

**Use of unapproved medication to perform dermal filling procedure
(10HDC00986, 29 June 2012)**

*Medical practitioner ~ Cosmetic procedure ~ Dermal filling ~ Granuloma formation
Informed consent ~ Follow-up care ~ Rights 4(1), 4(2), 6(1), 7(1)*

This case involves a woman who attended a consultation with a medical practitioner as she wanted a cosmetic procedure to help her achieve a healthier appearance. The medical practitioner recommended a procedure called the “mid-face volumisation”, which involved the injection of a dermal filler into her cheeks. The product he used as the dermal filler (the product) was not an approved medicine in New Zealand under the Medicines Act 1981.

The medical practitioner informed the woman that the product included the same chemical compound that he had been using for the previous four years, and that he had considerable experience performing the procedure, but did not inform her that the product was not approved in New Zealand. The medical practitioner did not inform her about the possible side effect of granuloma formation.

Following the procedure, the woman developed granuloma formations, which the medical practitioner was unsuccessful in treating.

It was held that the medical practitioner failed to ensure that the product was safe and appropriate for use as a dermal filler and failed to provide adequate follow-up, breaching Right 4(1) of the Code. He did not provide the woman with information about the risk of granuloma formation or independent clinical literature about the product’s safety, or tell her that the product was not an approved medicine in New Zealand, breaching Rights 6(1) and 7(1).

The medical practitioner was also found to have inadequate documentation and therefore breached Right 4(2) of the Code. He was referred to the Director of Proceedings. The Director decided to issue proceedings, which are pending.