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

Thank you for your letter of 20th March 2013 requesting information regarding the status of Sativex with respect to the Australian Register of Therapeutic Goods (ARTG). This letter responds to the three substantive questions that you posed.

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.

Advice on the medicines scheduling for Sativex was obtained from the Advisory Committee on Medicines Scheduling in March 2013. That committee recommended that in addition to its Schedule 8 classification, Sativex also be included in Part 1 of Appendix D of the Poisons Standard.

The Poisons Standard consists of decisions of the Secretary or a delegate of the Secretary regarding the classification of poisons into nine different Schedules signifying the degree of control recommended to be exercised over their availability to the public. Medicines included in Schedule 8 are Controlled Drugs. This means they are substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Inclusion in Appendix D means that additional specified controls apply on possession or supply. For Sativex the additional control that was recommended is that Sativex be available only from or on the prescription or order of an authorised medical practitioner.

For Sativex to be considered for approval by the TGA for use in other medical conditions would require that the TGA receive an application to extend the indications for use of Sativex. The application should contain evidence to support the safety and efficacy of Sativex

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for its intended additional indication. The TGA would evaluate that evidence and if it was considered adequate the proposed additional indication would be approved.

Yours sincerely

Jane Halton PSM
Secretary

8 April 2013