Clear rules for prescribers must be adhered to when medicines sit at the margin

In New Zealand it is not uncommon for doctors to prescribe unapproved medicines or approved medicines for unapproved purposes. HDC previously considered the use of an approved medicine for an unapproved purpose in a case relating to the prescription of ketamine to patients with treatment resistant depression (11HDC01072).

Recently another case has been concluded which involved the use of an unapproved medicine, ibogaine (13HDC00966). An unapproved medicine is a medicine for which consent has not been given by the Minister of Health for sale, distribution or marketing in New Zealand. Such medications have not been through the Medsafe regulatory process.

Ibogaine is a naturally occurring indole alkaloid derived from the roots of the rainforest shrub *Tabernanthe iboga*. Its use for the treatment of drug dependence is based on anecdotal reports from America and Europe. Ibogaine has diverse effects on the central nervous system and the pharmacological targets underlying the physiological and psychological actions of ibogaine are not completely understood. There is little data available in the scientific literature regarding ibogaine but it has been hypothesised that ibogaine may cause sudden cardiac death up to several days after ingestion.

In 2007 Medsafe concluded that given ibogaine's potential therapeutic use in treating addiction and the need for this treatment to be under supervision, there was a case for classifying ibogaine and its metabolite noribogaine as prescription medications in order to limit attempts at self treatment and prevent their recreational use. Accordingly, in 2010 ibogaine and noribogaine were listed as prescription only medications. However, ibogaine is an unapproved medication.

A GP had become interested in ibogaine and began providing ibogaine treatment at a clinic he operated. A 45 year woman who had a history of opiate drug use consulted the clinic for assistance with her drug addiction and was offered treatment with ibogaine. There was no evidence that the GP had any direct contact with the woman prior to her arrival at the clinic as all communication had been between the woman and the GP's assistant, who was not a trained health professional. There was limited evidence of information having been provided to the woman and she did not sign a consent form. It was unclear whether the woman had received the consent form at all and, in any event, the form was misleading, as it indicated that the risk of death was confined to the circumstances where a consumer combined ibogaine with other drugs. The form provided reassurance that ibogaine was safe and contained no information about the risks of ibogaine or the international evidence of previous adverse effects from ibogaine.

The woman travelled to the clinic and, after examination and assessment of her suitability for treatment, she was treated with six doses of ibogaine. The day the last dose was administered the GP departed to travel overseas, leaving the responsibility for ongoing monitoring of the woman with his assistant. Subsequently, the woman was discovered dead in her bed at the clinic.

Prescribers may prescribe a medicine (if within their scope of practice) to a patient whether or not the medicine is approved in New Zealand. Section 25 of the Medicines Act 1981 allows an authorised prescriber to procure the sale and supply of any medicine for a patient in his or her care. The Medical Council of New Zealand publication, "Good Prescribing Practice" (April 2010) provides that if medicines are unapproved or are used for a purpose for which they have not been approved, the prescribing doctor should take responsibility for overseeing the patient's care, including monitoring and follow up treatment. The publication states that doctors may also like to discuss the patient's treatment with a senior colleague. The doctor should inform the patient:

- whether there are any other options available;
- of any risks, side effects, costs or benefits;
- that the medicine being prescribed is for an unapproved use; and
- that details regarding the supply of the unapproved medicine will be supplied to the Director General of Health.

In this case it was found that it was the prescribing GP's responsibility to oversee the required monitoring and ensure that the woman's vital signs and other physical signs were assessed regularly and recorded. If he was unable to monitor the woman adequately because he would not be present, he should not have commenced the treatment. It was not appropriate for the GP to leave the monitoring responsibility to his assistant.

It was concluded that the doctor's use of ibogaine was experimental and so the requirements of Right 7(6) of the Code of Health and Disability Services Consumers' Rights (the Code) applied, in that informed consent was required to be given in writing. The woman was not sufficiently informed to be in a position to give informed consent to her treatment with ibogaine, as a reasonable consumer in her circumstances would expect to be fully and accurately informed about the risks and side effects of ibogaine and the experimental nature of its use. It was found that the doctor breached Right 6(1) and Right 7(6) of the Code. It was also found that the doctor failed to monitor the woman adequately or keep appropriate records.

If a patient experiences an adverse event while taking an unapproved medicine or a medicine prescribed for an unapproved use, the responsibility rests with the prescriber. The patient's records should include the rationale for prescribing the unapproved medicine and include information about the information discussed with the patient. Prescribers should obtain written consent from patients when prescribing unapproved medicines, particularly where the use of the medicine is experimental. It is also important to put in place and document a plan for monitoring the treatment and any adverse effects.

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