Prescription of contraindicated medication
(13HDC01300, 20 June 2016)

General practitioner ~ Pharmacy ~ Rest home ~ District health board ~ Contraindicated medication ~ Rights 4(1), 4(2),5(1), 6(1)(b), 7(1)

An elderly rest home resident developed a severe rash, and her general practitioner (GP) prescribed ketoconazole to treat this. Ketoconazole has a high risk of causing liver injury and is contraindicated with simvastatin, which the woman was taking at the time for high cholesterol

The pharmacy which dispensed the ketoconazole (the pharmacy) had dispensing software which highlighted drug interactions. However, no one from the pharmacy contacted the GP about the drug interaction between simvastatin and ketoconazole. The woman's rash occurred a second time, and again the GP prescribed ketoconazole. No one from the pharmacy advised the GP of the drug interaction. When the woman presented a third time with the same rash, the GP prescribed ketoconazole at double the previously prescribed dose and for double the length of time. Again, no one from the pharmacy advised the GP of the drug interaction. The GP did not monitor the woman's liver function on any of the occasions on which he prescribed ketoconazole.

Approximately two months later, the woman had a fall and was taken to hospital. On arrival, her medications were documented but ketoconazole was not included. Her creatine kinase (CK) levels were recorded as 2,740 units per litre (normal levels being 30–180).

A registrar viewed the CK test result electronically. Although the result was highlighted on the system as being abnormal, the registrar did not inform the ordering consultant. Two days later, the woman's CK test was reviewed and due to the elevated result, her simvastatin treatment was discontinued. Clinicians reviewed the woman's computerised pharmacy dispensing records and discovered for the first time that she had been prescribed ketoconazole. The woman suffered from acute kidney failure and, sadly, died.

It was held that by failing to establish the woman's medical history appropriately, either by questioning her adequately or reviewing her medical notes, and by failing to monitor her liver function adequately when prescribing ketoconazole, the GP breached Right 4(1). By failing to communicate effectively with the woman, in a manner that would have enabled her to understand the information provided to her, the GP breached Right 5(1). By failing to provide the woman with information that a reasonable consumer in her circumstances would expect to receive, the GP breached Right 6(1)(b), and by not discussing the risks of ketoconazole, the woman was not in a position to make an informed choice and give her informed consent to taking ketoconazole, and, accordingly, the GP also breached Right 7(1).

The pharmacy failed to have in place an appropriate dispensing standard operating procedure, and failed to act on the alert when prompted. In addition, several staff members, on three separate occasions, failed to follow the professional standards for dispensing medications. Accordingly, the pharmacy was found to have breached Right 4(2).

The district health board breached Right 4(1) by not having in place appropriate systems to ensure that the woman's recent medications were known to staff. Criticism was also made of the failure to ensure that an abnormal test result was acted on appropriately.

Adverse comment was made about the rest home, regarding the woman's progress notes having been completed on an irregular basis while she resided at the rest home and for the lack of nursing support.

It was recommended that the Medical Council of New Zealand consider whether a review of the GP's competence is warranted.

In response to recommendations made in the provisional opinion the GP provided a written apology to the family for his breaches of the Code, and underwent further training on good prescribing practice.

It was recommended that the company that traded as the pharmacy provide a written apology to the family for its breach of the Code, obtain an independent review of the dispensing SOPs for all pharmacies that it owns and report to HDC on the outcome of the review, and provide training to its pharmacists on its dispensing SOPs.

It was recommended that the district health board provide a written apology to the family for its breach of the Code.