

During the Committee's hearing in Canberra on Monday, 30 March 2015, Senator Macdonald asked about doctors and prescribers using a Schedule 8 drug "wrongly" and whether it evoked "criminal sanctions" under state and territory law (see page 34 of the Hansard). I undertook to take that question on notice.

The answer is as follows:

Some Schedule 8 drugs (including DRONABINOL (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use and NABIXIMOLS*) are subject to additional controls on possession or supply as set out in Appendix D (*Additional controls on possession or supply of poisons included in Schedule 4 or 8*) of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard).

DRONABINOL is, under Item 3 in Appendix D, subject to the requirement that it is "available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health under section 19 of the Therapeutic Goods Act". Under that section, prescribers can get approval for the use of unapproved medicines for individual patients under the Special Access Scheme or if they are Authorised Prescribers for the purposes of prescribing that drug, or through the Clinical Trial Exemption (CTX) process.

NABIXIMOLS (which includes Sativex) is, under Item 1 in Appendix D, subject to the requirement that it is "available only from or on the prescription or order of an authorised medical practitioner". As with other aspects of the Poisons Schedule, the limits set out in Appendix D are imposed and enforced under state and territory law, noting that NSW legislation does not pick up Appendix D automatically by reference.

State and territory laws regulate the prescribing of Schedule 8 drugs generally. In relation to their "wrongful" use, it is, for instance, an offence under regulation 78 of the NSW Poisons and Therapeutic Goods Regulations 2008 for a medical practitioner to issue a prescription for a "drug of addiction" (ie one that is in Schedule 8) otherwise than for medical treatment. Offences also are created for nurse practitioners, midwives and dentists. Similarly, under regulation 8 of the Victorian Drugs, Poisons and Controlled Substances Regulations 2006, it is an offence for a registered medical practitioner to administer, prescribe, sell or supply a drug a Schedule 8 poison unless for the medical treatment of a person under the care of the medical practitioner where he or she has taken all reasonable steps both to ascertain the identity of the person and to ensure a therapeutic need exists for the drug.

* Botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.