The Hon Greg Hunt MP
Minister for Health
Minister Assisting the Prime Minister for the Public Service and Cabinet

Ref No: MC19-016328

Mr Andrew Wallace MP
Member for Fisher
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29 OCT 2019

Dear Mr Wallace Andrew

I refer to your letter of 9 October 2019 on behalf of Mr Herschel Baker concerning medicinal cannabis products supplied in Australia.

Concerning Mr Baker's first question, Sativex (nabiximols) remains the only medicinal cannabis product currently included in the Australian Register of Therapeutic Goods (ARTG).

In order for a medicine to be included in the ARTG, a sponsor is required to submit an application to my Department through the Therapeutic Goods Administration (TGA). However, pharmaceutical companies are private businesses and cannot be compelled by the Australian Government to make an application for registration. In addition, the TGA does not release information about applications under evaluation because it is considered commercial-in-confidence.

Regarding Mr Baker's second question, it is the policy of the Government that medicinal cannabis products are regulated like other medicines. Medicines imported into, supplied in and exported from Australia must be included in the ARTG. However, the therapeutic goods legislation recognises there might be clinical circumstances where there are no ARTG-registered medicines available that are suitable for a particular patient.

In these circumstances, the TGA can authorise supply of medicines not registered on the ARTG, known as 'unapproved' medicines. The pathways that can be used to access unapproved medicinal cannabis products are the same as for other unapproved medicines.

One of these pathways is the Special Access Scheme (SAS). From July 2018 to June 2019, there were approximately 88,000 unapproved medicines authorised or notified for supply through the SAS. In relation to unapproved medicinal cannabis products there have been 17,000 SAS Category B approvals granted to over 1000 individual prescribers as at 30 September 2019.

Finally, regarding clinical trials for medicinal cannabis, the TGA does not conduct clinical trials. However, it does facilitate lawful access to unapproved therapeutic goods in clinical trials by administering the Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes. Most clinical trials using unapproved medicinal cannabis products are conducted under the CTN scheme.

Around half of the clinical trials for unapproved cannabis products are conducted in New South Wales. The rest of the trials are mainly conducted in Victoria and Queensland, while only a small number are conducted in Western Australia and South Australia. Clinical trials that involve the use of 'approved' cannabis products such as Sativex are not subject to CTN or CTX requirements.

My Department is unable to disclose information about individual trials conducted under the CTN scheme. However, currently several trials for unapproved medicinal cannabis are being sponsored by the NSW state government. Information is available at: www.medicinalcannabis.nsw.gov.au/clinical-trials. In addition, currently 32 clinical trials are being funded by both government and private sector companies for unapproved medicinal cannabis products. Public information about these and other clinical trials conducted in Australia is available at: www.australianclinicaltrials.gov.au.

Thank you for bringing Mr Baker's concerns to my attention.

Yours sincerely

Greg Hunt