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THE LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

Government Response to Standing Committee on Health, Ageing, Community and Social Services

Report No 6 of 2015: Inquiry into the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and related discussion paper

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Government Response

Standing Committee on Health, Ageing, Community and Social Services Report No 6 of 2015: Inquiry into the Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and related discussion paper.

Introduction

On 21 July 2014 ACT Greens Minister, Mr Shane Rattenbury MLA, released an exposure draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (the Draft Bill) and a related discussion paper. The Draft Bill and discussion paper were referred to the Standing Committee on Health, Ageing, Community and Social Services (the Committee) for inquiry and report.

The Committee presented its Report to the ACT Legislative Assembly on Thursday 13 August 2015.

A number of recommendations were made in the Committee's Report, including that the ACT Legislative Assembly reject the proposed Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014.

In total, the Committee made seven recommendations, some containing more than one point.

The ACT Government has responded to each of the recommendations of the Committee below.

Recommendation 1

4.47 The Committee recommends that the ACT Government write to the Commonwealth Minister for Health requesting the Commonwealth Government:

- ***consider including Sativex and Marinol on the PBS to improve affordability;***

Government Response
Agreed in principle
The ACT Government will write to the Commonwealth Minister for Health to request that consideration be given for Sativex to be included on the Pharmaceutical Benefits Scheme (PBS). Marinol is not currently listed on the Australian Register of Therapeutic Goods and will need to be registered prior to any application regarding potential listing on the PBS being pursued. Application to allow the sale of Marinol while unregistered in Australia can be made through the Special Access Scheme (SAS). However, the ACT notes that the decision to supply pharmaceuticals in Australia is a commercial decision that rests with the product sponsor.

It should also be noted that issues around the legal storage and distribution of Sativex will need to be addressed if it is to be remarketed in Australia, as it requires refrigeration.

- ***consider providing easily accessible guidance material to medical practitioners on:***
    - ***how to go about prescribing approved pharmaceutical cannabis products off-label;***

Government Response
Not agreed
There are no regulatory barriers to medical practitioners prescribing registered products for off-label use. However, a prescription itself does not guarantee that the sponsor will make the product available for the off-label purpose requested by a medical practitioner.

Further, the ACT Government considers that off-label prescribing of approved pharmaceutical products is common practice and well understood by medical practitioners.

    - ***the requirements of the Special Access Scheme and associated importation requirements;***

Government Response
Agreed
The ACT Government will write to the Commonwealth Minister for Health suggesting that guidance materials be developed in relation to the Special Access Scheme and associated importation requirements.

- ***simplify off-label prescribing and Special Access Schemes so that the processes can be navigated by medical practitioners with ease and are not excessively protracted; and***

Government Response
Agreed
The ACT Government notes that there are multiple steps involved in accessing the Special Access Scheme. However, these steps are considered necessary to ensure the TGA can meet its obligations of responsibility in maintaining a balance between ensuring individuals gain timely access to important new therapeutic developments and maintaining broader community interest that therapeutic products available in Australia are evaluated for quality, safety and efficacy.

There may, however, be some scope to streamline these processes. The ACT Government will write to the Commonwealth Minister for Health requesting that opportunities to simplify and streamline processes related to the Special Access Scheme be explored.

- ***consider expanding access to approved pharmaceutical cannabis products for additional indications.***

Government Response
Agreed
The ACT Government supports a timely, proactive response from the Commonwealth when new research supports the medicinal use of cannabis in the treatment of additional conditions. For this to occur, the product sponsor must agree to expand the indications for use – a commercial decision. The ACT Government will write to the Commonwealth Minister for Health requesting that the TGA work with relevant sponsors to explore the potential for indications to be expanded.

However, it should be noted that medical practitioners already have the ability to prescribe pharmaceutical cannabis products (through the Special Access Scheme) for any indication they consider appropriate. It is noted that in such cases, the prescriber bears the responsibility for prescribing an unapproved product (as outlined in the Committee's Report) which could be one of the reasons medical practitioners are reluctant to prescribe products for off-label use.

Recommendation 2

5.27.1 To facilitate the research and development of medicinal cannabis and cannabinoid preparations, the Committee recommends that the ACT Government write to the Commonwealth Minister for Health requesting the Commonwealth Government investigate amending the Poisons Standard by:

- ***amending Schedule 9 to facilitate medical or scientific research; and***

Government Response
Not agreed
The ACT Government does not consider that this is necessary as there are already mechanisms under Commonwealth, ACT and other jurisdictions' medicines and poisons legislation to enable medical or scientific research (including clinical trials) with Schedule 9 substances.

- ***moving other non-psychoactive, non-addictive cannabinoids into a lesser schedule as has been done for cannabidiol.***

Government Response
Agreed
The ACT Minister for Health will write to the Commonwealth Minister for Health seeking consideration of the rescheduling of other non-psychoactive, non-addictive cannabinoids into a lesser schedule (as has been done for cannabidiol) where there is appropriate profiling and research.

It should be noted that this would be dependent on industry or another party submitting a rescheduling application to the TGA (as occurred in late 2014 when the Victorian and Western Australian Departments of Health made an application to the Commonwealth to have cannabidiol classified as a Schedule 4 substance, which is the least restrictive schedule for prescription medicines). After public consultation, the decision was made to classify cannabidiol as a Schedule 4 substance from 1 June 2015.

An alternative is for the Commonwealth to prepare its own internal rescheduling submission. There is minimal precedent for this, however, it has been done on occasions (e.g. rescheduling of sodium oxybate).

Recommendation 3

5.28 The Committee recommends that the ACT Government work together with other State, Territory and Commonwealth governments to conduct further clinical trials of pharmaceutical products and crude cannabis.

Government Response
Agreed in principle
The ACT Government will continue to work with the Commonwealth, States and Territory governments on a national medicinal cannabis scheme, noting that is has already given its support to the trials recently announced by the NSW Government.

The actual conduct of clinical trials depends on a number of factors including the funding, methodology (including population size) and availability of product.

The ACT Government will continue to facilitate awareness of the process required to conduct clinical trials within the ACT.

Recommendation 4

5.29 The Committee recommends that the ACT Government work together with other State, Territory and Commonwealth governments to help facilitate ACT patient access to upcoming interstate trials.

Government Response
Agreed
The ACT Government will continue to work with the Commonwealth, State and Territory governments to help facilitate ACT patient access to upcoming interstate trials, where appropriate. The ACT Government has been actively engaged with the process of developing the framework for the recently announced NSW trials.

It should be recognised that many of those patients potentially eligible for upcoming trials in NSW may already be accessing treatment within the NSW medical system, for example, children with complex seizure disorders.

Recommendation 5

9.164 The Committee recommends that the ACT Legislative Assembly reject the proposed *Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014*.

Government Response
Agreed
The ACT Government supports the compassionate intent behind the Draft Bill. However, the practical implementation of the scheme proposed in the Draft Bill would be extremely challenging.

The ACT Government reiterates its support for a national approach and the supply of a regulated, quality-controlled product.

Recommendation 6

10.41 The Committee supports a national approach to medicinal cannabis and encourages the ACT Government to continue to work with the Commonwealth, States and Territory on a national medicinal cannabis scheme.

Government Response
Noted
The ACT Government strongly supports the development of a nationally consistent regulatory framework.

The ACT Government will continue to work with the Commonwealth, State and Territory governments on a national medicinal cannabis scheme, noting the recent support given at a national level to the Regulator of Medicinal Cannabis Bill 2014 (the National Bill).The National Bill proposes the establishment of a national Office of Medicinal Cannabis.

Recommendation 7

10.96 The Committee recommends that if the ACT acts independently of the Commonwealth or other State and Territory jurisdictions on a medicinal cannabis scheme it needs to address the regulatory concerns raised in this report.

Government Response
Noted
The ACT Government agrees that there are regulatory concerns as well as other issues to address in relation to the Draft Bill. These have been outlined previously in the ACT Government's submission to the Standing Committee.

The ACT Government is supportive of the compassionate intent of the Draft Bill and notes that there is scope for further investigation of appropriate means for making medicinal cannabis available in the ACT. It acknowledges recent developments in cannabis policy

nationally. The ACT Government prefers a national approach in which standardized medicinal cannabis products are available.

On 17 October 2015 the Commonwealth Government announced that it would seek parliamentary approval to amend the Narcotics Drugs Act 1967 to allow the controlled cultivation of cannabis for medicinal and scientific purposes in Australia. The Commonwealth expects that material grown under its licensing scheme would be available in 2017 at the earliest.

Commonwealth legislation would facilitate cannabis being grown to manufacture medicinal or research products, and may lead to commercial growers becoming established in Australia. It will be designed to allow 'farm to pharmacy' control of the cannabis crop to be compliant with Australia's obligations under the Single Convention on Narcotic Drugs 1961. The licensing of a commercial supply of cannabis, either in the ACT or another state, could facilitate the provision of standardized medicinal products in the ACT. Commonwealth legislation would not alter the legal status of non-licensed medicinal cannabis products.

The Government of Victoria has, on 6 October 2015, announced its intention to license the cultivation of cannabis for distribution under the authority of a medical practitioner. The exact form of this scheme will not be known until legislation is introduced into the Victorian parliament, and it will take some time for a production and regulatory process to become established. The licensing of a cannabis crop in Victoria will require Commonwealth agreement.

The ACT Government is supportive of the use of medicinal cannabis in a clinical trial setting. Palliative care is a potential area of interest in which clinical trials could be performed in the ACT. However, clinical trials are subject to ethical approval processes, require the engagement of clinicians wishing to conduct them, and have a prescribed duration. The ACT Government cannot dictate these methodological requirements.

The ACT Government is supportive of further investigation of the feasibility of a Terminal Illness Cannabis Scheme (TIC scheme) similar to that which operates in NSW. There are several regulatory models under which such a scheme could operate, including administrative and legislative options for providing legal relief to people possessing cannabis for the management of a terminal illness. A TIC scheme could operate in parallel with the existing Simple Cannabis Offence Notification (SCON) scheme in the ACT.

There are options for capacity building which could assist people accessing medicinal cannabis products. Education of medical professionals as to the appropriate indications and methods of using cannabis is currently lacking and could be formally supported by the tertiary education sector. Laboratory testing of cannabis products would provide information about the medical suitability of strains currently being accessed for medicinal use and could be technically achieved with appropriate laboratory resourcing.

The ACT Government is committed to ensuring that any medicinal cannabis scheme introduced addresses the regulatory concerns outlined in the Standing Committee's Report.