Australian Government

Department of Health and Ageing

SECRETARY

The Hon Sarah Mitchell MLC
Committee Chair
General Purpose Standing Committee No. 4
Parliament House
Macquarie Street
SYDNEY NSW 2000

Dear Ms Mitchell

I respond to your letter of 13th March 2013 with regard to the current Inquiry into the use of cannabis for medical purposes in New South Wales. In particular, you sought advice with respect to the regulation of the supply of cannabis under the Therapeutic Goods Act 1989.

The *Therapeutic Goods Act 1989* (the Act) regulates the import, export and supply in Australia of certain goods (i.e. those defined as "therapeutic goods" under the Act) by a person who is a sponsor (i.e. the exporter, importer or manufacturer of the goods, as defined under section 3 of the Act). Generally speaking, it is unlawful for sponsors to import, export or manufacture for supply therapeutic goods in Australia if the therapeutic goods are not entered on the Australian Register of Therapeutic Goods (the Register), unless a relevant exemption or authorisation applies.

There is one relevant therapeutic good, a registered medicine, Sativex Oromucosal Spray (nabiximols 80mg/mL pump actuated metered dose aerosol), that is entered on the Register. The specific indication for this medicine is shown on the Public Summary for the entry as "Sativex is indicated as treatment, for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy"

In addition, the Act also provides the framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of poisons in Australia (Part 6-3 of the Act "Scheduling of substances" refers). The Poisons Standard (known as the Standard for the Uniform Scheduling of Medicines and Poisons) includes schedules containing the names or descriptions of substances. These schedules may be referred to under State and Territory legislation for regulatory purposes, which enable restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk and the degree of control recommended to be exercised over their availability in the interest of public health and safety. The Commonwealth also takes into account the

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scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the Act, such as those relating to the advertising of therapeutic goods.

Cannabis is included in Schedule 9 of the Poisons Standard (except (a) when separately specified in another schedule; or (b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre) and nabiximols (botanical extract of Cannabis sativa which includes certain specified cannabinoids - please refer to the Poisons Standard for details- 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, are included in Schedule 8 of the Poisons Standard, with the additional controls on possession or supply in Appendix D, i.e. that nabiximols are poisons 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 and Ageing under section 19 of the Act.

I note that the relevant State/Territory poisons legislation would need to be examined to see how the regulation of the supply, storage, handling, prescribing etc. of the goods within the State/Territory by persons other than the sponsor has been given effect.

In summary, the controls imposed by the Commonwealth and State/Territory jurisdictions deal with different aspects of the regulation of therapeutic goods.

Then, in relation to whether the Act would operate to regulate the supply of any particular product in the future, this will depend upon an application of the law to the facts. That is, it would involve considering such matters as whether the particular product comes within the definition of "therapeutic goods" (which may depend upon any claims made in relation to the goods), whether there is a relevant import, export, manufacture/supply by a "sponsor" and the circumstances of the supply. Should any particular product potentially come within the definition of a "therapeutic good" it would be regulated under the Act and import, export or supply would not be allowed unless the product was on the Register or else had an approval to supply as an unapproved product e.g. through the Special Access Scheme or through a clinical trial. I note that before any registration of a product could occur under the Act, an application from a willing sponsor would be need to be made, with supporting data to assess the product's quality, safety and efficacy.

For completeness, I note the requirements of the Single Convention on Narcotic Drugs, 1961 and subsequent related treaties (e.g. the 1972 Protocol) and draw your attention to the fact that the Convention requires Australia to give effect to measures to prohibit cultivation, sale and use etc. of cannabis, although it contains an exception in Article 4(c) for medical and scientific uses in the obligation imposed to 'limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs'.

I also note that there are other Commonwealth laws relevant to the regulation of cannabis. I particularly note subparagraph 5(10)(b)(iii) of the Customs (Prohibited Imports) Regulations 1956, which allows import permission to be granted for medicinal or scientific purposes in relation to drugs in schedule I and II of the Single Convention on Narcotic Drugs (including cannabis products) and paragraph 5(12) of the Customs (Prohibited Imports) Regulations 1956, which requires that the quantity imported must not exceed the quantity determined for

that year for Australia under the Single Convention on Narcotic Drugs. Cannabis products are border controlled drugs and plants under the Criminal Code Act 1995 and therefore automatically prohibited imports and subject to regulation 5 of the Customs (Prohibited Imports) Regulations 1956. Also, I particularly note the controls required under article 28 of the Single Convention on Narcotic Drugs, which links to article 23, in relation to cultivation and the requirement to have a Government agency responsible for controls.

Yours sincerely

Jane Halton PSM
Secretary

11 April 2013