Pharmacists, Mr C and Mr F

A Pharmacy

A Report by the

Health and Disability Commissioner

(Case 01HDC11914)

Health and Disability Commissioner
Te Tiriwa Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mr and Mrs A	Complainants / Consumer's parents
Dr B	Consumer's Psychiatrist
Mr C	Provider / Pharmacist
Ms D	Clinical Psychologist, Child and Adolescent Mental Health Centre
Mr E	Locum Pharmacist
Mr F	Provider / Pharmacist
Mr G	Clinical Psychologist, Child and Adolescent Mental Health Centre
A Pharmacy	Provider

Complaint

On 15 October 2001, the Commissioner received a complaint from Mr and Mrs A about services provided to their daughter, Ms A, by a pharmacy. The complaint was summarised as follows:

- *On 8 August 2001 the pharmacy dispensed Serzone instead of the prescribed quetiapine (Seroquel) to Ms A.*
- *On 15 September 2001 the pharmacist incorrectly advised that Seroquel and Serzone were essentially the same medicine.*
- *It was inappropriate for the pharmacist to advise that Ms A should take 400mg of quetiapine on the night he visited her home.*

An investigation was commenced on 8 November 2001.

Information reviewed

- Information from the family
- Information from the pharmacy
- Relevant medical records and information from Dr B
- Relevant medical records and information from the Child and Adolescent Mental Health Centre
- Accident Compensation Corporation file concerning Ms A's claim for medical misadventure

Independent expert advice was obtained from pharmacist Mrs Andrea Shirtcliffe.

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

Information gathered during investigation

Ms A has a diagnosis of schizophrenia. She was 18 years old at the time of the events complained about.

Until August 2001, Ms A had been progressing well on the anti-psychotic medication risperidone. She was stable and her thoughts were not disordered. However, Ms A experienced unacceptable side effects from the risperidone, including galactorrhoea (lactation) and weight gain. Ms A's psychiatrist, Dr B, in consultation with Ms A and her family, decided to try Ms A on a different anti-psychotic medication, quetiapine. The brand name for quetiapine is Seroquel.

On 3 August 2001, Dr B wrote Ms A a prescription for a month's supply of quetiapine (120 x 100mg tablets), one tablet to be taken in the morning and three at night. Dr B wrote out the prescription using the generic name "quetiapine", and provided Ms A with directions for tapering the risperidone and gradually increasing the quetiapine over a period of several weeks. The prescription included two repeats.

On 8 August 2001, Ms A's mother, Mrs A, took the prescription to the pharmacy. Pharmacist Mr C dispensed the medication, entered the details of the prescription into the computer records, and printed a label for 120 100mg quetiapine tablets. He gave Mrs A a receipt for quetiapine.

Following a session with Ms A at the Child and Adolescent Mental Health Centre (the Centre) on 30 August 2001, clinical psychologist Ms D recorded in the clinical notes:

> "[Ms A] reported that while she thought her new medication was working well, it made her feel very restless. She also presented as quite 'racey', in terms of her speech being rapid and talking about lots of different ideas one after the other, in addition she appeared to 'jiggle' her leg a lot and play with her fingers, tapping on her leg, etc. I noted this and [Ms A] admitted she probably was a bit more 'frantic' than usual and that this could be due to the medication."

On 7 September 2001, Ms A had a medical review with Dr B, who made the following entry in the clinical records:

> "[Ms A] reports feeling 200% better on the quetiapine. She is not getting any voices at all, she is more energetic and has 'lost heaps of weight'. The galactorrhoea has gone. Unfortunately she has what sounds like akathisia [drug-induced restlessness] which is causing motor agitation, some internal restlessness, and restless sleep. I have suggested that she try reducing the quetiapine to 350mg daily and have added in diphenhydramine [a sedative] 50mg nocte [at night] to help with the nocturnal akathisia. … On examination [Ms A] is no longer parkinsonised [exhibiting drug-induced symptoms similar to Parkinson's disease] and, although perhaps a bit 'speeded up', she is neither irritable nor agitated."

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

On Sunday 16 September 2001, Mrs A returned to the pharmacy for a repeat of the quetiapine, taking with her the empty packet from the first month's supply. The pharmacy's locum pharmacist, Mr E, told Mrs A that there was no quetiapine in stock, but that he would try to obtain the medication and would take it to her home later in the day.

After Mrs A left the pharmacy, Mr E noticed that the quetiapine label was attached not to a Seroquel packet but to a Serzone packet. Serzone is the brand name for nefazodone, an anti-depressant. Mr E realised that Ms A had been dispensed Serzone, an anti-depressant, instead of Seroquel, the anti-psychotic she had been prescribed. Mr E immediately contacted the pharmacy's co-owner and pharmacist, Mr F. Mr F went straight to the pharmacy, checked the original prescription, and confirmed that Serzone 100mg had been dispensed instead of Seroquel 100mg.

Mr F then drove to the family's home, but was unable to contact anyone. He returned later in the day and found Mrs A at home. He advised the family that an error had been made and that, although the medicine label on the packet and the receipt for the drug dispensed on 8 August 2001 was for quetiapine (Seroquel), the actual drug dispensed was Serzone.

The following day, Monday 17 September 2001, Mr F telephoned Dr B to advise her of the error. He also telephoned Mrs A to explain and apologise for the error.

Information given about Seroquel and Serzone
There is a conflict in the evidence about the information Mr F gave the family regarding Seroquel and Serzone.

According to Mr and Mrs A, Mr F misled them into believing that Seroquel and Serzone were essentially the same medication, the only difference being the brand name. Mr and Mrs A said Mr F made a "curious" comment ("She's alright isn't she?") and said that he would telephone Dr B to discuss the situation the following day.

Mr F strongly denied having said that Seroquel and Serzone were equivalent medications. Through his lawyer, Mr F stated that he advised Mrs A that the two drugs were similar in that they are both used to treat psychiatric conditions. He wanted to reassure Mrs A. His lawyer advised me:

> "In saying this, [Mr F] was anxious to allay any fears that the medicine dispensed was in a class of medicines such as diabetic, blood pressure or anti-coagulant treatment which have narrow therapeutic indices. [Mr F] acknowledges that what he said could have been misinterpreted by [Mrs A], but it was not his intention to mislead her at all."

On Monday 17 September 2001, the Centre's clinical psychologist, Mr G, telephoned Ms A's father to offer the family support following the dispensing error. Mr G recorded in Ms A's clinical notes:

> "According to [Mr A], the pharmacist turned up last night and had told the family that the medication is the same but with a different brand name. I explained that my understanding was that [Ms A] had been given the wrong medication altogether."

Commissioner's finding of fact
As I am faced with conflicting evidence concerning the information Mr F gave the family regarding Seroquel and Serzone, I am required to make a finding of fact.

I am satisfied that the evidence provided by Mr and Mrs A – that Mr F told them the two medications were essentially the same – is credible for the following reasons. First, it is corroborated by Mr G's note, written the following day and stating that the family was told the medications were "the same but with a different brand name". Secondly, it was not clearly conveyed to the family that Ms A had been dispensed an anti-depressant (Serzone) instead of the prescribed anti-psychotic (Seroquel). Mr F acknowledged that Mrs A could have misinterpreted what he said, and the family were left under a misapprehension about the seriousness of the dispensing error.

In his response to my provisional opinion, Mr F advised me that he did not accept that he had misled the family. Through his lawyer, he advised me that the sole purpose of his visit to the family's home on Sunday 16 September 2001 was to explain that an error had occurred. He advised me that his priorities were to ensure that the error was not continued further and that Ms A saw her doctor as soon as possible to remedy the error.

Mr F advised me that he did not consider it appropriate to provide a full explanation of the differences between the two medications and their effects, because he did not know Ms A's medical history and was "therefore unable to know the impact of the error with any certainty". He also wanted to avoid creating any unnecessary anxiety, which he believed was important in a patient with mental health issues. Mr F advised me that he asked after Ms A's general condition to ascertain whether Ms A required immediate medical treatment. The response suggested it was appropriate for Ms A to wait until the following day, and Mr F felt the error would be clarified with the doctor in the morning.

Mr F is adamant that he did not mislead the family, and I accept that he did not intend to mislead them. However, the fact remains that the family were left under the erroneous impression that Seroquel and Serzone were essentially the same. In that sense, the family were misled, whether or not that was Mr F's intention.

Seroquel tablets taken to the family's house
Mr F took some Seroquel tablets to the family's home when he went to explain the error. I have also received conflicting information regarding what Mr F recommended Ms A do with the tablets.

According to Mr and Mrs A, Mr F advised that Ms A should take four Seroquel 100mg tablets that night. Mr and Mrs A advised me:

> "We decided to wait and check with [Dr B] first since it is our understanding that a pharmacist has no mandate to prescribe restricted medicine let alone a drug such as quetiapine. We were confused by the explanation regarding the relationship/difference between Serzone and Seroquel."

Mr F denied advising that Ms A take 400mg of the Seroquel that night. He advised that he left 20 100mg Seroquel tablets for her in the event that Dr B wanted her to start taking them immediately. His lawyer advised me:

> "[Mr F] proposed no change to [Ms A's] routine until the prescribing specialist had been consulted at the first opportunity, the following morning.
>
> …
>
> At no time did he suggest that [Ms A] should take the quetiapine [Seroquel] before having consulted her specialist. Nor did he suggest that she should take 400mg of the medicine. The label read 1 tablet at morning and 3 at night (the original directions). [Mr F] did not suggest that 4 tablets should be taken at night."

The lawyer advised me that Mr F had a number of years' experience dispensing psychiatric medicines to individuals and to patients in residential homes specialising in psychiatric care, using the drugs prescribed to Ms A. A few weeks prior to the dispensing error, both Mr C and Mr F had attended a continuing education course on Seroquel and similar medicines. They were aware of the graduated dosage regimes that may be prescribed in changing from one medication to another. This was another reason why Mr F wanted to consult a specialist and did not advise any change to Ms A's medication regime.

In a letter to the Accident Compensation Corporation dated 31 October 2001, in relation to a medical misadventure claim filed by Ms A, Dr B wrote:

> "[Mr F] told me that he had been round to the [family's] house, had explained the problem, and had given them quetiapine [Seroquel], removing the remainder of the nefazodone [Serzone] prescription. He stated that he had tried not to distress them. He had suggested that [Ms A] take the quetiapine [Seroquel] at 400mg nocte. [Ms A] and her parents elected to wait and consult with me as to what they should do."

Dr B later confirmed with me that when she spoke to Mr F, he told her that he had suggested to Ms A that she take 400mg of the quetiapine at night. She recorded in Ms A's clinical notes on 1 October 2001, two weeks after the dispensing error was discovered, that the family were concerned not only that the incorrect medication had been dispensed, "but the pharmacist was not up front about the mistake and suggested that [Ms A] just switch straight to 400mg quetiapine [Seroquel] daily".

Commissioner's finding of fact

Faced with this conflicting evidence, I am required to make a finding of fact concerning what Mr F recommended Ms A do with the tablets.

I am satisfied that the evidence provided to me by Mr and Mrs A – that when Mr F visited their home on Sunday 16 September 2001, he advised that Ms A should take 400mg of Seroquel that night – is credible since it is supported by the corroborative evidence of Dr B. When Mr F telephoned Dr B on Monday 17 September 2001, he told her he had suggested Ms A take 400mg of Seroquel that night. Dr B's clinical notes dated 1 October 2001 also

record the family's concerns that Mr F had suggested that Ms A switch straight to 400mg Seroquel daily.

In his response to my provisional opinion, Mr F advised me that he did not accept my conclusion. Through his lawyer, he advised me that he took a small quantity of the correct medication to the family's home so that Ms A would have it to take after contacting Dr B. Mr F advised me that he could not understand why Dr B would report that he told her he had suggested Ms A take 400mg of Seroquel that night. He noted that Dr B had made no note to that effect in her clinical notes dated 17 September 2001. Mr F suggested that Mr and Mrs A had misunderstood him, and that Dr B had repeated their misunderstanding. Mr F further advised that he would not have recommended four tablets (400mg) as the directions on the label were for one tablet in the morning and three at night.

I accept that the parties recollect events differently and that Mr F is clear he did not suggest Ms A take Seroquel on Sunday 16 September 2001. Faced with these two different accounts of events, however, I continue to prefer the evidence of Dr B. In doing so, I note that Dr B is an independent third party, and that her letter to ACC was written six weeks after the dispensing error was discovered when she could be expected to accurately remember events.

As noted above, Dr B advised ACC that Mr F "had suggested that [Ms A] take the quetiapine [Seroquel] at 400mg nocte". I was aware of the possibility that the family had misunderstood Mr F and that the information reported by Dr B had not come from Mr F. I therefore wrote to Dr B and asked the following question: "Who told you that the pharmacist had suggested that [Ms A] take the quetiapine at 400mg nocte – the pharmacist himself? [Ms A] ? her parents?" Dr B confirmed verbally that it was Mr F. She also responded in writing, stating: "The pharmacist told me that he had suggested that [Ms A] take the quetiapine 400mg nocte." As Dr B is clear that it was Mr F who gave her that information, I am satisfied that her evidence is correct.

Monday 17 September 2001
Dr B's clinical notes dated 17 September 2001 record:

> "phone call from pharmacist ([Mr F] …) re having given [Ms A] nefazodone [Serzone] rather than quetiapine [Seroquel] for the past month. Phoned [Ms A] who was insistent that she had had the right thing, re-phoned pharmacist who was equally sure that she had not. Suggested that she increase the quetiapine from 50mg bd [morning and night] from today, [increasing by 50mg] every two days to [a total of] 100mg mane [in the morning] and 300mg nocte [at night]."

Dr B advised me that as well as speaking to Ms A on the telephone, she saw Ms A and her mother briefly that afternoon at her private practice, mainly to reassure them. She gave Ms A instructions to gradually increase the Seroquel.

On Monday 17 September, Mrs A went to the pharmacy to pick up more Seroquel. The pharmacists advised me that Mr C typed the extended new graduated dosage into the

computer and gave her the balance of the Seroquel 100mg for one month. Through their lawyer, they advised me:

> "At that time, [Mrs A] commented that [Ms A] had been trying new medicines in recent weeks as Risperidone (her former medication) did not seem to be suiting her and the doctor was trying a new type of medication."

The pharmacists advised me that Mr F again discussed the issue with Mrs A to ensure that she understood that Seroquel was the correct medication and was to replace the Serzone. They advised me that Mr F again apologised for the error and that, at the time, Mrs A did not appear distressed or particularly unhappy.

File note and incident report

In the pharmacists' initial response to my investigation, they advised me that on Monday 17 September 2001, Mr F made a file note relating to his interactions with Mrs A. A copy of the file note was not included with the pharmacists' response, and the pharmacists' lawyer subsequently corrected the information originally provided and confirmed that Mr F had not made a file note on 17 September.

It appears that after receiving notice of my investigation, Mr F made a file note of the events that occurred to assist in answering the complaint to my Office. The undated file note reads:

> "[Mr F] B.Pharm M.P.S. Reg. No. …
>
> I was notified by [Mr E] on Sunday 16th Sept 2001 locum pharmacist that there appeared to be a dispensing error in a prescription for [Ms A]. I came over to the pharmacy and with [Mr E] checked out the incident, found the original prescription and it appeared that Serzone 100mg was given instead of Seroquel 100mg at the original dispensing. I drove up to the [family's] home but even though all the back doors were open, T.V. and computer going, I could not find anyone. I left for home and came back an hour or so later. I then spoke to [Mrs A] and asked how [Ms A] had been over the past 4 weeks. She said she was very well and not having any problems. I explained what seemed to be the mix-up and that I would leave a few Seroquel 100mg for her subject to confirmation with the doctor tomorrow.
>
> The next day after a discussion with [Mr C] (my partner) on what he could recollect of the dispensing incident I rang [Dr B] ([Ms A's] doctor) and managed to contact her at about midday. She said she was going into their group meeting soon and would ring back after discussing the issue of Serzone vs Seroquel. I commented that [Ms A] was reported by her mother and even herself to be very well.
>
> [Dr B] rang back later and suggested we phase her onto Seroquel with a graduated increasing dosage building up to one in the morning and three at night. I rang [Mrs A] and apologised for the mistake and explained the situation.

> On her arrival at the pharmacy to pick up some more Seroquel [Mr C] typed out the extended new graduated dosage and she was given the balance of the Seroquel 100mg for 1 month. She commented that [Ms A] was trying new medicines in recent weeks as risperidone her former medication did not seem to be suiting her and the doctor was trying a new type of medication.
>
> I confirmed she knew the full situation and that Seroquel was the correct medicine and Serzone was to be replaced. I again apologised on our behalf for the error and she indicated she understood and left seemingly happy mid-afternoon Mon 17th Sept.
>
> We filled out our incident report and as there seemed to be no major or any problems arising or reported either from the doctor or family, left it at that."

On 30 November 2001, Mr C wrote a letter of apology to Ms A and Mr and Mrs A, and sent it to my Office to be forwarded to the family.

In the pharmacists' initial response to my investigation, they also advised me that they had "filled out an incident report" after Mrs A collected the balance of the correct medication. I could not find the incident report in the documents provided to my Office. The pharmacists' lawyer subsequently advised me that the incident report was a copy of the prescription form with hand-written notes on it as follows:

> "(Serzone not Seroquel Disp. 8/8/01) Phone Dr 17/9/01 and graduated dose given for start of Seroquel 100mg up to one in the morning and three at night."

I was advised that on 17 September 2001 Mr F had photocopied the prescription, written on it, and filed it in the pharmacy's incident book.

Pharmacists' response to dispensing error

Mr C could not remember dispensing the specific prescription. However, in the pharmacists' response to the complaint, Mr C "accept[ed] that he [had taken] the wrong tablets from the dispensary shelf and while attaching the label and doing the usual checking process, did not notice the error".

Mr C noted that the following factors may have contributed to his error. He advised me that he was not attempting to excuse himself from full responsibility for the error, but that he wanted to explain how the error had occurred.

- Seroquel (quetiapine) and Serzone (nefazadone) have similar names and are next to each other on the dispensary shelf (dispensary medicines are stored alphabetically);

- At the time there were a number of changes in medication for different patients to new anti-psychotics and anti-depressants which may have contributed to confusion in the dispensing procedure;

- Mr C recalled that there was some difficulty with the availability of the special authority Chem. No. for the subsidy of quetiapine, which may have distracted him from the dispensing and checking procedure; and

- Mr C was required to annotate three separate parts of the prescription form to comply with subsidy requirements and regulations, in particular the A1 coding, the patient's address and the Chem. No. and expiry date. This took more time than usual and Mr C believed he may have been uncomfortable as Mrs A was waiting for the prescription. He therefore may have rushed through the checking procedure.

Ms A's condition after the dispensing error

While the pharmacists advised me that they accepted full responsibility for the dispensing error and any adverse consequences caused by it, Mr C and Mr F believed that there was insufficient evidence "at this time" (December 2001) to accept that the return of Ms A's psychotic symptoms was caused as a result of the dispensing error. They stated:

> "Regrettably, that may be proved to be so, but at this stage there is insufficient information to support that view."

Mr and Mrs A advised me that as a result of the dispensing error Ms A's psychotic symptoms returned and, day by day, she slipped more and more into psychosis. They stated:

> "This was extremely distressing for [Ms A] who knew that she was slipping back into psychosis and desperately did not want to get sick again. Unfortunately due to the slow effect of the anti-psychotic medication, and the added complication of an abrupt end to a high dose of Serzone, [Ms A] quickly (over several days) slipped back into a psychotic state. We could do nothing to prevent this."

Ms A's clinical notes from the Centre record that she became increasingly unwell. By the time of her appointment with Dr B on 1 October 2001, there had been "a resurgence of psychotic symptoms", with Ms A describing auditory and somatic hallucinations and the feeling that "her thoughts have escaped from her head".

Three days later, on 4 October 2001, Ms D recorded that Ms A's voices were getting worse and more frequent. She noted:

> "[Ms A] said when she had first become unwell again last week, the voices had mostly started at night. Now they are starting as early as 9am and going all day.
>
> … [T]hroughout the session, [Ms A] continued to report hearing voices now and again, while talking to me. These were both 'running commentary' and 'suspicious' voices."

The pharmacists advised me that their computer records indicated that risperidone 1mg tablets were dispensed to Ms A on 10 August 2001, two days after the dispensing error occurred.

Dr B confirmed that when the decision was made to try Ms A on quetiapine, she provided a written cross-over regime from risperidone to quetiapine. Dr B advised me that her usual practice was to write out a clear list for the patient. She advised that her usual practice was to introduce the quetiapine at low doses (50mg increments), before gradually reducing the risperidone (half-milligram decrements).

In her letter to ACC dated 31 October 2001, Dr B stated that when Ms A started on quetiapine [Seroquel] after the dispensing error was discovered, she initially experienced some adverse effects. Dr B stated:

> "We therefore started [on an] even lower [dose]. Unfortunately, having had several weeks without anti-psychotic treatment, [Ms A's] mental state deteriorated. She then became psychotic, experiencing auditory hallucinations, disorder of thought form, anxiety, persecutory ideation and also started expressing some suicidal ideation. This continued to occur unabated despite increasing the quetiapine [Seroquel] dose. It was therefore decided to add in risperidone, despite the adverse effects, as we knew that she responded well to this medication.
>
> Currently [Ms A] is taking 5mg risperidone daily, as she has not responded to the previous effective dose of 4mg daily. She remains auditorily hallucinated and with subjectively jumbled thoughts, but the formal thought disorder has improved. Her mother in particular has had to take significant time off work to be with [Ms A] and the whole family has naturally become very distressed because of this. [Ms A] is currently attending [a youth programme] at [the Centre] but is finding it hard to achieve full benefit because of her ongoing positive psychotic symptoms."

Dr B advised ACC that Ms A's prognosis was reasonable, as she had previously responded well to anti-psychotic medication. However, in October 2001 Dr B observed:

> "Unfortunately it appears recurrent episodes of psychosis make an individual more vulnerable to further episodes of psychosis, and this episode is slower to respond and is requiring higher doses of medication than her previous episodes. It has set her back significantly in her aims to resume a normal life. She has had some suicidal ideation and is feeling quite hopeless at present."

Independent advice to Commissioner

The following advice was obtained from independent pharmacist Mrs Andrea Shirtcliffe:

> "***1. What standards apply in this case and were these standards met?***
>
> All standards that the pharmacist is required to comply with have been covered by the questions asked of me in this request for advice. My comments as to whether these standards were met are covered under the relevant questions following.

2. What is quetiapine prescribed for?

Quetiapine is indicated for the treatment of acute and chronic psychoses, including schizophrenia. [A]

3. What is nefazodone prescribed for?

Nefazadone is indicated for the treatment of depression including depression accompanied by anxiety or sleep disturbances. [B]

4. What are the similarities/differences between quetiapine and nefazodone? What are the risks?

Nefazadone and quetiapine are different medicines and are used to treat different types of mental illness. Nefazadone is essentially used to treat depression and quetiapine is essentially used to treat schizophrenia. However there is some commonality in their mode of action. Nefazadone essentially works at one receptor and quetiapine works at many receptors, which includes the receptor that nefazadone affects. This means that there is some similarity in the adverse drug reaction (ADR) profiles of these two agents.

The following is a table which summarizes the receptor sites that nefazadone and quetiapine affect. [A, B]

	$5HT_2$ (serotonin)	**D1 (dopamine 1)**	**D2 (dopamine 2)**	**Histamine**	**Alpha 1**	**Alpha 2**
quetiapine	√	√	√	√	√	√
nefazadone	√					

There are a number of ADRs that quetiapine can cause that nefazadone does not cause. I have not attempted to comment on these. I have made the assumption that any risk associated with quetiapine's potential ADRs has been covered in the patient's initial interaction with the prescriber.

I have therefore attempted to collate ADRs that nefazadone can cause that quetiapine is unlikely to cause. This is one of the two areas that I feel that the potential 'risk' is located. I have gone to the manufacturer's data sheet, Maudsley Prescribing Guidelines and the Psychotropic Handbook to find this information. As these medicines are comparatively new agents, or certainly were at the time of this dispensing error I feel that these sources of information would be a fair representation of the information available at the time of the incident.

When discussing ADRs it is important to remember that where a 'numerical value' or range is given, that these are population statistics. It is not inevitable that when a person is given a medicine that they will get some or all of that medicines ADRs. It is also possible that a person may get most ADRs, one ADR and not others, or they may get one ADR to an extreme. That is to say that there is a significant degree of inter-patient variability with ADRs, and all ADR data should be read with this in mind.

I have also limited my report to the more common ADRs listed in the literature. With all medicines there is the potential for rare and idiosyncratic adverse events. I did not feel that it was practical or relevant at this stage to investigate this area.

Comparison of ADRs between quetiapine and nefazadone: [C]

	Sedation	Cardio-toxicity	Anti-cholinergic
nefazadone	++	-	-
quetiapine	++	-	+

Comparison of ADRs between quetiapine and nefazadone: [A, B, D, E, F]

ADR	Nefazadone	Quetiapine
Anticholinergic	**>10% (except sweating and delayed micturition ~ >2%)**	**>2%**
Sedation	**>10%**	**>10-30%**
Hypotension	**>10%**	**>10%**
EPS	**<2%**	**>2% (akathisia >2%)**
Epileptic seizures	**<2%**	**<= 0.8%**
Sexual disturbances	**<2%**	
Weight gain (over 6kg)	**-**	**25% incr. >7% from baseline wt gain**
Dyslipidaemia	**?**	**11% incr in cholesterol and 17% incr in triglycerides**
Hypothyroidism	**?**	**~0.4%**
Dermatitis, rash	**<2%**	**?**
GI distress	**>10%**	**1-10%**
Tachycardia, palpitations	**<2%**	**4.2%**
ECG changes	**<2%**	**?**
Cardiac arrhythmias	**<2%**	**?**
Insomnia	**>2%**	**Up to 17% (?)**
Disorientation/confusion	**>10%**	**?**
Asthenia, fatigue	**>10%**	**Asthenia ~4.3%**
Headache	**>10%**	**?**
Excitement/hypomania	**>2%**	**?**

By way of summary I feel that there is a potential increase in risk of experiencing the following ADRs when a patient is given nefazadone instead of quetiapine:

- anticholinergic ADRs (except sweating and delayed micturition). Eg dry mouth, blurred vision, postural hypotension
- asthenia/fatigue
- seizures

There appear to have been reports of the following with nefazadone and not with quetiapine: rash, sexual disturbances, ECG changes, cardiac arrhythmias, confusion, headache, excitement and hypomania. I was not able to find information on the actual incidence of these adverse effects. I have requested this information from the Centre for Adverse Reactions Monitoring (CARM) but this has not arrived in time to include in my report. I will forward this as soon as it arrives.

It needs to be said that rash and headache have been reported with almost all drugs and the above information should be read with this in mind.

Finally, there had been 8 reports of liver dysfunction reported to the Australian Adverse Reactions Advisory Committee between when nefazadone was marketed in mid-1997 and March 1999. This is an additional risk associated with being given nefazadone instead of quetiapine.

The other source of 'risk' to the patient is that caused by not having treatment with an antipsychotic medicine for in excess of one month. An antipsychotic's activity is essentially related to a medicine's activity at dopamine receptors (in particular D2). As can be seen in the above table, nefazadone does not have any documented activity at dopamine receptors. So by having this medicine instead of quetiapine for a period in excess of one month means that a patient is at risk of experiencing deterioration in their schizophrenia.

5. [Mr C] accepted that he had dispensed the wrong drug. He noted a number of factors which may have contributed to his error. Please comment on those factors.

Quetiapine and Nefazadone have similar names and are next to each other on the dispensary shelf: there are other examples of this, and although it would be more acceptable for drug companies to choose names for their products to avoid such similarities – the fact is that these situations exist and it is the pharmacist's responsibility to take steps in their dispensing procedures and protocols to minimize the chances of dispensing errors. Extra checking steps are required in such cases, and it is the pharmacist's professional responsibility to ensure that these happen.

At the time there were a considerable number of changes in medication for different patients to new anti-psychotics and anti-depressants which may have contributed to confusion in the dispensing process: if there are a considerable number of medication changes occurring in a given prescribing area then, again it is the pharmacist's professional responsibility to be aware of these prescribing trends in their area and include extra steps in the dispensary checking process.

There was some difficulty with the availability of the special authority Chem. No. for the subsidy of quetiapine. Nefazadone has not required a special authority Chem. No. in recent times (if ever). If time was taken to ascertain the particulars of [Ms A's] quetiapine Chem. Number, then this should be more likely to make the dispenser pay more (rather than less) attention to what they were dispensing.

[Mr C] was required to annotate 3 separate parts of the prescription form to comply with subsidy requirements and regulations, in particular the A1 coding, the patient's address and the Chem. No. and expiry date. This required more time than usual and [Mr C] believes he may have been uncomfortable as [Mrs A] was waiting for the prescription. He may therefore have rushed through the checking procedure. It should be noted that it is the prescriber's responsibility to provide these particulars on a prescription, and omission of such details can increase a pharmacist's workload and subsequently their stress level. However, whether a patient is waiting for a prescription or not should be irrelevant with respect to the dispensing checking process. It is a pharmacist's professional responsibility to complete all dispensing and checking procedures thoroughly regardless of whether there is a shop full of patients waiting for prescriptions – or no-one! If a patient is getting impatient then it would be acceptable standard of practice for either the pharmacist or another staff member to explain politely to the patient that the various checking processes were for their safety so that the patient knew WHY they were waiting.

6. When a pharmacist discovers that a dispensing error has occurred, what is the appropriate action to take?

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

i [Mr F] states that he made two verbal apologies
ii [Mr F] states that he changed the medicine for the correct one
iii It was evident from comments made by [Mr and Mrs A] that [Ms A] had taken some of the medicine
iv [Mr F] notified the prescriber on the Monday. It would be reasonable to assume that although no guarantee of success could be given on a Sunday, an attempt to contact the prescriber on this day should at least be made. However [Mr and Mrs A's] letter refers to the pharmacist speaking with the doctor on the 16th which was the Sunday. There appears to be some discrepancy here.
v There is insufficient evidence to ascertain whether the [family] incurred any doctor's fees, and if so whether [Messrs F or C] attempted to reimburse these costs
vi According to the letter from [Messrs F and C] a written apology was provided on 17 December 2001

vii According to documentation provided it would appear that [the pharmacy's] dispensing and checking procedures were reviewed soon after this incident. It would appear from the documentation provided that these procedures have been reviewed annually for at least the last 2-3 years

7. [Mr F] took 20 x 100mg of quetiapine to [Ms A] at her home. Please comment on the appropriateness of this action.

It would be acceptable standard of practice for [Mr F] to leave behind some quetiapine tablets to enable [Ms A] to have access to the correct treatment as soon as the prescriber was able to be contacted. I would consider it responsible to leave [Ms A] with some medication to enable immediate treatment to be commenced as soon as the correct dose is ascertained. However I would not consider it acceptable to leave behind an entire month's supply until direction had been received from the prescriber. [Mr F] did have a legitimate prescription for supply of quetiapine for [Ms A], however he has been cautious in his actions and ensured that he has provided sufficient medication to see the [the family] through. That is 20 x 100mg tablets would allow the pharmacy time to get sufficient medication to [Ms A] to ensure no further delay in her treatment.

8. [Mr F] took the incorrectly dispensed nefazodone away with him. Please comment on the appropriateness of this action.

It is regarded as acceptable practice (see question 6) to remove the incorrect medication from the patient's premises when attempting to rectify a medication dispensing error. This would be for the patient's safety to minimize the chances of the patient taking any more of the incorrect medication.

The manufacturers suggest that tapering the dose of nefazodone can reduce the chance of withdrawal effects. It should be noted that the prescriber has not had any experience of withdrawal problems with nefazodone and was happy that this medication be stopped without requiring the dose to be tapered. It should also be noted that withdrawal events are uncommon following abrupt withdrawal of nefazodone, according to the manufacturer's data sheet, so withdrawing the incorrectly dispensed nefazodone is unlikely to result in complications for [Ms A]. The time line is pertinent here as well. This exchange happened on a Sunday and at the latest it is likely that [Mr F] would be able to contact [Ms A's] doctor on the Monday. If the prescriber wished [Ms A] to continue taking nefazadone for a period of time, this course of events would result in [Ms A] only missing one day's supply of this medicine. This is unlikely to cause any withdrawal problems, and removing this medication from the [family's] premises would decrease the chance of [Ms A] taking more of an unintended medication. On balance I feel that it was a responsible act for [Mr F] to remove the nefazadone.

9. What information/advice should [Mr F] have given the [family] about the two drugs and what to do next?

[Mr F] should provide information/advice on what the two different drugs are used to treat, and it would be considered acceptable standard of practice for a pharmacist to

provide information on common ADRs that either medication could cause. The pharmacist should talk the patient through the common ADRs and help the patient to identify if they had had any problems with these. The pharmacist should also reassure the patient where possible as to when these ADRs would go away.

It would also be reasonable to expect [Mr F] to advise the patient that a pharmacist will contact the prescriber and not to take any medication until this contact had been made.

10. Please comment on the [family's] version of what they were told. Was it appropriate?

If the [the family] were told that quetiapine and nefazadone were essentially the same medicine and that it was just a matter of a difference in brand name – then this information is incorrect and it would be irresponsible for a pharmacist to give out such incorrect information.

For a pharmacist to 'look at a patient and say "she's alright isn't she?"' would be an unacceptable comment to make, especially when commenting on a mental health illness. Pharmacists are not qualified to diagnose mental health illnesses and would be insufficiently qualified to diagnose deterioration in schizophrenic illness – particularly from a brief encounter as that described by [Mr and Mrs A].

11. Please comment on [Mr F's] version <u>of what he told the [family]</u>. Was it appropriate?

[It would be reasonable and acceptable standard of practice for [Mr F] to apologize, and cover those points referred to in section 9 of this report.]

'he explained the error'

'I then spoke with [Mrs A] and asked how [Ms A] had been over the past 4 weeks. She said she was very well and not having any problems. I explained what seemed to be the mix-up and that I would leave a few quetiapine 100mg tablets for her subject to confirmation with the doctor tomorrow.'

'I confirmed she knew the full situation and that quetiapine was the correct medicine and Serozone was to be replaced.'

[Mr F's] documentation of what he told the [the family] is rather sparse. It would appear that [Mr F] did not apologize to the [family] at the time of his visit to their home on the Sunday, but he did apologize to [Mrs A] when she came to pick up the new prescription on the Monday.

I have given information in section 9 of this report as to what I feel would be acceptable professional practice in this situation. I think it would be reasonable to assume that when [Mr F] states that he 'explained what seemed to be the mix-up', that he means that he advised on what the two different drugs were used to treat. However, I feel there is

insufficient evidence provided by [Mr F] to ascertain whether he went through the common ADRs with the [family].

[Mr F's] documentation does not make it clear that he told the [family] that he would contact the prescriber. However, I feel it is reasonable to assume that since the [family] did not contact the doctor themselves, that they have been left under the impression that [Mr F] would be doing this and getting in contact with them.

12. Please comment on the complainants' allegation that [Mr F] advised [Ms A] to take 400mg of quetiapine that night. If this is correct, was it appropriate?

It is an unacceptable standard of practice for a pharmacist to provide advice of this nature especially given that a dispensing error had occurred which resulted in the patient taking something in the region of 39 days' worth of an incorrect medication. This complicating factor could potentially affect any advice that the prescriber may give as to intended dose and initial dose titration.

It would be reasonable to expect that advice from the prescriber would be received before the patient would be notified of a dosage schedule.

13. Please comment on the pharmacy's dispensing protocol. What standards should it meet? Does it meet appropriate standards?

- Dispensing protocol issued on 6 May 1999, and reviewed on 30 August 2000.
- Checking prescriptions protocol issued 18 May 1999, reviewed 30 August 2000 and 30 August 2001.
- Dispensing of repeat prescriptions procedure issued on 12/5/99, reviewed on 12/5/00 (or 30/8/00?) and 30/8/01.
- Telephoned/faxed prescription procedure issued 27-4-99, reviewed 30-8-00 and 30-8-01.

According to the documentation provided the above protocols are reviewed approximately annually which is acceptable standard of practice.

These protocols are by and large modeled around templates provided by the Pharmaceutical Society of New Zealand (PSNZ) which is an acceptable standard for practice. Some evidence of 'individualization' of such protocols would be expected and there is little if any evidence of this in the protocols provided by [the] Pharmacy. Having said this – if what is presented in these protocols is what is actually done in practice in this pharmacy, then these levels are of an acceptable standard.

14. Please comment on the incident report completed after the dispensing error was discovered. What standards should it meet? Does it meet appropriate standards?

It is good practice to provide a copy of the original prescription in the incident report. However, it is also good practice to provide information about what was actually done by the pharmacist and his/her staff eg information about phoning the patient, what

information was given to the patient at the time, what corrective action was taken with respect to providing the correct medication and apologies made.

It is recommended by the PSNZ that a written incident reporting procedure is followed in pharmacies. However there is little official information as to what is a minimal acceptable standard for such procedures. Attached is a copy of the standardized form that the Pharmacy Guild of NZ provides to their members (of whom >80% of pharmacies in the country are members), and forms that the Pharmaceutical Society of New Zealand provide to their members (of whom 100% of practising pharmacists are members). A lot of pharmacies would use these as a minimal recording process, and I would consider this level of recording as acceptable.

The information provided in this case is in the form of a file note and not a formal 'form' layout. It is not clear as to whether this is the incident report or a 'file note'. There also appears to be some uncertainty as to when this information was recorded. However, the level of detail in the documentation is of a sufficient detail to record who did what at the time. If it is the opinion of the pharmacist that the patient is happy with the outcome then I would not expect any more detailed documentation to occur.

There is concern about the apparent time lapse between the dispensing error and when the 'file note' or 'incident report' was written. Even if the patient is apparently happy with the outcome it is acceptable standard of practice to document incidents such as dispensing errors at the time that they occur (or as soon as is practical after the event) to ensure completeness and accuracy. As we do not have the date that this file note/incident report was written I am unable to comment on whether the time between the incident and the documentation is acceptable.

15. Please comment on any other matter you consider relevant.

[Mr and Mrs A's] letter refers to 'due to the slow effect of the antipsychotic medication, and *the added complication of an abrupt end to a high dose of nefazadone, [Ms A] quickly (over several days) slipped back into a psychotic state'. [Messrs C and F] state that '[Dr B] advised a transitional course of medication to address this issue…[and that] the pharmacy's computer records indicate that Risperidone 1mg tablets were dispensed to [Ms A] on 10 August, 2 days after the dispensing error occurred.*

[Messrs C and F] also state that 'there is insufficient information at this time to accept that [Ms A's] "return of psychotic symptoms" was caused as a result of the dispensing error'.

This is a difficult area to comment on as a pharmacist is not qualified to diagnose schizophrenic illness. However it should be noted that:

– from the 8th August to 15th September (a period of 37 days) a total of 30 days supply of medication appears to have been taken. This amounts to approximately 23% of

doses potentially being missed. This of course depends on what date [Ms A] was told to start taking the quetiapine by the prescriber
- it is not clear how much Risperidone was taken by [Ms A] over this time (from the information provided).
- quetiapine would be a new medicine for [Ms A] and her clinical response to this would be difficult to predict with 100% accuracy
- it is difficult to predict with any degree of accuracy whether the abrupt discontinuation of nefazadone had any impact on [Ms A's] mental health

Documents provided:

- **Letter from [Mr and Mrs A] to the Health and Disability Commissioner dated 11 October 2001 'A'**
- **Letter from [the Commissioner] to [Mr and Mrs A] dated 8 November 2001 'B'**
- **Letter from [Mr C]/[Mr F] to [the Commissioner] dated 17 December 2001 with the following attached: 'C'**
  - **Dispensing protocol (for original, repeat telephones and faxed prescriptions)**
  - **Photocopied pages from Dispensing Guide**
  - **Photocopies of two prescriptions both with the same Rx No …**
- **HDC file note of phone call between [Investigation Officer] and [Mrs A] dated 21/10/02 'D'**
- **HDC file note of phone call between [Investigation Officer] and [the pharmacists' lawyer] dated 21/10/02 'E'**
- **Letter from [the pharmacists' lawyer] to [Investigation Officer] dated 22 October 2002 'F'**
- **HDC file note of phone call between [Investigation Officer] and [the pharmacists' lawyer] dated 25-1-02 'G'**
- **Letter from [the pharmacists' lawyer] to [Investigation Officer] dated 8 November 2002 'H'**
- **Letter from [Senior Investigation Officer] to [Dr B] dated 25 October 2002 'I'**
- **Letter from [Dr B] to [Senior Investigation Officer] dated 29 October 2002 'J'**
- **Photocopy of [a public hospital's] prescription for [Ms A] dated 3 August 01 Rx No …**

References

A Seroquel data sheet, Medsafe New Zealand Website http://www.medsafe.govt.nz/DatasheetPage.htm <accessed 6-01-03>

B Serzone data sheet, Medsafe New Zealand Website http://www.medsafe.govt.nz/DatasheetPage.htm <accessed 6-01-03>

C Taylor D. McConnell H. McConnell D. Kerwin R. The South London and Maudsley NHS Trust 2001 Prescribing Guidelines. 6th ed. London, Martin Dunitz Ltd 2001

D Bezchlibnyk-Butler K. Jeffries J. Clinical Handbook of Psychotropic Drugs 8th ed. Toronto, Hegrefe & Huber

E Rxfiles antipsychotic comparison chart http://www.sdh.sk.ca/rxfiles/acrobat/Cht-Psyc-Neuroleptics.pdf <accessed 6-01-03>

F Murasaki M. Yamauchi T. Yagi G. Nakajima T. Nakane Y. Kudo Y. Early phase II study of quetiapine fumarate on schizophrenia Nihon Shinkei Seishin Yakurigaku Zasshi 1999 Apr; 19(2):52-66 (abstract)

APPENDIX I

Mode of action of Seroquel and Serzone from the manufacturers' data sheets

Mode of action of Seroquel

Quetiapine is an atypical antipsychotic agent which interacts with a broad range of neurotransmitter receptors. Quetiapine exhibits affinity for brain serotonin ($5HT_2$) and dopamine D_1 and D_2 receptors. It is this combination of receptor antagonism with a higher selectivity for $5HT_2$ relative to $Dopamine_2$ receptors which is believed to contribute to the antipsychotic properties and low extrapyramidal side effects (EPS) liability of SEROQUEL. Quetiapine also has high affinity at histaminergic and adrenergic $alpha_1$ receptors, with a lower affinity at adrenergic $alpha_2$ receptors, but no appreciable affinity at cholinergic muscarinic or benzodiazepine receptors. Quetiapine is active in tests for antipsychotic activity, such as conditioned avoidance. It also reverses the action of dopamine agonists, measured either behaviourally or electrophysiologically, and elevates dopamine metabolite concentrations, a neurochemical index of $Dopamine_2$ receptor blockade.

In pre-clinical tests predictive of EPS, quetiapine is unlike standard antipsychotics and has an atypical profile. Quetiapine does not produce dopamine D_2 receptor supersensitivity after chronic administration. Quetiapine produces only weak catalepsy at effective dopamine D_2 receptor blocking doses. Quetiapine demonstrates selectivity for the limbic system by producing depolarisation blockade of the A10 mesolimbic but not the A9 nigrostriatal dopamine-containing neurones following chronic administration. Quetiapine exhibits minimal dystonic liability in haloperidol-sensitised or drug-naive Cebus monkeys after acute and chronic administration. The results of these tests predict that SEROQUEL should have minimal EPS liability, and it has been hypothesised that agents with a lower EPS liability may also have a lower liability to produce tardive dyskinesia.

Mode of action of Serzone

SERZONE® (nefazodone hydrochloride) is an antidepressant for oral administration with a chemical structure unrelated to selective serotonin reuptake inhibitors, tricyclics, tetracyclics, or MAO-inhibitors.

The antidepressant action of nefazodone is presumed to be linked to potentiation of serotonergic activity in the central nervous system. Unlike selective serotonin reuptake

inhibitors, nefazodone exerts dual effects on serotonergic neurotransmission through blockade of serotonin type 2 ($5HT_2$) receptors and inhibition of serotonin reuptake. These two properties combine to increase serotonergic neurotransmission through other serotonin receptors such as the $5\text{-}HT_{1A}$ receptor.

In *in-vitro* studies nefazodone was found to have no significant affinity for α_2 and β adrenergic, histaminergic, dopaminergic, cholinergic, benzodiazepine receptors, or serotonergic receptors of the $5\text{-}HT_{1A}$ subtype. Nefazodone has weak alpha 1-adrenergic blocking activity. In clinical studies, adverse effects suggestive of anticholinergic effects were noted.

Unlike most antidepressants, nefazodone does not adversely affect sleep architecture. It decreases the number of awakenings but does not suppress REM sleep."

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.*

RIGHT 6
Right to be Fully Informed

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

Opinion: Breach – Mr C

Dispensing error
It is not disputed that, on 8 August 2001, Mr C dispensed the anti-depressant nefazodone (brand name Serzone) to Ms A, instead of the prescribed anti-psychotic quetiapine (brand name Seroquel).

In response to my investigation, Mr C stated that he "accept[ed] that he [had taken] the wrong tablets from the dispensary shelf and while attaching the label and doing the usual checking process, did not notice the error".

While Mr C accepted full responsibility for the dispensing error and for any adverse consequences caused by it, he advised me of a number of factors that may have contributed to his error. He advised me that he was not attempting to excuse himself from full responsibility for the error, but that he wanted to explain how the error had occurred.

In relation to his point that the brand names for the two medications are similar, and that they are stored next to each other on the dispensary shelf, I note the comment of my independent pharmacist that it would be preferable for drug companies to choose different names for their products. However, the fact is that a number of very different medications have similar names. I accept my expert advice that in such cases it is the pharmacist's responsibility to implement extra checking steps, to ensure dispensing errors do not occur.

Mr C also advised me that he may have been confused because, at the time of the dispensing error, a number of patients were changing to new anti-psychotics and new anti-depressants. Again, I accept my expert's advice that it is the pharmacist's professional responsibility to be aware of prescribing trends. If a considerable number of medication changes are occurring in a given prescribing area, extra steps need to be included in the checking process. I further note that both Mr C and Mr F had recently attended a continuing education course on Seroquel and similar medicines. That being the case, I would have expected particular vigilance when dispensing such medications.

Mr C also advised me that he may have become distracted from the dispensing and checking procedure because of a difficulty with the availability of the special authority Chem. No. for the subsidy of quetiapine. I note my independent pharmacist's advice:

> "If time was taken to ascertain the particulars of [Ms A's] quetiapine Chem. Number, then this should be more likely to make the dispenser pay more (rather than less) attention to what they were dispensing."

Finally, Mr C advised me that to comply with subsidy requirements and regulations, he was required to annotate three separate parts of the quetiapine prescription form. As this required more time than usual, Mr C believed he may have rushed through the checking procedure because he was aware that Mrs A was waiting for the prescription. I accept my expert advice that, regardless of how many people are waiting or how long they have been waiting, pharmacists must complete all dispensing and checking procedures thoroughly. If Mr C had been concerned about how long Mrs A had been waiting, rather than rushing through the dispensing and checking procedures, he should have explained to her the reason for the delay.

The pharmacists' lawyer enclosed with the response to my provisional opinion an article entitled "Medication errors associated with Serzone and Seroquel". The article was prepared by medication error prevention officers at the United States Food and Drug Administration ("FDA"), which regulates pharmaceutical products in that country. The article, published in the 7 January 2002 issue of the magazine *Drug Topics*, reported that in the four year period from September 1997 to November 2001, the FDA was notified of 23 medication error reports involving Serzone and Seroquel.

The pharmacists' lawyer provided the article to support his contention that confusion between the two drugs is "relatively common". I have not been provided with sufficient information, either about dispensing errors in the United States or about the prevalence of confusion between Serzone and Seroquel in New Zealand, to draw that conclusion. In any event, if confusion between Serzone and Seroquel is "relatively common", that is all the more reason for pharmacists to be especially vigilant when dispensing either medication.

In a recent case where it upheld a charge of professional misconduct (*Director of Proceedings v Catchpole*, September 2001), the Disciplinary Committee of the Pharmaceutical Society of New Zealand stated:

> "[T]here is no room to challenge the proposition that pharmacists must always maintain the highest level of vigilance when dispensing medicines. Accurate dispensing is a lynchpin of community pharmacy. The profession and the community expect pharmacists to be constantly vigilant when dispensing medications because of the obvious potential risk that may follow from a dispensing error."

I accept that the factors listed by Mr C may have contributed to his error. I note Mr C's acknowledgment that the contributing factors do not lessen his responsibility for the error. A pharmacist has a professional responsibility to dispense medications accurately, and checks must be in place to ensure that, regardless of any difficulties that may arise, medication is correctly dispensed.

In dispensing Serzone to Ms A, instead of the Seroquel she had been prescribed, Mr C failed to provide services with reasonable skill and care and breached Right 4(1) of the Code.

Opinion: Breach – Mr F

Information given about Seroquel and Serzone

Mr and Mrs A complained that Mr F misled them into believing that Seroquel and Serzone were essentially the same medication, the only difference being the brand name. Mr F does not accept that he misled the family. He stated that he advised Mrs A that the two drugs were similar in that they are both used to treat psychiatric conditions. Mr F advised me that he was "anxious to allay any fears that the medicine dispensed was in a class of medicines such as diabetic, blood pressure or anti-coagulant treatment which have narrow therapeutic indices". He sought to reassure the family.

While it may not have been Mr F's intention to mislead the family, the evidence strongly suggests that Mr F was not as clear about the dispensing error as he should have been. Mr F did not convey to the family in an unambiguous manner that Serzone is an anti-depressant and Seroquel is an anti-psychotic. Because he did not clearly convey that information, the family ended up being misled, both as to the exact nature of the medication Ms A had been dispensed and the seriousness of the error. According to a note in Ms A's clinical records

made by clinical psychologist Mr G after talking to Mr A the day after the error was discovered, the family was under the impression that Serzone was "the same" as Seroquel, but with a different brand name.

In my opinion, Mr F communicated the error in a way that downplayed its seriousness. It was Mr F's responsibility to ensure the family clearly understood the implications of the error. Their sense of being misled would have been avoided if Mr F had been clearer in his explanation.

I asked my independent pharmacist what information Mr F should have given the family about the two drugs. She advised me:

> "[Mr F] should [have] provide[d] information/advice on what the two different drugs are used to treat, and it would be considered acceptable standard of practice for a pharmacist to provide information on common ADRs [adverse drug reactions] that either medication could cause. The pharmacist should talk the patient through the common ADRs and help the patient to identify if they had had any problems with these. The pharmacist should also reassure the patient where possible as to when these ADRs would go away."

According to my advisor, it would be irresponsible for a pharmacist to advise that Seroquel and Serzone were essentially the same medicine and that it was just a matter of a difference in brand name.

Mr F did not make it clear that the two different drugs are used to treat two different psychiatric conditions. Nor did he provide any information on the common adverse reactions of either drug, or help Ms A identify whether she had experienced any adverse reaction from the Serzone. It is unclear whether Mr F advised Ms A that he would contact Dr B the next day.

Mr F acknowledges that what he said could have been misinterpreted by Mrs A, but denies that it was his intention to mislead her. Rather, he wanted to reassure the family and avoid creating unnecessary anxiety, which he believed was important in a patient with mental health issues. He did not consider it appropriate to provide a full explanation of the differences between the two medications and their effects, because he did not know Ms A's medical history and was "therefore unable to know the impact of the error with any certainty". He asked after Ms A's general condition to ascertain whether she required immediate medical treatment. The response suggested it was appropriate for Ms A to wait until the following day, and Mr F felt the error would be clarified with the doctor in the morning.

I am not satisfied by Mr F's explanation for not being completely frank about the error. Mr F left the family with the impression that Seroquel and Serzone are essentially the same medications. While it is true that both medications are used to treat psychiatric conditions, schizophrenia and depression are very different psychiatric conditions. Nor do I consider lack of knowledge about Ms A's medical history a valid reason not to provide adequate information about the error. Mr F knew Ms A had been prescribed Seroquel, which is

indicated for the treatment of schizophrenia. He knew that she had been dispensed Serzone, which is indicated for depression.

In my opinion, it was not appropriate for Mr F to attempt to protect Ms A or her parents from the full facts. For all he knew, they may have wanted to seek immediate medical advice. In not providing them with full information he deprived them of that opportunity. In fact, Mr F's lack of full disclosure ended up increasing the anxiety for Ms A and her parents. Ms A had been dispensed the wrong medication and had been taking it, oblivious to the error that had occurred, for several weeks. In these circumstances, a reasonable consumer would expect full disclosure from the pharmacist who discovered the error. A pharmacist has an ethical and legal duty of candour in such a situation. That duty applies equally to mental health patients.

In my opinion, in not giving Ms A or her parents clear information about the differences between Serzone and Seroquel, or any information on the common adverse reactions of the two drugs, Mr F failed to provide information that a reasonable consumer in Ms A's circumstances would expect to receive. Mr F therefore breached Right 6(1) of the Code.

Mr F's advice regarding Seroquel tablets
Mr and Mrs A complained that when he visited their home Mr F advised that Ms A should take 400mg of Seroquel that night. It was their understanding that a pharmacist had "no mandate to prescribe restricted medicine let alone a drug such as quetiapine".

It is not in dispute that Mr F took Seroquel tablets with him to the family's home. My independent pharmacist advised me that it was appropriate for Mr F to leave a supply of tablets to enable Ms A to have access to the correct medication as soon as Dr B had been contacted. Mr F advised me that he left 20 x 100mg tablets, which according to my advisor was an appropriate and sufficient amount to leave to ensure that there was no further delay in Ms A's treatment.

Mr F denied advising the family that Ms A take 400mg of the Seroquel that night and said he left the tablets in case Dr B wanted Ms A to start taking them immediately once she had been consulted the following morning.

In Dr B's letter to ACC, she advised that when Mr F telephoned her on Monday 17 October 2001 to advise her of the dispensing error, he told her that he had suggested that Ms A take 400mg of the quetiapine at night. To avoid any possibility that I had misunderstood Dr B's advice to ACC, I asked her to provide me with the name of the person who told her that Mr F had suggested that Ms A take 400mg of the quetiapine at night. Dr B advised me that it was Mr F. Further, on 1 October 2001, two weeks after the dispensing error was discovered, Ms A's clinical notes record the family's' concern that Mr F "was not up front about the mistake and suggested that [Ms A] just switch straight to 400mg quetiapine daily".

As discussed on page six of my report, Dr B is clear that it was Mr F who gave her the information that he had suggested Ms A take quetiapine on 16 September 2001. I conclude that Mr F advised Ms A to take 400mg quetiapine that night.

In response to my provisional opinion, Mr F advised me that he did not accept my conclusion, and that he could not understand why Dr B gave me that information. I am satisfied, however, that Dr B's evidence is reliable. Dr B is an independent third party and recorded the information in writing to ACC six weeks after the dispensing error was discovered, when she could be expected to accurately remember what happened. Accordingly, on the balance of probabilities, I prefer the account of events provided by the family and Dr B.

My independent pharmacist advised me that it was "unacceptable" for Mr F to advise that Ms A take 400mg of the quetiapine that night. My advisor noted that this was especially the case as, due to the dispensing error, Ms A had been taking the incorrectly dispensed Serzone for about 39 days. My advisor noted that the length of time Ms A had been taking Serzone might have influenced Dr B's advice on the initial Seroquel dose titration.

According to my independent pharmacist, Mr F should not have given Ms A any information about the dosage schedule until the prescriber, Dr B, had advised the appropriate dosage.

In my opinion, while it was not inappropriate that Mr F took a limited quantity of Seroquel to the family, in advising that Ms A take 400mg of the quetiapine the night he visited their home, rather than waiting until Dr B had been contacted the following day, Mr F did not provide services to Ms A with reasonable skill and care. He therefore breached Right 4(1) of the Code.

Opinion: Breach – The Pharmacy

Vicarious liability
Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights (the Code). Under section 72(5) it is a defence for an employer to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing that breached the Code.

The pharmacy employed Mr C and Mr F as pharmacists. I accept that the pharmacy has taken reasonable steps to prevent its employees from making dispensing errors, having in place standard operating dispensing and checking procedures that conform with accepted professional standards. However, in relation to Mr F's response to the dispensing error, the pharmacy has provided no evidence of steps taken to ensure that its pharmacists respond appropriately to dispensing errors.

In response to my provisional opinion, the pharmacists accepted that they did not have a written procedure or any particular training programme for dealing with dispensing errors. They argued that the pharmacy should not be held vicariously liable, as such procedures are not commonplace in pharmacies where the working pharmacists also own the pharmacy.

They argued that it was appropriate for the pharmacy to rely on Mr F to act appropriately and professionally.

I do not agree. The potential for a pharmacy to harm a consumer is greatest in the area of dispensing errors. Dispensing errors are an unfortunate reality, and it is vital that when one occurs the pharmacy responds appropriately. For that reason, I consider pharmacies should be able to provide evidence of steps taken to ensure their pharmacists respond appropriately. I note that when pharmacies are audited by Medsafe they are required to have a written and implemented incident reporting procedure, and a corrective action process for when incidents occur. The pharmacy has provided me with no such documentation.

I do not consider that the position is altered by the fact that Mr F and Mr C are co-owners and co-pharmacists of the pharmacy. When a dispensing error occurs, a pharmacy owner needs to have a clear process to follow. Furthermore, it is common for pharmacies to employ locums and other staff, all of whom need to know where to turn for guidance in the event of an error. Indeed, in this case it was a locum pharmacist who was originally alerted to the error with Ms A's medication. In my opinion, the pharmacy has not demonstrated that it took such steps as were reasonably practicable to prevent Mr F, its employee, from breaching the Code. Accordingly, the pharmacy is vicariously liable for Mr F's breaches of the Code.

Other comments

Pharmacists' response to investigation
The pharmacists advised me in their initial response to my investigation that on Monday 17 September 2001, the day after the dispensing error was discovered, Mr F made a file note relating to his interactions with Mrs A. That information was later corrected. A file note was written by Mr F to assist him to answer the complaint to my Office, but no file note was made on 17 September 2001.

In their initial response to my investigation, the pharmacists also advised me that they had "filled out an incident report". When I could not find an incident report, I was subsequently advised that this report was a photocopy of the script with handwritten notes on it, which had been filed in the pharmacy's incident book.

In their response to my provisional opinion, the pharmacists, via their lawyer, stated that my opinion suggested they may have manufactured the documents in order to mislead my Office, and that this was not correct. I am not suggesting that the documents were manufactured. I am, however, concerned that the information initially supplied to me was not entirely accurate.

Standard of incident reporting
I am concerned that the pharmacists did not record details of the dispensing error or the follow-up action taken in sufficient detail to provide a reliable record of what happened. I note the advice of my independent pharmacist that, while it is good practice to supply a copy of the original prescription when writing an incident report about a dispensing error, it is also good practice to provide information about what the pharmacist actually did about the error. I have reviewed standardised forms from the Pharmacy Guild of New Zealand and the Pharmaceutical Society of New Zealand. The forms provide for a record of details such as a description of the incident, an account of who was involved, immediate action taken, and action taken after the event.

In response to my provisional opinion, Mr F accepted that the incident report contained minimal information and that it might have contained more. He advised me that it contained "the essential information for him to be able to recall the specific facts which took place in the evening after the discovery of the dispensing error". I accept that the information recorded may have been sufficient to enable Mr F to recall what happened. I do not accept, however, that the information recorded was sufficient to enable a third party to have a reliable record of what happened. I consider that Mr F's manner of recording the incident was deficient and did not conform to professional standards.

Adverse consequences
In Dr B's opinion, Ms A's mental state deteriorated because, due to the dispensing error, she went several weeks without anti-psychotic treatment. Dr B observed that the dispensing error "set [Ms A] back significantly in her aims to resume a normal life" and that recurrent episodes of psychosis make an individual more vulnerable to further episodes. While the extent of any adverse consequences Ms A suffered has no bearing on my findings, I do not accept the pharmacists' assertion that there is insufficient evidence to show that the dispensing error caused a return of Ms A's psychotic symptoms.

Actions

- I will refer this matter to the Director of Proceedings under section 45(f) of the Health and Disability Commissioner Act 1994 to decide whether any further action should be taken.
- A copy of this report will be sent to the Pharmaceutical Society of New Zealand.
- A copy of this report, with identifying features removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

The Director of Proceedings issued proceedings against Mr C before the Pharmaceutical Society of New Zealand. A charge of professional misconduct was upheld by the Society on 12 August 2004 and it imposed a fine of $1,500 plus costs of $5,205.80. The Society ordered publication of its findings without identification of Mr C. A charge of professional misconduct in relation to Mr F was withdrawn.

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