Pharmacy

Report on Opinion - Case 97HDC7651

Complaint

Parents ("the complainants") complained as follows:

- *The complainants' son ("the consumer"), was prescribed Frusemide 500mgs tablets by a doctor.*
- *In early March 1997 the prescription was taken to a Pharmacy. 40mg tablets of Frusemide were dispensed. The label on the bottle stated "30 Frusemide 500mg tablets." The consumer commenced taking the 40mg Frusemide tablets, unaware that he was taking a dose substantially less than was prescribed.*
- *Fluid built up around the consumer's heart and kidneys and he was admitted to Hospital. The Hospital could not control the fluid build up and in early May 1997 the consumer died.*

Investigation

The complaint was received by the Commissioner on 30 July 1997 from the Pharmaceutical Society of New Zealand, who forwarded the complaint made to them by the complainants. An investigation was undertaken, and information was obtained from:

The Complainants / Parents of the Consumer
Provider/Pharmacy Director
Provider/Pharmacist ("the First Pharmacist")
Provider/Pharmacist ("the Second Pharmacist")
A Diabetic Specialist, Hospital

The consumer's clinical records were obtained and reviewed.

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Outcome of Investigation

The consumer (deceased) was diabetic. Complications related to his diabetes meant that in March 1997, the consumer (at age 35), did not enjoy good health. The family doctor regularly prescribed Frusemide 500mgs tablets for the consumer, with half a tablet to be taken twice a day.

In early March 1997 a pharmacist dispensed Frusemide tablets for the consumer from a repeat prescription from the family's doctor. The original prescription had been dispensed in mid-January 1997. The repeat in March 1997 was dispensed off a computer generated certified repeat copy which the Pharmacy advises is standard practice for repeats.

The pharmacists on duty at the Pharmacy on that day were identified and are referred to in this opinion as "the first pharmacist" and "the second pharmacist". Neither pharmacist can remember who dispensed the repeat Frusemide prescription. Unfortunately, neither complainant collected the prescription for their son, and if the consumer himself collected it, he did not say who the dispensing pharmacist was. The Pharmacy recognise (in a letter dated mid-August 1997) that the actual pharmacist who dispensed the Frusemide tablets on that day in March 1997 cannot be identified out of the two who were on duty that day.

Soon after that day the consumer became ill, with what he thought was a bad cold. In mid-March 1997, the consumer's mother visited him, and noticed that his legs were swollen. This is a sign of fluid build up within the body which Frusemide is designed to combat. The complainants took their son to Hospital, where he was admitted. The hospital recognised that the consumer was experiencing a fluid build up around his heart and kidneys, and when his Frusemide tablets were checked, they were discovered to be only 40mgs instead of 500mgs as prescribed.

A nurse from the Hospital phoned the Pharmacy and spoke to the dispensary manager. The nurse told the dispensary manager that Frusemide 40mg tablets were found in the consumer's bottle which was labelled as Frusemide 500mg tablets.

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Outcome of Investigation, *continued*

Three days after this, the Pharmacy Director phoned the consumer's mother to express concern about the consumer and offer support.

At the end of March 1997 the consumer was discharged from the hospital for a few days. He saw a lawyer about the incorrectly dispensed Frusemide tablets and was advised to fully recover before commencing any legal action.

Soon afterwards, the consumer was re-admitted to Hospital under the care of a diabetic specialist. Unfortunately, the hospital could not control the fluid build up, and the consumer died in hospital in early May 1997. The cause of death was listed as ischaemic cardio myopathy and type 1 diabetes mellitus.

Advice

The Commissioner sought and obtained advice from the Diabetic Specialist who supervised the consumer's care during his final stay in hospital.

The Diabetic Specialist advised that the consumer had advanced complications of insulin-dependent diabetes. In particular, the consumer had left ventricular failure secondary to ischaemic heart disease. This causes body organs to send out various hormonal signals to the kidneys, which leads to retention of salt and water. This in turn leads to a rise in blood volume, which can result in generalised oedema and pulmonary oedema.

Frusemide is a diuretic, which works by stimulating the kidneys to secrete salt and water. The consumer needed a high dose of Frusemide for this to be effective because his kidneys had lost a significant amount of function. The excess fluid, which was probably caused by the lower dose of Frusemide, would have caused the consumer's heart muscle to be overstretched and to enlarge, and would have reduced efficiency of the cardiac function.

The Diabetic Specialist believes that the consumer's prognosis was extremely poor, and he would have died in the near future with or without the problem of the fluid overload. The Diabetic Specialist bases his advice on two factors.

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Advice, ***continued***

Firstly, the consumer had been seen and treated in hospital for fluid overload but did not respond well. The Diabetic Specialist believes that this was because the consumer's heart and lung function were more the determining factor in his death rather than the reduced strength Frusemide tablets he had been taking prior to his decline.

Secondly there are generally no long-term consequences of taking reduced strength Frusemide. The Diabetic Specialist states that he frequently sees people who have stopped taking Frusemide, who as a result react by swelling up, having pulmonary oedema, and breathing trouble. However, once these people are back on the correct treatment they recover within a short period, generally in a couple of days. The Diabetic Specialist believes that the consumer's lack of recovery was a reflection of his underlying heart and kidney problems rather taking reduced strength Frusemide for a short period.

Similarly, it was the consumer's GP's view that lack of Frusemide would not have caused the consumer's death but might have hastened it.

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Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights apply:

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.

Applicable Standards

The Code of Ethics of the Pharmaceutical Society of New Zealand

The following rules of the Code of Ethics of the Pharmaceutical Society of New Zealand apply:

Rule 2.1 *A pharmacist must safeguard the interests of the public in the supply of health and medicinal products.*

Rule 2.12 *A pharmacist must dispense the specific medication prescribed…*

Rule 2.13 *The pharmacist responsible for a dispensed product must always be readily identifiable. Unless there is only one pharmacist on duty at one time and a diary record is sufficient to identify that pharmacist, each prescription must be annotated with the initials of the person dispensing the prescription and the initials of the pharmacist responsible for the finished product.*

Quality Standards for Pharmacy in New Zealand (As outlined by the Pharmaceutical Society of New Zealand. By the year 2000 all pharmacies must meet these standards in order to register)

1.1 Pharmacy Management

1.1b *The pharmacy manager is responsible for establishing and leading the quality work in the pharmacy.*

1.1c *The owner/manager ensures that all regulations covering the operations of the pharmacy are complied with.*

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Opinion: No Breach, First and Second Pharmacists

I do not have the evidence to determine which pharmacist dispensed the medicine and therefore must form the opinion that there has been no breach of the Code by either the first Pharmacist, the second Pharmacist or the Pharmacy Director.

The evidence shows that on the day in question, the dispensing pharmacist at the Pharmacy who filled the repeat prescription dispensed the wrong strength Frusemide tablets. The dispensing pharmacist did not comply with professional standards of care, and therefore was in breach of Right 4(2) of the Code. However, it is impossible to establish which was the dispensing pharmacist. Therefore, I am unable to determine an individual pharmacist who breached Right 4(2) of the Code of Rights.

Opinion: Breach, Pharmacy/ Pharmacy Director

In my opinion, the Pharmacy and Pharmacy Director who was managing the Pharmacy breached Right 4(2) of the Code of Rights.

The quality control procedure in place on the day in question states that *"all prescriptions should be documented with the initial of the pharmacist checking and releasing the dispensed prescription."* The Pharmacy Director advised the Commissioner that while this procedure was intended to apply to repeats, it was potentially ambiguous, as repeats are not specifically referred to.

In addition, the Pharmacy Director advised that he was aware at the time that staff checking and releasing repeats were not always signing the certified copy of the prescription. The Pharmacy Director advised that subsequent to this dispensing error the ambiguous wording in the written policy was amended and staff were reminded of their obligations.

In summary, by failing to ensure that the pharmacist who dispensed the consumer's prescription was identifiable the Pharmacy and Pharmacy Director breached the obligations set down by the Pharmaceutical Society of New Zealand and therefore breached Right 4(2) of the Code of Rights.

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Actions

I note that the Pharmacy has reviewed its quality control procedures to specifically require repeat prescriptions to be initialled by the dispensing pharmacist, and pharmacy staff have been reminded of their responsibilities. I recommend that:

- The Pharmacy be vigilant in ensuring that staff adhere to these procedures.
- Where possible when there is more than one pharmacist on duty, one pharmacist dispenses medication and one checks the dispensing. While the Pharmaceutical Society does not require this I am advised the Society recommend this as best practice.

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