Pharmacy and Pharmacist

Report on Opinion - Case 97HDC8296

Complaint

The Commissioner received a complaint that in July 1997 a pharmacy dispensed 250mg Pentasa tablets to the consumer with a label giving dosage instructions for 500mg Pentasa tablets.

Investigation

The complaint was received by the Health and Disability Commissioner on 25 August 1997 and an investigation undertaken. Information was obtained from:

- The Consumer
- The Provider, a Pharmacist
- The Pharmacist/Owner of the Pharmacy

Outcome of Investigation

A consumer has a long-term health condition that requires ongoing and extensive amounts of medication. The daily use of Pentasa is a requirement for the treatment of the consumer's condition.

In early June 1997 the consumer's specialist wrote a prescription for one hundred and eighty 500mg Pentasa tablets, with two repeats. The dosage instructions were two tablets three times daily. In late July 1997 the consumer collected the third repeat of the prescription from the pharmacy. The prescription was dispensed by the provider, a Pharmacist, who was employed by the Pharmacy owner (also a pharmacist), to be the sole dispensing pharmacist at the Pharmacy on Sundays.

The provider dispensed one hundred and eighty Pentasa tablets to the consumer but the tablets were 250mg strength instead of the prescribed 500mg. In her response to the Commissioner's provisional opinion the pharmacist advised that at the time she dispensed the Pentasa to the consumer 500mg tablets were unavailable and therefore 250mg tablets were dispensed in their place.

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Outcome of Investigation, *continued*

The consumer took the tablets in accordance with the dosage instructions on the box; two tablets three times daily, but in doing so was taking half the required dose. The consumer's health condition deteriorated over a period of weeks and as a consequence she took sick leave from work on two days in mid-August 1997. During her first day's sick leave the consumer had a further prescription for Pentasa 500mgs filled at the pharmacy, dispensed by the owner/pharmacist.

On a Sunday in mid-August 1997 the consumer became concerned that the reason for the earlier deterioration in her condition may be associated with her medication. She checked all her medications and found one set of Pentasa boxes had been dispensed with a label for Pentasa 500mgs, giving dosage instructions in accordance with that particular strength of Pentasa, but the contents of the box were Pentasa 250mg and the boxes themselves were printed with a label "Pentasa 250mgs".

A consumer immediately went to the pharmacy with the 250mg printed Pentasa boxes where she presented an empty Pentasa box and one about half-full box to the pharmacy assistant. In her response to the Commissioner's provisional opinion the pharmacist advised that she was presented with one half-full box of Pentasa tablets. Based on evidence provided during the investigation it is my view that the consumer's recollection is correct regarding the number of boxes presented to the pharmacy assistant. The consumer explained the error to the pharmacy assistant, who in turn brought the error to the attention of the sole dispensing pharmacist, the provider.

The provider came to the counter and spoke to the consumer, asking why the consumer did not just take double the amount of Pentasa. The consumer explained that she had taken the tablets in accordance with the dosage instructions on the box. The pharmacist then removed the incorrect label from the box, edited the label on the pharmacy computer system for the Pentasa 500mg dispensed by the owner/pharmacist on the consumer's first day of sick leave in August 1997, printed this off and attached the new label to one of the refilled Pentasa boxes. The pharmacist did not save the changes made to the earlier label. The pharmacist left the label that she had removed from the Pentasa box, with a note of the events for the Monday pharmacist. As the owner/pharmacist did not retain the label or the note, they were unable to be viewed as part of the investigation.

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Outcome of Investigation, *continued*

The following day, Monday, the owner/pharmacist read the provider's note, rang the consumer, and apologised for the error and advised that the provider had made the dispensing error.

The provider advised that the prescribing error occurred on the day of the consumer's sick leave (four days earlier), on a day when she was not working at the pharmacy and that she corrected the label the day before (i.e. the Sunday). However by that day, the consumer had used one and a half boxes of Pentasa tablets dispensed a month earlier in July 1997, and experienced a deterioration in her condition over a period of weeks. The low number of tablets remaining in the boxes that the consumer presented to the pharmacy on the Sunday in mid-August is evidence that the dispensing error must have occurred when the prescription was presented in mid-July 1997.

Additionally, the provider then prescribed further tablets (250mg) with a correct label instructing the consumer to take twice the quantity. In part this compounded the error because not only was this too late for the consumer but also the doctor's prescription was to dispense 500mg tablets.

Following notification of the complaint the owner/pharmacist phoned the consumer twice and visited her house once. The owner/pharmacist advised the Commissioner that his purpose in contacting the consumer was to determine the exact date of the prescribing error.

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.

Opinion: Breach - Provider/ Pharmacist

Right 4(2)
In my opinion the provider/pharmacist breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights by making an error in labelling the 250mg Pentasa tablets as 500mg.

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Opinion: Breach - Provider/ Pharmacist, *continued*

The Code of Ethics of the Pharmaceutical Society of New Zealand, Rules 2.11 and 2.12 state that:

> *A pharmacist must be responsible for maintaining and supervising a disciplined dispensing procedure that ensures a high standard is achieved. (2.11)*
>
> *A pharmacist must dispense the specific medicine prescribed and must not substitute any other medicine unless authority has been given in advance by the prescriber or in cases of obvious emergency. (2.12)*

The Pharmaceutical Society views the dispensing of the correct medicine as a basic professional standard.

The pharmacist had an obligation to meet professional standards by correctly dispensing medication in strict accordance with the prescription. The pharmacist did not meet her obligations when she dispensed the incorrect dose of Pentasa to the consumer and then re-labelled these at a later date.

Opinion: Breach - Pharmacy/ Pharmacy Owner

Right 4(2)

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

The Pharmacy was unable to provide the Commissioner with evidence that it had written checking procedures in place at the time of the error to ensure that medicines dispensed by a pharmacist working alone were dispensed in accordance with prescriptions. Following the complaint, the Pharmacy has advised that it has ceased opening on Sundays and that was the only time a pharmacist was working alone.

It further concerns me that in August 1997 the provider was able to prescribe extra tablets without a prescription and that this was done by altering the computer generated dispensary label of three days before. This indicates a lack of control on the computer system. There should have been a stocktake capable of picking up such an error.

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Actions

I recommend that the provider, and the owner of the Pharmacy, apologise in writing to the consumer for their breaches of the Code. The apologies are to be sent to my office and I will forward them to the consumer. A copy of the apology letters are to remain on the investigation file.

A copy of this report will be sent to the Pharmaceutical Society of New Zealand.

The owner/pharmacist is to confirm in writing that his computer system ensures correct record keeping and that scripts cannot later be altered. The owner/pharmacist is also to confirm he now has adequate review processes in place to ensure correct dispensing and labelling of medicines.

I note that the provider and the owner of the pharmacy have complied with my recommendations, and the file will now be closed.