Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963

Complaint

The Commissioner received a complaint from the Pharmaceutical Society of New Zealand about a dispensing error made by a Pharmacist to a Consumer. The complaint is that:

- *In mid-June 1998 the Consumer saw a Dermatologist for a severe skin allergy. The Consumer was prescribed 5mg of prednisone to be taken 8 times a day after food for one week and then a reduction in the usual way.*
- *The prescription was dispensed by a pharmacist at a Pharmacy. The rash cleared up but the Consumer's wellbeing deteriorated rapidly until she had to give up work and seek further advice from her specialist. The Consumer could not readily get around, her memory failed, she was confused and gained weight, couldn't sleep, her bowels and bladder misfunctioned, her heart beat increased to dangerous levels, she felt as if she was shaking inside and she is still affected with the withdrawals.*
- *The Consumer's specialist discovered that the Pharmacy had dispensed 20mg tablets instead of the 5mg prescription. Instead of a daily dosage of 40mg the Consumer had been taking 160mg.*

Investigation

The complaint was received by the Commissioner on 11 August 1998 and an investigation was undertaken. Information was obtained from the following:

The Consumer
A Pharmacist, the Pharmacy
A Dermatologist

Three Pharmaceutical Companies provided information and a copy of the prescription form was obtained from Health Benefits.

The Commissioner sought advice from an independent Medical Toxicologist.

The Pharmacist who dispensed the medication did not respond to the complaint directly and advised the Commissioner that the other Pharmacist had responded on her behalf.

Continued on next page

Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963, continued

Outcome of Investigation

In June 1998 a Dermatologist was treating the Consumer for a difficult, recurrent skin problem. The Dermatologist started the Consumer on Prednisone. The Dermatologist wrote a prescription which included 40mg of Prednisone daily after food for one week and then 30mg for a further week. The tablet strength was not stated.

The Consumer had the prescription filled by a Pharmacist at the Pharmacy. The Pharmacy uses Prednisone supplied by Douglas Pharmaceuticals in 1mg, 2. 5mg, 5mg and 20mg tablets. The tablets are presented in a white matt plastic bottle which are identical in appearance apart from the labelled dosage. The tablets themselves are small, round and white apart from the 20mg tablet which is light pink with a "P" on one side and a break line on the other.

In preparing to fill the prescription the Pharmacist proceeded with 5mg tablets of which 8 per day were required to fill the first week, (40mg per day) and 6 per day were required for the second week, (30mg per day). In total this required 98 tablets and it became apparent that this would require such a large number of tablets that it would exhaust the Pharmacy's immediate stock of tablets and might be impractical for the customer.

The Pharmacist then went on to consider the use of 20mg tablets which would necessitate splitting the prescription for the second week, but only requiring two tablets per day for the first week.

The Pharmacist dispensed 20mg tablets as she intended but did not adjust the instructions or description that she subsequently placed on the bottle into which she put the 20mg tablets. The label dispensed read: "Prednisone 5mg Tablets. Take EIGHT tablets daily for ONE week and then SIX tablets daily for ONE week. Take immediately after food".

The Consumer took the tablets as directed for eight days before she rang the Dermatologist as she was feeling very sick and feeling side effects. Adverse effects suffered by the Consumer included:

- Unable to readily get around
- Memory failed
- Confusion
- Weight gain
- Inability to sleep
- Bowels and bladder misfunctioned

Continued on next page

Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963, continued

Outcome of Investigation, *continued*

The Dermatologist asked the Consumer what the tablets were like and realised they were the wrong strength. The Consumer had been taking 160mg daily instead of 40mg daily.

The Consumer suffered a number of significant and disturbing symptoms as a result of this dispensing error. The Consumer was placed in a difficult situation in her new position at work, had to take the first week off and for the next two weeks had to rest extensively and she has suffered considerable distress.

The Dermatologist reported in mid-July 1998 that she saw the Consumer while she was on this extremely high dose. The Consumer was emotionally labile and had difficulty concentrating and remembering. The Dermatologist reduced the dosage and the Consumer improved, however, in the Dermatologist's opinion it would be some time before the Consumer was completely back to normal.

The Medical Toxicologist has confirmed that the Consumer took an inappropriately large dosage of the corticosteroid prednisone. This overdosage was so profound it is very likely to have caused the majority of symptoms suffered by the Consumer. Symptoms of confusion, failed memory, weight gain and inability to sleep are likely to be due to the overdosage of prednisone. Fortunately the overdosage was relatively short-term and it is very unlikely that there will be any long-term effects from this occurrence.

Continued on next page

Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963, continued

Code of Health and Disability Services Consumers' Rights

RIGHT 4
Right to Services of an Appropriate Standard

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

Relevant Standards

The Code of Ethics of the Pharmaceutical Society of New Zealand, Rule 2.1 states that:

A pharmacist must safeguard the interest of the public in the supply of health and medical products.

Rule 2.11 states:

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

The Pharmacy's Dispensing Protocol states:

The Pharmacist maintains a disciplined dispensing procedure that ensures the appropriate product is selected and dispensed correctly and efficiently.

Continued on next page

Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963, continued

Opinion: Breach, Pharmacist

Right 4(2)

In my opinion the Pharmacist breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights.

I recognise that the Pharmacist considered both her stock and the circumstances for the Consumer in deciding to dispense 20mg tablets. I also accept that the Pharmacist became distracted and her previous experiences regarding an armed hold up affected her. However, it was a material error to dispense 20mg tablets without altering the number of tablets and the instructions.

Further the Pharmacist did not confirm or consult with the Consumer regarding the change in the strength of the medication. The Pharmacist did not discuss with the Dermatologist her intentions regarding the dispensing of 20mg prednisone tablets when she realised that the Pharmacy did not have a sufficient stock of the 5mg tablets to meet the prescription.

In my opinion the Pharmacist dispensed 20mg predisone tablets and incorrectly labelled the bottle to read:

Predisone 5 mg tablets
Take Eight tablets daily for ONE week and then SIX tablets daily for ONE week. Take immediately after food.

This did not meet appropriate standards as defined in the Code of Ethics of the Pharmaceutical Society of New Zealand. Further the Pharmacist has not demonstrated that reasonable review procedures were in place to ensure dispensing is checked as correct.

Continued on next page

Pharmacy / Pharmacist

Report on Opinion - Case 98HDC16963, continued

Actions

I recommend the Pharmacist:

- Apologises in writing to the Consumer for her failure to dispense as prescribed. This apology is to be sent to my office and I will forward it to the Consumer.

- Ensures all dispensing procedures are updated and comply with currently accepted practice in the industry.

A copy of this opinion will be sent to the New Zealand Pharmaceutical Society who will be requested to undertake an audit of the Pharmacy's procedures.