

**Monitoring of patient following administration of an unapproved,
prescription-only medication
(13HDC00966, 16 June 2015)**

Rural GP ~ Clinic ~ Unregistered provider ~ Unapproved medication ~ Drug addiction ~ Rights 6(1), 7(6), 4(1), 4(2)

A 45-year-old woman with a history of opiate drug use sought assistance with her drug addiction from a clinic offering treatment using an unapproved medicine under the Medicines Act. The clinic is run by a doctor who is a qualified rural medicine general practitioner, and his assistant.

The woman was booked for treatment. Prior to treatment the woman had an ECG done and bloods taken to assist the doctor to assess her suitability for treatment.

The woman missed her flight to the clinic and arrived one day late for her scheduled treatment. The doctor told HDC that he assessed the woman prior to commencing treatment, including reviewing her blood test findings and ECG, and carrying out a physical examination, but this assessment was not documented.

The treatment was commenced. The first dose of the medicine was administered at 7.50am. Further doses were then administered at 8.50am, 5.45pm, 7.25pm and 8.40pm on the first day, and at 7am the following day. The woman's blood pressure was recorded once at 9am following the administration of the final dose. At midday the doctor then left the country, leaving sole responsibility for ongoing monitoring of the woman with his assistant.

The woman was noted throughout the rest of the day to be lying still sleeping. The assistant carried out her final check of the woman at 11pm that night. At 6am the following day the assistant found the woman was dead, lying in the same position as she had been at the final check.

It was held that the doctor breached Right 6(1) for failing to provide the woman with adequate information about the risks and side effects of the medicine, or about the experimental nature of its use to treat drug addiction. Furthermore, the doctor also breached Right 7(6) for failing to obtain the woman's written informed consent for treatment, which was required because of the experimental nature of the treatment.

The doctor was found to have departed from the treatment protocol, and he did not monitor the woman adequately and therefore breached Right 4(1). He did not keep comprehensive and accurate records and, as such, failed to comply with professional standards and breached Right 4(2).

The assistant was found to have breached Right 4(1) for failing to monitor the woman adequately. Concern is also raised about the assistant's immediate response when she found the woman dead.

The clinic did not operate safely, and failed to provide the woman with services with reasonable care and skill, in breach of Right 4(1).