

Did we have the wrong debate about Elixinol™ and medicinal cannabis?

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The recent approval of a cannabis-derived product Elixinol™ for the treatment of a coma patient suffering from *status epilepticus* has renewed the public debate on medicinal cannabis reform in New Zealand.¹ The Associate Minister of Health, Peter Dunne, approved the one-off use of Elixinol™ “on compassionate grounds”, despite the lack of clinical evidence about the efficacy of the product for the treatment of this particular condition.² The public and media debate which followed ignored the fact that Elixinol™ is not a medicine or a pharmaceutical-grade cannabis product.

Elixinol™ is actually marketed and sold as a dietary supplement, with claimed benefits limited to the antioxidant properties of cannabidiol (CBD).³ It is 18% CBD oil extract produced from pressing stalks and seeds of industrial hemp,³ ie, a variety of *cannabis sativa* plant with low tetrahydrocannabinol (THC) content (generally below 0.3%).⁴ Although there is a growing evidence base supporting the therapeutic benefits of CBD,⁵ the US manufacturer of Elixinol™ does not make any therapeutic claims. The product is non-psychoactive as it does not contain any THC, the psychoactive constituent of *cannabis sativa*. Despite being a non-psychoactive and non-medicinal product, in New Zealand Elixinol™ falls either under the Misuse of Drugs Act, 1975 (MODA) which prohibits the use, possession and supply of cannabis preparations, or under the medicines regime if granted ministerial approval for therapeutic use on case-by-case basis (as in the recent case).

Cultivation of industrial hemp is licensed in New Zealand⁶ and there are a number of hemp-derived products available on the

market.⁷ For example, hemp soap is regulated as a cosmetic product, hemp seed oil (a non-psychoactive oil pressed from industrial hemp seeds) is regulated as a food product, hemp protein powder and whole hemp seeds are allowed for sale in animal fodder.⁷ These examples show that the default classification of *cannabis sativa* under the MODA does not preclude regulation of non-psychoactive hemp products under alternative legal regimes, as long as the products comply with the requirements of these regimes, including product safety standards. Non-psychoactive CBD oil extracts, such as Elixinol™, could be regulated in a similar way, resulting in wider access to these products. According to the MedSafe categorisation of products guidelines,⁸ the CBD oil extracts appear to fit under the legal regime for dietary supplements.

The issue of products with broadly the same ingredients being regulated under different regulatory regimes with implications for legal status has assumed greater importance since the enactment of the Psychoactive Substances Act, 2013 (PSA). For example, kava (*Piper methysticum*), a plant traditionally used in Pacific cultures, can be legally sold when it falls under the Food Act (traditional representation as a drink) and the Dietary Supplement Regulations (pills marketed for their nutritional value),⁹ but is currently prohibited as an ingredient in ‘legal highs’, ie, when it is represented as a recreational drug under the PSA.¹⁰ In such a complex regulatory environment, there needs to be greater transparency about how products are classified and more clarity about the legal status of different products.

Competing interests: Nil**Author information:**

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