.28 Generic Substitution Policy.
- Key relevant data into the computer and produce labels which are legible and complete in the information which they provide. Labels should be prepared in accordance with the recommendations of the Pharmaceutical Society Council, and should ensure that the intentions of the prescriber are properly represented.
- Check the strength and quantity of the medicine against the prescription and check the expiry date.
- Dispense product in a suitable container, and affix the label so that directions area clean, and if using an original container, no important information on the label is obscured. Affix Cautionary & Advisory labels if required.

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- Check the labelling against the prescription.

- If a calculation is involved, this is recheck[ed] and if possible check[ed] by another pharmacist.

- If unable to supply the full amount ordered, use the computer "owe" function to indicate this on the label. Generate a "balance owing" label and file beside the computer. Package up balance of prescription when new stock arrives (see also Working Documents 8.6).

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

- On return of the patient (or patient's agent) check the items against the receipt label and hand them over to the patient (or patient's agent). Any prescription charges will be calculated using guidelines in HFA contact. The patient is advised if any approved substitutions have been made.

- Eligible members of a family unit are identified and linked in the computer. Prescription numbers from other pharmacies are added to the record. Evidence for these is obtained from customer receipts or by contacting the relevant pharmacy(ies).

A record is maintained of prescription numbers for each individual or family in accordance with the Prescription Subsidy Card scheme.

As soon as 20 items are recorded an exemption form and card are completed. The form is signed by the patient and pharmacist and stored in the dispensary. The card is signed and stamped on the back and handed to the patient as required by HBL protocol.

- The pharmacy takes responsibility for providing its customers with sufficient information so that they derive maximum therapeutic benefit and encounter minimum untoward side effects from their medication. The Pharmacy Guild statement (QA) Manual 6.3a) is used as a guide on patient counselling.

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

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

- Prescriptions for delivery will be packaged with an invoice slip and receipt label. Delivery will be undertaken by pharmacy staff, according to appropriate standard procedures see 8.5.

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- Repeat prescriptions are generated by the computer and dispensed as described above.

PRACTITIONERS SUPPLY ORDERS:

The order is checked against the requirements of HBL ie the product and quantities are permissible under the Pharmaceutical Schedule and the order is signed and dated by the practitioner.

Labels are prepared in the normal manner and the products dispensed. The order form is stamped, annotated and stored for claiming through HBL.

BULK SUPPLY ORDER:

Check that the bulk supply order comes from an approved HFA institution. The order is checked against the requirements of HBL ie the product and quantities are permissible under the Pharmaceutical Schedule and the order is signed and dated by the designated qualified person.

Labels are prepared in the normal manner and the products dispensed. The order form is stamped, annotated and stored for claiming through HBL.

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