Poisons and Therapeutic Goods Regulation 2008

128I Clinical trials

It is a condition of a licence or authority under Part 8 authorising the use of a designated non-ARTG product in a clinical trial that the holder of the licence or authority must ensure that:

(a) the product is not supplied for the treatment of a person in the clinical trial unless:

(i) the product is supplied for the person on the prescription of a medical practitioner who holds an authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the practitioner to treat the person with the product, and

(ii) in the case of a medicinal cannabis product—the product is supplied at the place identified in the prescription, and

(b) a record is made in the records of the clinical trial of the number of the authority of any medical practitioner who prescribes the product for the treatment of a person in the clinical trial.