General Purpose Standing Committee No. 4

The use of cannabis for medical purposes

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Executive summary

This unanimously adopted report makes five important recommendations to address the issue of the use of cannabis for medical purposes.

Chapter 1 - Introduction

The inquiry into the use of cannabis for medical purposes was referred by the Legislative Council to General Purpose Standing Committee No. 4 on 22 November 2012. Its terms of reference are set out on page iv. The Committee received a total of 123 submissions and seven supplementary submissions, and held two public hearings on 11 and 18 March 2013. The Committee thanks all who participated in the inquiry, whether by making a submission, giving evidence, or attending the hearings.

Chapter 2 – Cannabis

This chapter provides the foundation for the report by setting out factual information in relation to cannabis and cannabis products. It provides a brief description of cannabis and its chemical substances, discusses the efficacy and safety issues related to the use of cannabis for medical purposes, then documents key policy developments in New South Wales, along with regulatory frameworks in Australia and other jurisdictions.

In this report the Committee use the term 'cannabis' in general terms, to refer to processed, unprocessed and synthetic materials containing cannabinoids. We draw a key distinction between pharmaceutical cannabis products, that is, products containing synthetic or natural cannabinoids in pharmaceutical form, and crude cannabis products in plant, resin or liquid form.

Chapter 3 – Pharmaceutical cannabis products

This chapter focuses principally on pharmaceutical cannabis products, but commences by examining participants' broad views about the potential use of cannabis - in its general sense - for medical purposes. Here it documents participants' views on the priority to be afforded to the issue, ideological considerations and the risks and harms that might arise from the use of cannabis for medical purposes. It then examines views on pharmaceutical cannabis products, noting a number of important advantages of cannabis in this form, before turning to the critical issue of whether there is now sufficient scientific evidence to justify the expanded use of pharmaceutical cannabinoids and for which medical conditions.

The Committee considers that in general terms medical cannabis has potential as an effective treatment for some medical conditions with appropriate safeguards in place. Our reading of the evidence gathered during the inquiry – including rigorous scientific evidence – is that cannabis products are emerging as a promising area of medicine, most notably in respect of a number of painful conditions that do not respond to existing treatments. Given this evidence, a compassionate approach is appropriate here.

While we recognise the risks and negative effects of crude cannabis use particularly via smoking, and by no means do we endorse the recreational use of cannabis, we agree that there is sufficiently robust scientific evidence to indicate that cannabis products can be an effective treatment for certain conditions in very specific circumstances.

We recognise that particular attitudes have perhaps prevented us from recognising and harnessing the therapeutic potential of cannabinoids in Australia to date. Such attitudes include those about the harms

of illicit drugs, along with concerns about how progress in regard to medical cannabis might be perceived by the public and media.

The Committee notes public opinion in relation to medical cannabis, with 69 per cent of people in a recent Australian Institute of Health and Welfare survey indicating that they support legislation to allow medical use of cannabis, matched with 74 per cent of participants showing support for clinical trials investigating the benefits of cannabis for medical conditions.

We consider that on the present medical evidence, cannabis based treatments will only be appropriate for a small number of people in specific circumstances, and under the supervision of medical practitioners with suitable expertise. Those patients would necessarily be people with severe and distressing symptoms that are not able to be addressed by existing medications.

While we are not convinced that allowing medical use of cannabis will lead to greater non-medical use, we do recognise that government needs to be cautious about the messages it sends to the broader community in such a sensitive area of policy, but we are confident that appropriate communication strategies can be developed in this respect.

While we take seriously the harms associated with cannabis, we note the point made in evidence that all medicines have harms that must be balanced against benefits in order to determine their therapeutic potential. We have a robust system in place to make these judgments – the Therapeutic Goods Administration (TGA) regime – and consider any such harms are more able to be controlled in a therapeutic context.

Turning specifically to pharmaceutical cannabis products, we see this as a promising and workable area of reform, not least because such products are by definition subject to a robust regulatory system. Their active ingredients and doses are standardised and their unwanted effects are able to be controlled. In addition, pharmaceutical cannabis products are more acceptable to many individual patients, to the broader community and of course from a law enforcement perspective. Significantly, the product nabiximols (under the trade name Sativex) has demonstrated effectiveness is now available for prescription in Australia for the treatment of a highly specific condition, muscle spasticity arising from multiple sclerosis. While the Committee explicitly does not endorse any particular pharmaceutical product, we recognise that this is presently the only pharmaceutical cannabis product on the horizon for which there is an evidence base that can be recognised by the TGA.

In relation to side effects, we are sufficiently reassured by the available evidence that short term use of pharmaceutical cannabinoids is reasonably safe. It will be very important to build up the evidence base in respect of risks arising from long term use.

While there is clear support for a compassionate approach to the use of pharmaceutical cannabis medications by people in the terminal stages of illness, we recognise the dilemma in providing them to people over a long period in the absence of studies on the effects of long term use. This needs to be balanced with the desirability of relieving serious and distressing symptoms. We feel comfortable with the provision of pharmaceutical cannabis products to such patients over a longer period within the context of careful and ongoing biopsychosocial assessment of the patient by a medical practitioner with recognised expertise in pain management, as is good medical practice and occurs with other medications.

The Committee also notes certain participants' views regarding the urgent need for more options to treat pain, and that there is ample scientific evidence to justify the introduction of cannabis

pharmacotherapies. At the same time, we appreciate the need for such products to be subject to standard regulatory processes. As a committee of the NSW Parliament we urge in the strongest possible terms that action proceed as quickly as possible to enable access by various groups of patients to medicine which could have a profoundly relieving effect.

The Committee respects that other target groups will be appropriately determined over time, according to the proper evidence based processes of the TGA. At the same time, we underscore that there is strong evidence on efficacy in relation to a range of conditions, and consider that access by patients should not be determined by the commercial decisions of pharmaceutical companies alone.

We thus strongly encourage the expansion of the evidence base across a range of treatment groups, as well as the development of products by other companies. We are especially mindful here of people suffering from chronic pain for whom existing pain management is not effective.

Finally, the Committee underscores that the affordability of pharmaceutical cannabis products will be a critical determinant of patient access, and like numerous inquiry participants, we observe that many patients who would benefit from these products are of very limited means at a most vulnerable time of their lives. We agree that the affordability of such products would appropriately be addressed via the Pharmaceutical Benefits Scheme.

The Committee notes that the NSW Government's role in this regulatory area is extremely limited, and that we are unable to make recommendations to the Commonwealth Government. We consider it appropriate, however, for the NSW Minister for Health to write to the Commonwealth Minister for Health and Ageing, expressing in principal support for the timely, evidence based expansion of access to approved pharmaceutical cannabis products by additional patient groups including those suffering from chronic pain for whom existing pain management is not effective, for further clinical trials of pharmaceutical cannabis products to continue to build this evidence base, and for approved pharmaceutical cannabis products to be affordable to patients.

Chapter 4 – Crude cannabis products

Chapter 4 explores participants' views on whether and how the use of crude cannabis products for medical purposes might be decriminalised. First, it presents the arguments put forward by a number of inquiry participants that a pharmaceutical approach, as proposed in the previous chapter, will not be sufficient to address this policy issue at this time. It then paints a picture of current use of crude cannabis for medical purposes, and notes participants' comments on the present legal consequences of such use. The Committee then charts participants' arguments for and against reform, before setting out the alternative models for reform presented to us which would provide for the legal use of crude cannabis for medical purposes.

While there was general agreement among inquiry participants about allowing use of pharmaceutical cannabis products for medical purposes in certain circumstances, the use of crude cannabis products such as plant material, resin or liquids was understandably more controversial.

The Committee agrees with the argument put forward by the majority of inquiry participants that provision be made for a very small and specific group of patients to use crude cannabis products for medical purposes legally.

Ideally, pharmaceutical cannabis products would be of sufficient efficacy and safety as to provide relief to patients who experience severe and distressing symptoms that do not respond to existing

medications, most especially people in the end stage of terminal illness. However, the only pharmaceutical cannabis product currently approved for use is allowed for a single specific indication, namely muscle spasticity arising from multiple sclerosis. As the TGA approval process is lengthy, it is likely to take years before the use of Sativex for other conditions might be approved. In addition, we are very mindful that unless subsidised by the taxpayer under the Pharmaceutical Benefits Scheme, this product would be unaffordable to many, who as we noted in the previous chapter, will be of very limited means at a most vulnerable time in their lives. We further recognise that the effectiveness of pharmaceutical cannabinoids will vary from individual to individual. In these and other understandable circumstances, some patients will use crude cannabis products.

Indeed, it is a given that some patients are already using crude cannabis for medical purposes, and we received evidence that this is often occurring with the knowledge of their doctor, and sometimes at his or her recommendation.

The Committee agrees with the argument put forward by inquiry participants that a compassionate approach that recognises individual needs and choices is highly desirable and morally justified. We have some sympathy for the argument that patients can be trusted to make the best decisions for themselves, and that it is preferable that they do so under the guidance of their doctor.

The Committee considers that provision should be made to allow medical use of cannabis by patients who have been advised by their treating specialist that they have end stage terminal illness, and those who have moved from HIV infection to AIDS.

We believe, like almost all inquiry participants, that people with terminal illness who take measures to relieve their severe pain should not be criminalised. While presently the Cannabis Cautioning Scheme provides a 'safety net' in these circumstances, it is a very limited and discretionary one. The Committee considers it important to protect this small and highly vulnerable group from any criminal justice consequences for their end stage health condition. Such individuals should not be subject to the humiliation and stress of arrest and appearing in court, and indeed, should be able to rest in the knowledge that they are actively protected from such consequences.

Thus we consider that a system which qualifies this group for the use of cannabis for medical purposes should be established by providing a complete defence from arrest and prosecution. We believe that this could be achieved via amendment to the *Drug Misuse and Trafficking Act*, by adding a complete defence to the list of present defences for use and possession, so as to cover the authorised medical use of cannabis.

We recommend that in order to qualify for the exemption that we are envisaging, a patient would need to be certified by their treating specialist medical practitioner as having been diagnosed with a specific incurable condition. Such a certificate would make the person and their carer eligible for inclusion on a register of 'authorised patients and carers' held by the NSW Ministry of Health. Registration would make the patient eligible to possess up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and to use but not supply cannabis. Upon registration, the patient and their carer would be issued with a photo identification card, linked to the register, which he or she would produce for inspection in the event that they are found by police to be in possession of cannabis. It is the Committee's intention that police take no action in respect of such possession or use, but that if arrest and charge do occur, the defence would protect the individual from criminal sanction. It will be important for Police to receive training which makes clear this intention.

The Committee is satisfied that providing an exemption from arrest and prosecution for personal possession and use would not in itself conflict with Commonwealth law. However, the supply of seeds, plants and equipment to a patient, whether by a carer or another third party, may contravene the *Therapeutic Goods Act*. We believe that provision should be made to exempt carers from arrest and prosecution for possession and supply (in order to provide a product to the patient) under New South Wales law, but note that they would remain vulnerable under Commonwealth law. We trust that Commonwealth law enforcers will adopt a compassionate approach to such persons, who are categorically different to other 'suppliers' as are captured by Commonwealth law.

At the same time, the Committee recognises that the issue of supply needs further careful and detailed consideration, as it was not possible for the Committee to examine it in sufficient detail within the timeframe for this inquiry. We believe that it would be preferable for patients and carers to purchase crude cannabis products, seeds and equipment legally. We recognise that this may not be realistic in the present environment.

The Committee acknowledges the many powerfully argued submissions made to us by people with chronic debilitating pain who wish to use cannabis legally to treat their medical conditions. We empathise strongly with them and take at face value that cannabis is an effective treatment for them. However, owing to the present absence of evidence on the long term effects of cannabis use, and the risks associated with smoking it, the Committee considers that at this stage, the target group for this provision should not include people with chronic conditions. This exclusion would apply to people with multiple sclerosis, although we note that in certain circumstances they can now access the pharmaceutical cannabinoid Sativex.

We further consider that the legislative amendments would appropriately exclude the use and supply of cannabis in a public place, and that a three year review of the amendment be written into the legislation. It would be valuable for the Ministry of Health to proactively prepare for this review by collecting qualitative and quantitative data, including from medical practitioners, patients and carers, from the commencement of the register.

We believe that provision for the legal use of cannabis for medical purposes within the context of an ongoing therapeutic relationship with a specialist medical practitioner will ensure two things: first, that eligibility is well guarded; and second, that the appropriate level of clinical oversight is afforded to this cannabis use. As with certain pharmaceutical products, we envisage that such specialist medical practitioners would necessarily provide ongoing 'biopsychosocial' assessment of the patient, noting the impact of this particular treatment on patients' pain and holistic functioning.

The Committee considers the risk of diversion arising from our recommendations to be minimal, given the very tight restrictions that we envisage on eligibility and on the amount of cannabis that might be possessed, as well as the present availability of cannabis within the community. We believe that the community will be prepared to tolerate this small risk on compassionate grounds, in light of the potential benefits to a very restricted group of eligible patients, not all of whom would pursue this option anyway.

We believe that the cost of regulating this system would not be significant, and would be offset to some extent by the police not taking action with respect to this group, as well as the court system not having to adjudicate such matters. We also consider that such a move is unlikely to normalise or legitimise broader cannabis use within the community. Nor is it intended to glamourise cannabis to potential recreational users.

Finally, we recommend that the Government accompany these reforms with an education strategy informing the medical profession, community and relevant patient groups about the changes to be brought about. This should include information for patients on the possible harms of smoking cannabis and on other methods of cannabis consumption than smoking

Summary of recommendations

Recommendation 1 **41**

That the Minister for Health write to the Commonwealth Minister for Health and Ageing, expressing in principal support for:

- the timely, evidence based expansion of access to approved cannabis pharmacotherapies by additional patient groups, including those suffering from chronic pain for whom existing pain management is not effective
- further clinical trials of pharmaceutical cannabis products to continue to build this evidence base, and
- approved pharmaceutical cannabis products to be affordable to patients.

Recommendation 2 **71**

That the NSW Government introduce an amendment to the *Drug Misuse and Trafficking Act 1985* to add a complete defence to the use and possession of cannabis, so as to cover the authorised medical use of cannabis by patients with terminal illness and those who have moved from HIV infection to AIDS. The features of this system would include:

- provision of a complete defence from arrest and prosecution for the use of cannabis and possession of up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and equipment for the administration of cannabis, by the patient
- provision of a complete defence from arrest and prosecution for the possession and supply of up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and equipment for the administration of cannabis, by the patient's carer
- that the defence be restricted to persons listed on a register of 'authorised cannabis patients and carers', with eligibility contingent upon certification by the patient's treating specialist medical practitioner that the patient is diagnosed with a specified condition
- the defence would only apply where the use and supply of cannabis does not occur in a public place, and
- a review of the amendment commence within three years of the date of commencement.

Recommendation 3 **72**

That, consistent with Recommendation 2, the NSW Ministry of Health establish and administer a register of 'authorised cannabis patients and carers' certified by the patient's treating specialist medical practitioner and issue patients and carers on this register with a photo identity card verifying that they qualify for exemption from arrest and prosecution.

Recommendation 4 **72**

That the NSW Ministry of Health and Department of Attorney General and Justice give further and detailed consideration to the issues surrounding lawful supply of crude cannabis products for medical purposes.

Recommendation 5 **72**

That the NSW Ministry of Health implement an education strategy to accompany the legislative amendment set out in Recommendation 2 to inform the medical profession, community and relevant patient groups about the intentions and provisions made under the amendment. This should include information for patients about the harms that accompany smoking cannabis, and alternative forms of administration.