Australian Government

Australian Government response to the Senate Legal and Constitutional Affairs Committee report:

Inquiry into the Regulator of Medicinal Cannabis Bill 2014

March 2021

Government Response to the Report on the Inquiry into the Regulator of Medicinal Cannabis Bill 2014

Preamble

The Regulator of Medicinal Cannabis Bill 2014 (the RMC Bill) was introduced into Parliament on 27 November 2014. It was referred to the Senate Legal and Constitutional Affairs Committee (the Senate Committee) on 12 February 2015 and the Committee produced a report on 11 August 2015. The RMC Bill lapsed at prorogation of Parliament on 17 April 2016 ahead of the July 2016 election.

On 17 October 2015, the Australian Government announced its intention to amend the *Narcotic Drugs Act 1967* (ND Act) to enable the cultivation of cannabis for medicinal and scientific purposes, consistent with Australia's international obligations relating to narcotic drugs. The changes were enacted on 29 February 2016 and commenced operation on 29 October 2016. These amendments provided a national licensing scheme allowing for the controlled cultivation of cannabis for medicinal and scientific purposes while also allowing the Government to enable a sustainable supply of safe medicinal cannabis products to Australian patients.

The amendments to the ND Act did not govern patient access to medicinal cannabis products as access to all therapeutic goods remain regulated through the *Therapeutic Goods Act 1989* (TG Act). The lead-up to the 2016 amendments included extensive and targeted consultation with the states and territories, including through the Intergovernmental Committee on Drugs. This was seen to be important to ensure that patient access to cannabis-derived products for medicinal use was consistent around Australia, and that there were no gaps in oversight of the supply chain that could be exploited, for example by organised criminal groups.

Recommendations - Report on the Inquiry into the Regulator of Medicinal Cannabis Bill 2014

In its Report on the Inquiry into the RMC Bill, the Senate Committee made six recommendations. These are set out below, followed by a short summary of the Australian Government's response.

Recommendation 1
The committee supports, in principle, the access to products derived from cannabis for use in relation to particular medical conditions where the use of those products has been proven to be safe and effective.

Government response - AGREED
Access to cannabis products for therapeutic purposes is possible principally under the pathways in the *Therapeutic Goods Act 1989* (TG Act), including registration of products in the Australian Register of Therapeutic Goods (ARTG), and access under the 'unapproved' medicines pathways which include the Special Access Scheme, Authorised Prescriber Scheme and through clinical trials.

Recommendation 2

The committee recommends that the Bill is amended, if necessary, to establish mechanisms by which scientific evidence about medicinal cannabis products can be assessed to determine their suitability for use in the treatment of particular medical conditions.

Government response – Not required

Registration of medicinal cannabis products in the Australian Register of Therapeutic Goods (ARTG) provides a mechanism by which the scientific evidence around efficacy of medicinal cannabis products in particular medical conditions can be thoroughly evaluated. In addition, the Commonwealth Department of Health, in conjunction with state and territory governments and with the involvement of leading clinical and patient groups, developed clinical guidance documents in 2017 which reviewed the clinical evidence for the use of medicinal cannabis published in refereed medical journals since 1980 for treating chemotherapy-induced nausea and vomiting, epilepsy, multiple sclerosis, chronic non-cancer pain and palliative care, as well as an overview document.

Additionally, on 6 October 2019, the Minister for Health, the Hon Greg Hunt MP, announced $3 million from the Medical Research Future Fund to examine the benefits of medicinal cannabis for pain, symptom and side effect management for cancer patients.

Recommendation 3

The committee recommends that the Bill is amended to address issues raised about its interaction with the existing Commonwealth regulatory framework for medicinal products, including the Therapeutic Goods Act 1989*, the* Narcotics Drug Act 1967 *and relevant customs legislation.*

Government response– Not required

Interactions between existing Commonwealth regulatory framework were addressed in the 2016 amendments to the ND Act.

Recommendation 4

The committee recommends that the Bill is amended to ensure that medicinal cannabis products can be made available in Australia consistent with Australia's international obligations, including under Articles 23 and 28 of the Single Convention on Narcotic Drugs (1961).

Government response – Not required

The 2016 amendments to the ND Act are consistent with Australia's international obligations, including under the Single Convention on Narcotic Drugs, 1961, as amended.

Recommendation 5

The committee recommends that the Commonwealth government consult with its state and territory counterparts about the interrelationship of relevant laws to ensure a consistent approach to accessing medicinal cannabis and to facilitate compliance with any such access scheme and Australia's international obligations.

Government response - AGREED
State and territory counterparts were consulted in relation to the 2016 ND Act amendments.

The Department of Health coordinates Medicinal Cannabis Access Working Group meetings, held 1-2 times annually as required with representatives from each of the state and territory health departments to promote collaboration across jurisdictions on issues relating to patient access to medicinal cannabis.

Recommendation 6
5.18 Subject to the preceding recommendations, the committee recommends that the Bill be passed.

Government response – Not required to achieve policy aim.
The 2016 amendments to the ND Act and existing provisions within the TG Act provide a scheme allowing for the controlled supply of cannabis for medicinal and scientific purposes.

Patients are accessing medicinal cannabis products in a timely manner via the current access schemes, with over 60,000 prescriptions estimated to have been written for medicinal cannabis by over 2,500 medical practitioners as of 31 August 2020.