Report on Opinion - Case 97HDC8969

Complaint	A consumer complained to the Commissioner about services provided by a Pharmacy. The complaint is that:
	 In early January 1997 the Pharmacy dispensed Warfarin 5 mg tablets with instructions "take as directed" written on the bottle. The prescription from the consumer's doctor states "Warfarin 5 mg tablets, 1 times daily".
Investigation	The Commissioner received the complaint on 2 October 1997 and an investigation was undertaken. Information was obtained from:
	The Consumer The Consumer's support person The Provider, a Pharmacist The Manager, the Pharmacy where the provider works Two General Practitioners, Medical Centre The bottle of Warfarin tablets was received. Relevant clinical records were obtained and viewed.
	The Commissioner sought advice from a medical toxicologist.
Outcome of Investigation	The consumer commenced taking Warfarin 1 mg tablets five times daily in September 1996. In early January 1997, as the consumer's usual general practitioner was not available she was seen by a different GP. This GP prescribed "Warfarin 5 mg tablets, take 1 daily" and "Warfarin 1 mg tablets, take as directed".
	The GP says that he prescribed "Warfarin 5 mg tablet, take 1 daily", as he thought the consumer would prefer to take one Warfarin 5 mg tablet instead of 5 Warfarin 1 mg tablets at night. The GP prescribed "Warfarin 1 mg tablets, take as directed" for future use as Warfarin doses were adjusted according to individual requirements.
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Outcome of Investigation, <i>continued</i>	The consumer went to the Pharmacy to have the prescription filled. Instead of stating "Warfarin 5 mg tablets, take 1 daily" on the bottle of dispensed medication, it stated "Warfarin 5 mg tablets, take as directed".
	The Commissioner was advised by the Pharmacy that the provider had dispensed the consumer's Warfarin tablets.
	The provider in his letter of response to the Commissioner dated 27 November 1998 stated:
	'[T]ake as directed' is a very common direction on Warfarin tablets. In fact, this is the exact direction that appeared on the other strength of Warfarin.
	On receipt of her Warfarin tablets the consumer mistakenly started taking five of the Warfarin 5 mg tablets which she did for 12 days.
	Ten days later the consumer consulted the GP, complaining of bruising to her left thigh and a heavy period, with clots, lasting longer than a week. During this consultation the GP established that the consumer had been taking five times the prescribed dose of Warfarin. The GP referred the consumer to Hospital where she was admitted due to a Warfarin overdose.
	On admission to Hospital the consumer's INR (International Normalised Ratio), was 20.4. The medical notes record that on examination by the admitting doctor she appeared well. The consumer's Warfarin was stopped and she was charted and given two units of Fresh Frozen Plasma and Vitamin K. The consumer was also taking Digoxin and Frusemide tablets.
	The medical toxicologist advised the Commissioner that the consumer's symptoms the day of admission were consistent with Warfarin overdose. Taking five Warfarin 5 mg tablets for 12 days would not have interfered with the consumer's other medication. The medical toxicologist also advised the Commissioner that the consumer, " should not [have] any long-term effects resulting from the Warfarin overdose."
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Outcome of Investigation, <i>continued</i>	Two days after admission the consumer was allowed to go home for weekend leave on the condition that she attended the hospital for blood testing over that time. Three days later the consumer was discharged from hospital with an INR level of 2.8.
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.
Professional Standards	 Pharmaceutical Society of New Zealand Code of Ethics Rule 2.11 states: <i>"A pharmacist must be responsible for maintaining and supervising a disciplined dispensing procedure that ensures a high standard is achieved. The pharmacist's responsibilities include: …ensuring the label is accurate, unambiguous and clear …"</i> The Pharmacy's Dispensing Procedures Protocols The relevant passage states: <i>"[I] n the interest of safety we ask that a pharmacist does not type into the computer, count and check a prescription on their own if other staff are also working. We ask that if two or more people are working (e.g. pharmacist and a technician) that they check each others' work."</i>

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Opinion: Pharmacist/ Provider	 In my opinion, the provider breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights. The instruction on the prescription form was for <i>"Warfarin 5 mg tablets, take 1 daily"</i>. The provider did not label the Warfarin 5 mg tablets' bottle correctly. By mislabelling the medication the provider failed to comply with relevant professional standards as contained in the Pharmaceutical Society of New Zealand's Code of Ethics. Furthermore, the provider failed to comply with the dispensing procedures of the Pharmacy in which he worked.
Opinion: Pharmacy/ Management	In my opinion the Pharmacy did not breach the Code of Rights, as appropriate procedures were in place for ensuring correct dispensing and labelling.
Actions	 The following actions have been taken: The provider has forwarded to the Commissioner a written apology addressed to the consumer for his breach of the Code of Health and Disability Services Consumers' Rights. The provider has confirmed in writing that he has read the Code of Health and Disability Services Consumers' Rights and fully understands his obligations as a provider of health services.

19 March 1999

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Other Actions A copy of this opinion will be forwarded to the Pharmaceutical Society of New Zealand and the provider's current employer.

The Commissioner will also write to both GPs involved in this case and bring this matter to their attention. An article will be written for General Practitioners and Pharmacists discussing the need for all parties to be vigilant in their communication, prescribing and dispensing of Warfarin.