

# **Report of the Working Party**

**on the**

## **Use of Cannabis for Medical Purposes**

**VOLUME I**

**EXECUTIVE SUMMARY**

**AUGUST 2000**



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The Honourable Bob Carr MP  
Premier of New South Wales  
Parliament House  
Sydney, NSW 2000

Dear Premier

As Chair of the Working Party on the Use of Cannabis for Medical Purposes I have pleasure in presenting the Final Report of the Working Party that you appointed in August 1999.

The Working party has reviewed the scientific evidence on the safety and efficacy of cannabis (the plant that is usually smoked) and cannabinoids (substances derived from those uniquely found in the cannabis plant, or those that act on the same brain receptors) used for medical purposes. It has also considered legal advice on the ways in which cannabis and cannabinoids may be made available for medical purposes that do not contravene International Drug Control Treaties to which Australia is a signatory.

In light of the evidence, the Working Party has agreed with the conclusions of the British House of Lords and the United States Institute of Medicine that some cannabinoid substances may have value in the treatment of a limited range of medical conditions, namely, HIV-related wasting, nausea caused by cancer chemotherapy, muscle spasm in some neurological disorders, and pain that is unrelieved by conventional analgesics. The Working Party has made recommendations on the type of research that is required to better assess the therapeutic value of cannabis and cannabinoid substances in these conditions.

The Working Party has concluded that crude cannabis cannot be prescribed and is unlikely to ever be prescribed in Australia. There are also substantial obstacles to the medical prescription of cannabinoid substances. At best it will be some years before any cannabinoid drugs are registered for medical use in Australia. Given evidence that patients with some of the conditions indicated are currently using smoked cannabis for therapeutic reasons, the Working Party has recommended a regime for limited compassionate provision of cannabis to patients who may benefit from its use. This is as an interim measure until medical cannabinoids become available. It would allow limited medical exemptions to criminal prosecution to patients who have been certified as suffering from a restricted set of medical conditions by an approved medical practitioner who has also counselled them about the risks of smoking cannabis.

The Working Party hopes that this report will assist the Government and the Parliament in deciding how best to address the needs of patients who may benefit from the medical use of cannabis and cannabinoid drugs. We also trust that it will contribute to a more informed public debate on the medical uses of cannabis and cannabinoids in New South Wales.

Yours sincerely



Wayne Hall  
Chair  
Working Party on the Use of Cannabis for Medical Purposes



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The Working Party would also like to acknowledge the able contribution that Carl Green made as Secretary to the Working Party from August 1999 until May 2000. Phil Berry provide similar assistance to the Working Party in the final two months of its term.

We would also like to thank Eithne O'Donovan for her work in editing the draft report and her helpful suggestions for the structure of the final report.

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# 1 EXECUTIVE SUMMARY<sup>1</sup>

## 1.1 INTRODUCTION

The use of cannabis for medical or any other purposes is currently prohibited in all Australian States and Territories, although penalties for possession and use differ between jurisdictions<sup>2</sup>.

Over the past decade, there has been considerable controversy about the possible therapeutic uses of the *Cannabis sativa* plant, and the chemical substances (cannabinoids) it contains, for patients with certain medical conditions.

This report on the therapeutic potential of cannabis has been prepared by a group of clinicians, lawyers and researchers, who were asked to advise the NSW Government on:

- whether the NSW government should allow patients with some medical conditions to use cannabis for medical purposes; and
- if so, how this might be achieved without legalising or decriminalising the recreational use of cannabis.

In examining these issues, the Working Party:

- consulted two major reports, published recently in the US (The US Institute of Medicine) and UK (The House of Lords Select Committee on Science and Technology), on the medical uses of cannabis;
- analysed submissions received from interested parties;
- examined the scientific literature on the safety and effectiveness of cannabis and its constituent cannabinoids for medical purposes;
- considered the legal and logistical issues that would arise if cannabis were to be used for certain medical conditions; and
- explored ways in which cannabis and cannabinoids might be made available to people with certain medical conditions without contravening existing Commonwealth and State law or the international drug control treaties to which Australia is a signatory.

### 1.1.1 RECENT REPORTS ON THE THERAPEUTIC VALUE OF CANNABIS

The Working Party consulted two recent reports the medical uses of cannabis and cannabinoids – one from by House of Lords Select Committee on Science and Technology (SCOST) in the UK, and the other from the Institute of Medicine (IOM) in the US. Both reports found that cannabinoids have potential for use with certain medical conditions and that there was a need for further research on the clinical uses of crude cannabis plant products and cannabinoid compounds.

The reports also recommended that, while awaiting the results of this research, cannabis be made available on compassionate grounds to patients with a limited range of life-threatening and chronic health conditions, where there is evidence to suggest that they may benefit from its use. The nominated medical conditions

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<sup>1</sup> Detailed documentation of the material presented in the Executive Summary is presented in Volume II of the Working Party's Report.

<sup>2</sup> Ali et al (1999)

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included: HIV-related wasting; nausea and vomiting caused by cancer chemotherapy; neurological conditions such as Multiple Sclerosis; and pain unrelieved by conventional analgesics.

### 1.1.2 SUBMISSIONS TO THE WORKING PARTY<sup>3</sup>

The Working Party received many submissions (both invited and volunteered) from a wide range of interested parties, including: drug and alcohol interests; pharmaceutical interests; professional health and welfare associations; and community based health and welfare bodies. These submissions covered the following issues:

- the pharmacology of cannabis
- current cannabis use by patients
- health risks (with a heavy emphasis on the risks of smoking cannabis)
- methods of administration
- value of cannabis for certain medical conditions
- legal issues (supply and availability of cannabis )
- effects of current criminal sanctions on both patients and health professionals
- community education

The following is a summary of key points.

- Cannabis is a crude plant product, which contains a complex mixture of many chemicals. This makes production of a standard cannabis product extremely difficult, as it is not clear which chemicals are responsible for particular therapeutic effects. Cannabis smoke also contains a variety of substances that are dangerous to health.
- In Australia, cannabis use for medical purposes is reported to be common among gay men who are HIV positive and people with cancer.
- The health risks of cannabis use need to be considered. These include the adverse effects of cannabis on motor skills and on the mental health of vulnerable individuals. These health risks should not rule out the use of cannabis for medical reasons, but they must be taken seriously, particularly if long-term cannabis use is being considered for the treatment of a chronic condition.
- Several submissions noted that the use of cannabis by smoking posed health risks; others noted that smoking allowed better dose titration than other routes of administration, such as eating. Many submissions recommended that other ways of taking cannabis for medical purposes, or alternative cannabinoid products, should be developed.
- Submissions which advocated medical use of cannabis did so on the basis that cannabis may be appropriate as:
  - an anti-nausea agent during chemotherapy when first-line treatments have failed;
  - a treatment for wasting conditions and appetite loss among patients with cancer and HIV/AIDS;
  - a treatment for chronic pain.
- There were conflicting ideas on the use of cannabis in multiple sclerosis and chronic conditions involving muscle spasticity.

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<sup>3</sup> All submissions received are reproduced in Volume II of the Report.

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- There was little support for the use of cannabis to treat glaucoma, because of the high doses required and the need for chronic use to control the underlying disease process.
  - Several submissions recommended that cannabis be supplied for medical purposes and gave the following comments/suggestions:
    - obtaining an illegal substance placed an additional burden upon ill persons;
    - registered growers/buyers' co-operatives were proposed as a supply source;
    - legislative changes were suggested to remove legal sanctions against medical cannabis users.
  - Several groups supported the idea that cannabis should be prescribed by authorised practitioners.
  - Those who were opposed to the medical uses of cannabis were concerned about the social implications, particularly the possibility that medical use may promote recreational use.
  - Almost all submissions supported further research and clinical trials to obtain more information about the medical benefits of cannabis use.

### **1.1.3 THE APPROACH ADOPTED BY THE WORKING PARTY**

In describing its inquiries and recording its conclusions about the feasibility of using cannabis and cannabinoids for medical purposes, the Working Party divided the subject into two key areas:

- medical and therapeutic issues;
- legal and logistical (or regulatory) issues.

For clarity and consistency, the Working Party's findings and recommendations are similarly divided, even though many of the issues are interconnected and there are inevitable areas of overlap.

The division into two key areas was logical, since the substance of the Working Party's recommendations concerning the use of cannabis for medical purposes will determine the legal and logistical issues likely to arise and how these issues should be addressed.

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## 1.2 MEDICAL AND THERAPEUTIC ISSUES

### 1.2.1 CANNABIS AND CANNABINOIDS

The medicinal properties of cannabis have been recognised for thousands of years. Physicians in ancient China used it to relieve constipation, loss of appetite, and pain during childbirth. With the development of synthetic drugs in the 20<sup>th</sup> century, herbal remedies in general fell into disuse.

**The natural plant product:** The female *Cannabis sativa* plant contains both cannabis and cannabinoids (chemicals which act upon cannabinoid receptors in the body). The primary psychoactive component of cannabis is tetrahydrocannabinol (THC).

Cannabis may be smoked in a “joint” the size of a cigarette, or in a water pipe (“bong”). It may also be eaten; but smoking is the more common because it is the easiest way to achieve the desired effects.

Recent research has revealed that cannabinoids act on two types of receptors in the body (CB<sub>1</sub> and CB<sub>2</sub> receptors). The cannabinoid, THC, acts upon the CB<sub>1</sub> receptor, which is found in the regions of the brain involved in thinking, memory, pain perception, and motor co-ordination. Research to date suggests that THC is the most effective cannabinoid for alleviating nausea and vomiting and for stimulating appetite; research evidence for its other possible medical uses is limited.

**Synthetic cannabinoids:** Cannabinoids can also be synthesised in chemistry laboratories. The two synthetic cannabinoids that have been developed in this way are:

- dronabinol (a synthetic form of THC) which has been approved for use in the US;
- nabilone which has been approved for use in the UK.

In Australia, some HIV patients were given dronabinol under the **Special Access Scheme**. This was not very successful because the dronabinol had to be taken orally and patients found it difficult to titrate (fine-tune) the desired dose. Dronabinol was also very expensive – a significant deterrent for HIV patients with limited incomes.

### 1.2.2 POTENTIAL MEDICAL AND SCIENTIFIC USES OF CANNABIS

The numbers of ill Australians who currently break the law by using illicit cannabis for medical purposes is unknown. The numbers who might use cannabis for medical purposes if they did not risk criminal prosecution is also unknown. US experience suggests that the primary medical users are people with HIV-related wasting, cancer patients with nausea and vomiting, and people with chronic pain.

The primary medical use of cannabis and cannabinoids is relief of symptoms rather than cure of underlying disease. The IOM and SCOST reports concluded that the conditions for which cannabis has therapeutic potential include:

- HIV-related and cancer-related wasting;
- pain unrelieved by conventional treatments
- neurological disorders including (but not confined to) multiple sclerosis, Tourette’s syndrome, and motor neurone disease;
- nausea and vomiting in cancer patients undergoing chemotherapy, which does not respond to conventional treatments.

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In evaluating the available research on these conditions/symptoms, the Working Party used conventional medical standards of evidence.

#### WASTING SYNDROME AND APPETITE STIMULATION

Wasting syndrome in HIV is the involuntary loss of more than 10 per cent of average body weight. Anorexia can be caused by medications, mouth ulcers, diarrhoea, or depression; cachexia (the loss of lean body mass) can be caused by infections or tumours or the disease itself. There has been little research on the effectiveness of cannabinoids for treating these symptoms. Synthetic THC has been shown to be effective in the short term and dronabinol has been registered for this use in the US. Some HIV/AIDS patients do not like dronabinol because of its side effects; because it has to be taken orally they have difficulty titrating the required dose; and its onset is delayed and the duration of its effects is prolonged. As far as cannabis smoking by HIV/AIDS patients is concerned, the problem is complicated because they may be susceptible to any immunosuppressive effects of cannabis smoke and to micro-organisms present in the plant material.

#### PAIN MANAGEMENT

Research with animals suggests that cannabinoids may be useful as analgesics. The most promising evidence in humans comes from three controlled clinical studies of patients with severe cancer pain that had not responded to traditional treatment. The studies found that cannabinoids had moderate analgesic effects without the side effects of opioids and they improved appetite and mood. Cannabinoids may also improve the analgesic properties of opioids in patients who have not responded well to this treatment.

#### NEUROLOGICAL DISORDERS

There are claims that cannabis: reduces muscle spasticity in multiple sclerosis (MS) and spinal cord injury (SCI); improves movement disorders such as Parkinson's disease, Huntington's disease and Tourette's syndrome; and controls epilepsy.

- *Muscle spasticity*: Recent animal research suggests that the cannabinoid system may play an important role in controlling both spasticity and tremor. Muscle spasticity is common among MS patients (up to 90 per cent) and among SCI patients. Limited clinical surveys of cannabis use for muscle spasticity, and open studies in MS patients, report positive effects. Better studies are needed to evaluate the therapeutic effects of cannabinoids in these conditions.
- *Movement disorders*: There is some evidence of the value of cannabis for movement disorders (e.g. Tourette's syndrome) and more promising evidence of its value in the treatment of spasticity. The anxiety-relieving effects of cannabis may also help patients with movement disorders, since stress can exacerbate their symptoms.
- *Epilepsy*: Evidence of the value of cannabis for treating epilepsy patients comes from case reports and an observational study. Both of these sources suggest that cannabidiol (CBD), rather than THC, has the anticonvulsant effects. Clinical studies are not warranted.

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## GLAUCOMA

This disease is caused by elevated intraocular pressure (IOP). It is a chronic condition that causes blindness if untreated. Cannabis reduces IOP by about 25 per cent for three to four hours but its effects are too short-lived, and the doses required too high, to recommend long-term use for this purpose. Other, longer acting cannabinoids, with fewer psychoactive effects than THC, may be more useful.

## NAUSEA AND VOMITING

Most reports on the anti-emetic effects of cannabis have focused on the nausea and vomiting which accompany chemotherapy and sometimes prompt patients to abandon this treatment. Studies conducted in the 1970s and 1980s found that THC showed some modest anti-emetic effects. The recent development of new, more effective anti-emetic drugs has reduced interest in THC, although it may still be useful for patients who have not responded to existing anti-emetic drugs. There is little research evidence for the use of smoked cannabis for these therapeutic purposes.

## PSYCHOLOGICAL EFFECTS

People who have not previously used cannabis may find its psychoactive effects disturbing. On the other hand, patients with wasting conditions may benefit from a drug that simultaneously improves appetite and reduces pain, nausea, anxiety and distress.

### 1.2.3 POTENTIAL RISKS OF CANNABIS USE

#### TOLERANCE, PHYSICAL DEPENDENCE, AND WITHDRAWAL SYMPTOMS

Many drugs, both medicinal and non-medicinal, produce tolerance, physical dependence, and withdrawal symptoms. Chronic use of cannabis produces tolerance to many of the acute effects of THC. There is also evidence of withdrawal symptoms in heavy cannabis users, although these are milder than the withdrawal symptoms that accompany sudden abstinence by people who are alcohol- or opioid-dependent. The risk of dependence should not preclude the medical use of cannabinoids or cannabis: when faced with chronic, debilitating and life-threatening conditions, patients and their doctors may consider that the risk is worth taking to secure the therapeutic benefits.

#### PROGRESSION TO OTHER DRUG USE

The extent of *non-medical* or recreational use of cannabis among adolescents is an important predictor of their progression to other illicit drug use. Explanation of the reasons for this relationship remains controversial. It is unlikely, however, that a similar pattern of progression would apply to adults over the age of 35 years who were using cannabis for *medical* purposes.

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## LINK BETWEEN MEDICAL USE AND DRUG ABUSE

Some argue that the use of cannabis for medical purposes would undermine education programs warning of the dangers of cannabis and other drug use. The IOM report considered the following evidence on this issue: i) experience with the medical use of opioids; ii) the impact of decriminalising cannabis on rates of use; iii) the effects of the 1996 medical marijuana campaign on the perceived risks of cannabis use. The report found that:

- very few opioid dependent people start by using prescribed opioids;
- diversion of pharmaceutical opioids is not a major source of illicit opioids;
- medical use of cannabis is unlikely to be more of a problem than medical use of opioids.

Studies have also failed to find any impact of decriminalisation on rates of cannabis use. In the US, household surveys of drug use found that the perceptions of respondents in California (where the use of cannabis for medical purposes had been decriminalised) were no different from those of respondents in other states.

## DANGERS OF SMOKING

Most of the evidence of the harmful effects of cannabis relates to people who have smoked the substance; yet except for the psychoactive effects (which are due to THC), it is not possible to distinguish between the effects of the cannabis and the effects of smoke inhalation. Advocates of the medical use of smoked cannabis argue that this method of administration allows patients to titrate the required dose and so obtain the maximum therapeutic effects of THC. Smoking is not, however, a desirable method of administration for any therapeutic drug because it is an unreliable way of administering THC and smoking also delivers toxic and carcinogenic substances to the lungs.

## ACUTE ADVERSE EFFECTS OF CANNABIS

The main *acute* adverse effect of cannabis use is impaired psychomotor performance, which may affect a person's ability to drive or operate complex equipment safely. The acute side effects are within the range tolerated for other medications. The immunosuppressive effects are not well established; if they exist they are probably not great enough to preclude medical use.

## CHRONIC ADVERSE EFFECTS

The *chronic* effects of long-term use of cannabis for medical purposes are more significant. The most serious problems are caused by smoking. Cannabis smoke is associated with increased risk of cancer, lung damage and poor pregnancy outcomes, and so this method of administration is unlikely to be safe treatment for any chronic medical condition. Another concern about chronic cannabis use is the risk of developing dependence on the psychoactive effects of THC. This risk is small for most people, but greater for those with psychiatric disorders (including substance dependence). These patients should be advised against using cannabis. Adolescents with substance use problems or conduct disorders are also vulnerable.

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#### 1.2.4 DEVELOPMENT OF CANNABINOID DRUGS

A pharmaceutical company's decision to conduct pre-clinical and clinical research into a new drug is based on a judgement of the likely return on their investment. The research and development costs of cannabis are likely to be extremely high, and costs of meeting US Drug Enforcement Agency (DEA) requirements make it even higher. One synthetic cannabinoid has been developed in the US – dronabinol. The experience with dronabinol has been atypical because the US Government funded most of the research and development of this cannabinoid drug.

The development of cannabinoid drugs is likely to be difficult, given a) the small number of products in development; and b) the small size of the companies that have sponsored these products. Commercial interest in bringing the products to market is reduced by the inability of companies to patent a naturally occurring substances and the likelihood that any medically useful synthetic cannabinoids will be placed in the most restrictive schedule for medical use.

At present, there are no alternative ways of administering cannabinoids that are reliable and inexpensive and would permit easy dose titration, thereby eliminating the need to smoke cannabis. The Working Party concluded that further research is needed to develop and test alternative routes of cannabinoid administration. Locally invented nebulisers and inhalers hold the greatest promise for this purpose. Research into sublingually administered lozenges may also be fruitful.



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## 1.3 LEGAL AND REGULATORY ISSUES

Since cannabis is a prohibited drug in all Australian States and Territories, the Working Party's findings and recommendations concerning its therapeutic use raise a number of legal and regulatory issues.

This section considers those issues and presents various options that would allow cannabis to be made available in New South Wales *solely for defined medical purposes*. Decriminalisation and non-medical use are separate issues and outside the scope of this report.

The task of the Working Party was to consider ways of making cannabis and/or cannabinoids available in a way that would:

- be consistent with international agreements and Commonwealth and State laws;
- be practically feasible and easy for the police to enforce;
- respond to legitimate community concerns;
- provide access only to patients with serious illnesses who may benefit from its medical use.

The Working Party's first step was to examine the legal constraints imposed by existing laws and regulations on the use of cannabis and cannabinoids for therapeutic purposes and scientific trials; the second was to develop legal options and models to deal with these constraints without breaching existing laws and regulations.

### 1.3.1 INTERNATIONAL CONVENTIONS

States which are signatory to international conventions have an obligation to ensure that their domestic laws are consistent with the requirements of those conventions. In Australia, only the Commonwealth Government signs international conventions and they do not automatically become part of domestic law unless brought into effect by legislation. Generally, as a matter of principle, States and Territories comply with international conventions but they are not expressly prevented from passing or retaining inconsistent laws. It is, therefore, the responsibility of the Commonwealth Government, which has the power to over-ride inconsistent State and Territory laws, to ensure national implementation of these agreements.

The following international agreements to which Australia is signatory affect the use of cannabis for medical purposes:

- the United Nations' Single Convention on Narcotic Drugs 1961, which aims to codify all existing conventions and the obligations of signatory states under those conventions;
- the UN Convention Against Illicit Traffic in Narcotic Dangerous Psychotropic Substances 1988, which extended the provisions of the Single Convention to a range of behaviour and mood altering drugs but distinguished between those which are totally prohibited and those, such as cannabis, which may be used for restricted medical purposes.

Although the main purpose of these conventions is to eliminate the use of illicit drugs, they also recognise that some of these drugs can be useful for medical and scientific purposes and contain provisions to cover this use. In using cannabis for research and clinical purposes, Australia would not, therefore, be in breach of any international treaty obligations. In some signatory states, the UK for example, it is lawful to possess cannabis and most of its derivatives for the purposes of medical research. The definition of "medical and scientific purposes" is sufficiently broad to allow the prescription or certification of cannabis use for the treatment of medical conditions.

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### 1.3.2 COMMONWEALTH LEGISLATION

#### BEARING ON AVAILABILITY FOR MEDICAL /COMPASSIONATE USE

Commonwealth powers in relation to trade and commerce and external affairs have a critical bearing on the use of cannabis in New South Wales for therapeutic purposes and clinical trials.

Legislation relevant to this issue includes:

- *Customs Act 1901* (Cth)
- Customs (Prohibited Imports) Regulations
- *Narcotic Drugs Act 1967*
- *Therapeutic Goods Act 1989* (Cth)
- *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*

These laws give the Commonwealth controls over the importation of cannabis and extensive powers in relation to therapeutic goods. For cannabis to be imported legally for medical or scientific purposes, the Commonwealth Department of Health and Aged Care would have to give the International Narcotics Control Board an estimate of the amount required. Further investigation is needed to establish whether these obstacles at the Commonwealth level may be overcome.

The *Therapeutic Goods Act* establishes an Australian Register of Therapeutic Goods (ARTG) and makes special provision for goods not on the Register to be used in clinical trials. There are currently no cannabis or cannabinoid products registered on the ARTG. Two products – nabilone and dronabinol – are available overseas but the pharmaceutical companies who supply these products overseas do not wish to pursue their registration in Australia.

There are some problems with most of the legally possible ways of making cannabis or cannabinoids available for medical use in New South Wales.

#### REGISTRATION ON THE ARTG

*Cannabis as a natural plant product* is unlikely to meet the requirements for registration on the ARTG because:

- pharmaceutical companies are unlikely to register a natural plant product that cannot be patented;
- there is at present only limited data from clinical trials on the efficacy of cannabis in the treatment of recommended conditions;
- there are serious concerns about the safety of smoking cannabis, which is the most common method of administration;
- cannabis is of questionable pharmaceutical quality because the amount of THC and other cannabinoids may vary.

For all these reasons it is unlikely that cannabis will ever be prescribed by a medical professional or manufactured for use as a therapeutic good.

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## AUSTRALIAN ORPHAN DRUG PROGRAM

This program is designed to overcome sponsors' reluctance to develop products not deemed to be commercially viable. Under this program, the TGA waives application fees and other charges associated with registration and the initial evaluation of data. Approval time is also usually shorter than the statutory 225 working days. Strict rules apply to the classification of a drug under this program. Orphan drugs may be eligible for pharmaceutical benefits listing, which results in subsidised costs to patients. Because of this, overseas manufacturers of cannabis derivatives may give more thought to this option but it is still doubtful whether they would lodge an application.

Under s.19 of the *Therapeutic Goods Act 1989* (Cth) there are two ways the Secretary of the Department of Health and Aged Care may authorise the importation and/or use of a drug not registered on the ARTG: through the Personal Import Scheme or the Special Access Scheme.

### PERSONAL IMPORT SCHEME

Under this scheme individuals may import for medical uses (and at their own expense) a drug that is not registered on the ARTG. They may import no more than 3 months' supply at the maximum dose and must have a doctor's prescription for the medication, where this is required by State law. This is not a viable option because narcotic, psychotropic and other drugs subject to the Customs (Prohibited Imports) Regulations may not be imported under this scheme.

### SPECIAL ACCESS SCHEME

Under this scheme, certain categories of patients may obtain access to a drug. The controls applied depend on the category of patient for whom the drugs are intended. This scheme gave patients with HIV access to dronabinol, but as they had to bear the full costs many found this prohibitive and so were unable to take advantage of the drug's availability.

### 1.3.3 NSW LEGISLATION

In NSW there are two Acts relating to cannabis. These are:

- *Drugs Misuse and Trafficking Act 1985*
- *Poisons and Therapeutic Goods Act 1966*

The objectives of the *Drugs Misuse and Trafficking Act 1985* are to clarify the distinctions between:

- the statutory provisions governing the prohibition of drugs of misuse; and
- the statutory provisions governing the possession and supply of drugs for medical purposes.

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The Act makes a clear distinction between prohibited *plants* and prohibited *drugs*. Prohibited drugs are listed in Schedule 1 and their possession is prohibited unless authorisation for medical purposes has been obtained from the Director-General of the NSW Health Department, or the drugs fall within the appropriate schedule of the other key piece of State legislation (the Poisons Act).

#### BEARING ON AVAILABILITY FOR MEDICAL/COMPASSIONATE USE

Some of the ways cannabis and cannabinoids could be made available in New South Wales for medical purposes are outlined below. Most involve changes to existing laws.

- ***A non-enforcement agreement:*** An agreement involving the Commonwealth and a number of other agencies could allow cannabis to be imported for scientific or medical purposes. Although this option would remove the need for statutory amendments in New South Wales, it would do so at the cost of denying all those involved their rights to the sure and adequate protection of the law. The uncertainties of this approach, the potential for things to go wrong, and the possibility that any or all of the parties involved could revoke their agreement, would all need to be considered.
- ***Amendments to existing NSW legislation:*** These could extend existing exemptions under the research provisions of the *Drugs Misuse and Trafficking* by adding the words “scientific research” or “clinical trials”. Amendments could also be made to this legislation to exempt from criminal liability those who possess or cultivate cannabis and cannabinoids for personal medical use, and medical practitioners who certify the use of cannabis and cannabinoids for therapeutic purposes.
- ***Special legislation:*** Special legislation could be drafted to allow controlled amounts of cannabis to be made available for medical use or clinical trials.

#### 1.3.4 POSSIBLE SOURCES OF CANNABIS SUPPLY FOR MEDICAL AND SCIENTIFIC PURPOSES

There are various options for obtaining cannabis for medical or scientific purposes:

##### IMPORTATION

Importation of cannabis for *personal medical use* is illegal under Commonwealth law. Importation for *scientific research* or *clinical trials* could be authorised as long as the authorisation complied with appropriate regulations and procedures.

##### LICENCES OR AUTHORISATION

The Government could license agencies to cultivate cannabis for medicinal use. Since cannabis, as a crude plant product, is not currently registered on the ARTG (and is unlikely to be registered), it could only be licensed for use in scientific research or clinical trials. A licensing agreement with the Government could ensure quality and security of supply. There are, however, several potential problems with this model: a) agencies could use the license as a cover for cultivation of illicit cannabis; b) cannabis could be stolen and used illicitly; and c) cannabis could become a weed. Strict criteria for determining who should be granted a licence would have to be developed, as would accountability measures. The field trials of low-THC hemp, which have been operating since 1995, could be used as a guide.

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## USE OF CONFISCATED PLANTS OR CROPS

It remains contentious whether cannabis seized from illicit sources could be used for scientific research or clinical trials, given Australia's international obligations.

## SELF-SUPPLY

The NSW Government could decriminalise privately cultivated amounts of cannabis for personal medical use – the “*grow your own*” model – without threatening public health and welfare or contributing to illicit traffic, and without placing Australia in breach of its international obligations under the Single Convention. This model would probably not be feasible for patients who do not have access to a secure, private outdoor area; who lack the capacity or the funds to grow cannabis indoors; or who are too debilitated by their illness to grow cannabis themselves. In these cases cannabis could be supplied by a concerned individual such as a carer. Legislative amendments to the *Drugs Misuse and Trafficking Act* with regard to cultivation and supply would be required to make this possible.

## “BUYERS CLUBS” OR “COMPASSION CLUBS”

These terms have been used to describe cannabis dispensaries operating in several US cities and in Australia to supply cannabis on a non-profit basis to individual medical users. There are, however, some legal problems with these initiatives: they do not comply with international conventions, and supply of an unregistered therapeutic good would contravene the *Therapeutic Goods Act*.

### 1.3.5 POSSIBLE MECHANISMS FOR MAKING CANNABIS AND CANNABINOIDS AVAILABLE FOR MEDICAL PURPOSES

The Working Party considered the following regulatory options:

- medical prescription;
- medical certification.

#### MEDICAL PRESCRIPTION

Because of the inherent dangers of smoking, and the fact that cannabis does not comply with the provisions of the *Therapeutic Goods Act*, it cannot be made available for medical use by prescription. If, however, cannabis or cannabinoids, which could be delivered safely and in compliance with the TGA, were developed, a prescription model based on existing Poisons Act schedule 4 or schedule 8 drugs could be established.

The following prescription models would require only amendment of the relevant Regulations; it would not be necessary amend the Poisons Act:

- prescription approval from NSW Health;
- prescription approval by NSW Health for a specified class of doctor;
- NSW Health authorisation to become a prescribing doctor;
- prescription by a nominated class of prescriber for any patient who meets certain criteria.

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Even then, present data would not permit prescribing doses, dose frequency, and so on, with any confidence, for most categories of patients for whom cannabis or cannabinoids might be of medical use.

#### MEDICAL CERTIFICATION

Smoked cannabis could be made available for recognised medical conditions through a medical certification scheme. Under this scheme:

- people would not be prosecuted for the possession, cultivation and administration of cannabis if they had certification from an approved medical practitioner that they suffered from a condition which may benefit from cannabis use;
- the onus would be on the cannabis user to obtain appropriate prior medical certification;
- criminal sanctions against those who are genuinely ill would be removed;
- all prohibitions applying to recreational use would remain.

Guidelines for certification would need to stipulate that:

- an authorised medical practitioner must concur that the person is suffering from a medical condition for which cannabis use has been approved;
- the patient's well-being and response to treatment would be monitored.

A patient who had obtained this certification, but did not have it on his or her person when apprehended, could later produce it and avoid prosecution. Renewal of certification could occur every six months. This is the same length of time for which prescriptions for other controlled substances are made. It would mean that re-assessment of the use of cannabis for the specified condition could be made in the light of its effects on the progress of the condition and general well-being of the patient.

#### EXTENSION OF MEDICAL CERTIFICATION TO CARERS

Given the serious nature of illnesses for which cannabis may have a legitimate medical use, some patients who might otherwise benefit are too ill or debilitated to grow their own. It may, therefore, be necessary to extend certification which renders lawful the possession, supply, administration and cultivation of cannabis to carers of seriously ill patients who have received certification and who are too ill or debilitated to obtain cannabis or to cultivate cannabis plants themselves.

To avoid abuses of this system, carers would have to establish the patient's level of disability (based on the medical opinion of the certifying doctor). They would also have to demonstrate a close and caring relationship with the ill person and that they are cultivating cannabis *only* to meet the direct needs of that person.

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### 1.3.6 CIVIL LIABILITY OF RESEARCHERS AND CERTIFYING MEDICAL PRACTITIONERS

Important fundamentals in avoiding civil liability include:

- obtaining the patient's informed consent (in writing);
- obtaining the patient's agreement to waive the right to legal action;
- statutory exemptions;
- careful selection of trial participants;
- protection of confidentiality.

### 1.3.7 CRIMINAL LIABILITY

Individuals need to be made aware of the potential for criminal liability if they enter other jurisdictions with cannabis.

The concerns of police need to be addressed, in particular:

- diversion of cannabis;
- possibility of trafficking by trial personnel;
- patients supplementing licit with illicit cannabis;
- tension between patient confidentiality and the police need to know a patient's identity so that law enforcement may be carried out.

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## 2 KEY FINDINGS OF THE WORKING PARTY<sup>4</sup>

### 2.1 MEDICAL AND THERAPEUTIC ISSUES

#### 2.1.1 MEDICAL USES OF CANNABIS AND CANNABINOIDS

The Working Party agrees with the Institute of Medicine and the House of Lords reports on the therapeutic potential of cannabinoids. It concludes that the medical conditions for which cannabis may be of medical benefit are:

- HIV-related wasting and cancer-related wasting
- pain unrelieved by conventional treatments
- neurological disorders including (but not limited to) multiple sclerosis, Tourette's syndrome, and motor neurone disease
- nausea and vomiting which, in cancer patients undergoing chemotherapy, does not respond to conventional treatments

This list may need to be amended in the light of further medical research, but in the Working Party's judgement, it remains the list of candidate conditions for further research and for possible compassionate provision.

#### 2.1.2 PHARMACEUTICAL CANNABINOIDS AND RELATED SUBSTANCES

The Working Party agrees with the IOM and SCOST that delta-9 tetrahydrocannabinol (THC) is the principal psychoactive constituent of cannabis, and the cannabinoid that has accumulated the strongest evidence of efficacy in the treatment of many of the recommended conditions (Volume II – Section 3.1, 3.2).

There are two existing pharmaceutical cannabinoid preparations:

- dronabinol, which is synthetic THC, is marketed in the United States as Marinol and comes in the form of gelatine capsules;
- nabilone, a synthetic cannabinoid with similar actions to THC, has been approved for therapeutic use in the UK.

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<sup>4</sup> References in brackets refer to the sections of Volume II of the Working Party's report that contain the detailed justification for the Working Party's conclusions and recommendations.



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## DRONABINOL

The Working Party concludes that there is reasonable support from controlled clinical trials for the oral use of dronabinol as an anti-emetic agent (Volume II – Section 6.2) and as an appetite stimulant in HIV- and cancer-related wasting (Volume II – Section 6.3). Its anti-emetic effects are, however, modest compared with those of more recently developed anti-emetic drugs (Volume II – Section 6.2). Support for therapeutic use of THC for people with chronic pain and neurological disorders (e.g. multiple sclerosis) is based upon the findings of systematic studies in animals, limited clinical research, clinical case series, and anecdotal reports (Volume II – Section 6.1, 6.4).

The US Food and Drug Administration (FDA) has approved the use of dronabinol in oral form for the treatment for nausea and vomiting in cancer patients undergoing chemotherapy and as an appetite stimulant in the treatment of HIV-related wasting (Volume II – Section 3.2, 8.3).

Before any product can be marketed in Australia for therapeutic purposes it must first be listed on the Australian Register of Therapeutic Goods (ARTG; Volume II – Section 9.2.4). Dronabinol is not currently registered, although it would probably meet the necessary criteria as an anti-emetic and appetite stimulant *if any pharmaceutical company applied to have it registered*. American clinical experience (Volume II – Section 5.2, 8.3) and limited Australian experience suggest that, even if it were registered, it would not provide effective symptom relief for many patients.

Australian physicians had limited experience with the use of dronabinol during the 1990s when compassionate provision to individual HIV patients was authorised under the *Therapeutic Goods Act*. This experience was not systematically documented or evaluated but, anecdotally, few of the patients who tried dronabinol found it satisfactory (Volume II – Section 9.2.4).

Dronabinol does not adequately control symptoms of nausea in many patients (Volume II – Section 6.2). When dronabinol is administered orally, patients find it is difficult to titrate the dose of THC because the onset of its effects is delayed and they usually persist for much longer than the effects of smoked cannabis (Volume II – Section 9.2; 8.5). Patients complain that they either get too little THC to adequately control their symptoms, or they get too much and experience unpleasant side effects. The oral route of administration is also suboptimal for vomiting patients.

Dronabinol was not available on the Pharmaceutical Benefits Scheme. It was available only through the Special Access Scheme (SAS) for unlicensed medications so patients had to pay the full costs (Volume II – Section 9.2). This proved very expensive for patients with serious debilitating illnesses such as HIV who were often unemployed and receiving only social welfare payments. For these reasons some patients found cannabis smoking a cheaper and more attractive therapeutic option. SAS drug costs continue to be a concern.

## NABILONE

The synthetic oral cannabinoid, nabilone, is registered for therapeutic use in Britain for the treatment of nausea and vomiting, and HIV-related wasting (Volume II – Section 3.1). It is not registered for medical use in Australia.

As far as the Working Party could ascertain, there are no other cannabinoids registered for medical use in Australia or being considered for registration, although one company is considering an application for registration of nabilone.

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## BARRIERS TO THE REGISTRATION OF NEW DRUGS

The experience with dronabinol in Australia highlighted several key issues in the registering of new medications.

The *only* way a particular medication may become registered under our therapeutic goods legislation is if a pharmaceutical company makes the application (Volume II – Section 9.2). There is no mechanism for a drug to be listed in response to perceived clinical need. There is also no mechanism for a list of “essential drugs” to be developed and made available. Pharmaceutical companies will only pursue the expensive and long path of new drug registration if it sees sizeable market for the drug and adequate financial returns.

Pharmaceutical companies with patent over a drug may choose not to register a medication in the Australian market and not to allow other interested pharmaceutical companies to buy a local license for the medication. The current orphan drug program (a program designed to overcome companies’ reluctance to develop a product not considered viable), does not adequately address either of these issues (Volume II – Section 9.2).

Another barrier to registration is scheduling. Some cannabinoid preparations and synthetic cannabinoids may have lower potential for abuse than cannabis and should be re-scheduled accordingly. For example, in July 1999, the US Drug Enforcement Administration (DEA) re-scheduled dronabinol to Schedule III on the basis of evidence of low abuse potential (Volume II – Section 8.3).

### **Recommendation 1**

**While recognising the limitations of currently available pharmaceutical preparations of cannabinoids, the Working Party recommends that they should be subject to further clinical trials of safety and efficacy as described below.**

### **Recommendation 2**

**The Working Party recommends that the New South Wales Government through the Australian Health Ministers’ Forum explore avenues for greater flexibility in new medication registration by the TGA based on the clinical needs of special populations.**

### **2.1.3 MEDICAL USE OF SMOKED CANNABIS**

The IOM and SCOST reports (Volume II – Sections 3.2, 3.1), and the majority of submissions received by the Working Party (Volume II – Section 4.4), agreed that smoking a crude plant product is *not* a desirable way to administer any medication. In addition, smoking is an unreliable way of administering cannabinoids (Volume II – Section 8.5); plus it also delivers a host of undesirable substances, such as, tars, gases, and particulate matter, some of which are deleterious to health (Volume II – Section 7.5.2).

**The Working Party concludes that smoking a crude plant product is not a desirable way to deliver cannabinoids. Research is needed into alternative means of delivering cannabinoids that would make it unnecessary to smoke cannabis for medical purposes.**

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#### 2.1.4 OTHER ROUTES OF ADMINISTERING CANNABIS

There is no difficulty, in principle, in delivering THC in ways that are less injurious to health than by smoking (Volume II – Section 8.5). There are reasonable prospects of developing new cannabinoids (or of finding new ways of formulating existing cannabinoids) that would permit safer and more efficient administration for therapeutic purposes (Volume II – Section 8.5). There are, for example, medical devices that deliver closely controlled doses of other therapeutic substances to the lung without the smoke, tars and hazardous compounds produced by burning (Volume II – Section 8.5).

The present practical obstacle to using these devices for administering THC-type substances is that, unlike most therapeutic substances delivered in this way, THC is not water-soluble (Volume II – Section 8.5). Further research and development will be needed to circumvent this problem (Volume II – Section 8.5). At best, this research will take some years to produce a marketable device or method for delivering THC and other therapeutic cannabinoids.

**The Working Party concludes that alternative routes of administration of cannabinoids other than consuming the crude plant product are desirable and their development is feasible in the medium-to-long-term.**

The necessary research could be undertaken by Australian researchers who have already made important contributions to the development of alternative methods of delivering opioids and other drugs.

#### 2.1.5 OTHER RESEARCH RECOMMENDATIONS

Following from the previous discussion, the Working Party recognises that research in other areas is also needed to inform policy making in relation to the medical uses of cannabis and cannabinoids and to better understand the therapeutic effects of cannabis and its constituent chemicals. The areas recommended for additional research are:

- surveys of current users of cannabis for medical purposes;
- surveys of potential users for medical purposes;
- clinical trials of the therapeutic efficacy of cannabis and cannabinoids;
- research on the applied chemistry and pharmacology of cannabinoids.

#### CURRENT USERS OF CANNABIS FOR MEDICAL PURPOSES

The numbers of ill Australians who currently risk criminal prosecution by using cannabis for medical purposes is unknown (Volume II – Section 2.4). The numbers who might use cannabis for medical purposes if they did not risk criminal prosecution is also unknown. US experience suggests that the primary medical users are people with HIV-related wasting, cancer patients with nausea and vomiting, and people with chronic pain (Volume II – Section 2.4, 4.5).

Better information could be obtained by surveying patients (and their carers) with HIV-related wasting, with cancer and undergoing chemotherapy, or with chronic refractory pain and neurological conditions. The aim of the survey would be to discover what proportion of patients with these conditions are currently using

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cannabis for medical purposes; where they obtain their cannabis; what their positive and negative experiences have been; and what impact the illegality of cannabis has had on their use of it for medical purposes.

### **Recommendation 3**

**The Working Party recommends that the Government consider funding or otherwise facilitating surveys of current medical users of cannabis and their carers to obtain an indication of how many persons are at risk of criminal prosecution for medical use of cannabis.**

#### POTENTIAL USERS OF CANNABIS FOR MEDICAL PURPOSES

A survey of current medical cannabis users could be combined with a survey of potential medical users of cannabis among patients with one or more of the conditions listed in **Section 2.1.1 (this volume)**. The purpose of this survey would be to see how many patients may be prepared to use cannabis or cannabinoids for medical purposes, if such cannabis use was not a criminal offence, or if therapeutic cannabinoid drugs were provided on medical prescription.

### **Recommendation 4**

**The Working Party recommends that the Government consider funding or otherwise facilitating surveys of potential medical users of cannabis and cannabinoids to obtain an indication of how many persons would wish to use cannabinoids for medical purposes under a more favourable regulatory regime.**

#### CLINICAL TRIALS OF THE THERAPEUTIC EFFICACY OF CANNABIS AND CANNABINOIDS

More controlled clinical trials are required on the therapeutic efficacy of cannabis and cannabinoids. The US Institute of Medicine (Volume II – Section 3.2) and the House of Lords (Volume II – Section 3.1) recommended that a range of trials were required. The Working Party concurs with these recommendations, and concludes that the following trials are required:

- Randomised controlled clinical trials for HIV- and cancer-related wasting, pain, neurological disorders and nausea using the following:
  - Oral THC (in the form of the drug dronabinol)
  - Alternative oral cannabinoid preparations, such as, nabilone
  - Oral preparations of crude cannabis extracts
  - Smoked cannabis (with regulated cannabinoid content)
- These trials should also examine the possibilities of multimodal therapy, that is, of combining cannabinoids and cannabis with other treatments (e.g. opioid drugs for analgesia and other anti-emetic agents) to determine whether or not their addition enhances the efficacy of existing treatments.

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- Controlled studies in individual patients of cannabis and cannabinoids for less common medical conditions ("n-of-1 trials" in the Institute of Medicine's terms, which are studies in which a single patient is observed over time, with periods in which the active drug(s) is used and not used, and with behaviour and symptoms measured regularly over this time under double blind conditions).

Legal advice provided to the Working Party indicates that cannabis for clinical trials could be imported under existing Commonwealth legislation without endangering Australian compliance with international treaties and conventions (Volume II – Section 9.1). It would require approval from the International Narcotics Control Board, which permits the limited use of prohibited drugs for medical and scientific research including clinical trials (Volume II – Section 9.2).

Appropriately assayed and standardised cannabis cigarettes are produced by the University of Mississippi in the US for supply to accredited researchers having approved protocols (Volume II – Appendix G). GW Pharmaceuticals Ltd, a private research firm licensed by the United Kingdom Government to produce and undertake medical trials of cannabis, has developed sublingual and other trial preparations for research as an alternative to smoked cannabis (Volume II – Appendix G). This firm is currently developing a multi-national trial protocol. The Canadian Government is also currently conducting clinical trials of cannabis, including in its smoked form (Volume II – Appendix G).

#### **Recommendation 5**

**The Working Party recommends that randomised controlled clinical trials, and controlled studies in individual patients, be conducted on the therapeutic efficacy of cannabis and cannabinoids.**

#### **Recommendation 6**

**It urges the NSW government to consider funding or otherwise facilitating research for this purpose.**

#### **Recommendation 7**

**The Working Party recommends that the NSW *Drugs Misuse and Trafficking Act 1985* be amended to ensure that there are no legal obstacles to the conduct of such trials.**

#### RESEARCH ON THE APPLIED CHEMISTRY AND PHARMACOLOGY OF CANNABINOIDS

Additional research is also required into the applied chemistry and pharmacology of cannabinoids, with the aim of developing cannabinoid drugs that have appropriate therapeutic effects and that may be delivered more safely and effectively than by smoking cannabis (Volume II – Section 6.2.1, 6.4.4, 6.5.1, 6.3.1). This research should also include development and testing of alternative methods of administering THC and other therapeutic cannabinoids (Volume II – Section 8.5).

Research specified above could be undertaken by Australian researchers. This is especially true of research into alternative systems of delivering therapeutic agents because this is an area which Australian researchers have made important contributions to developing alternative methods of delivering opioid and other drugs.

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### Recommendation 8

**That additional research be conducted into the basic chemistry and pharmacology of cannabinoids with the aim of developing cannabinoids that have therapeutic effects and that may be delivered more safely and effectively than by smoking cannabis.**

Such research could be undertaken through the following avenues:

- either investigator-initiated or proposal requests from the National Health and Medical Research Council peer-reviewed system;
- funding from the Ministerial Council on Drug Strategy/ Intergovernmental Committee on Drugs;
- small grants provided by the State government for researchers to develop more detailed proposals to be funded through mechanisms for peer-reviewed research.

#### 2.1.6 AVAILABILITY OF CANNABIS FOR COMPASSIONATE USE

It will take some years before therapeutic cannabinoids and alternative delivery systems are approved by the regulatory process and marketed as therapeutic products (Volume II – Section 8.5). In the meantime, some patients with debilitating and life-threatening illnesses are exposing themselves to criminal prosecution by smoking or ingesting cannabis for medical purposes.

#### SITUATION IN THE US AND THE UK

The IOM and SCOST reports both recommended that *until safer and more efficient methods were developed to deliver THC* cannabis should be made available on compassionate grounds to patients with certain medical conditions including: HIV- related and other forms of wasting; nausea and vomiting caused by chemotherapy and unresponsive to existing treatment; pain which cannot be relieved conventional analgesics; and painful spasms in some neurological conditions (Volume II – Section 3.1, 3.2).

The US and UK reports differed over how this compassionate regime might be put into effect.

The IOM report recommended:

- randomised controlled clinical trials to determine the safety and efficacy of smoked cannabis for conditions such as HIV-related wasting, cancer chemotherapy, chronic pain, and multiple sclerosis;
- individual patient studies to determine the efficacy of smoked cannabis for less common medical conditions.

The SCOST report recommended that doctors in the UK should be allowed to prescribe cannabis for a limited range of medical indications and that the UK Government license the production and supply of cannabis to patients for these purposes.

### Recommendation 9

**The Working Party is in sympathy with the motivation and spirit of the recommendations in the Institute of Medicine and House of Lords reports. Accordingly, it recommends the introduction in NSW of a compassionate regime to assist those suffering from the range of illnesses identified above to gain the benefits associated with the use of cannabis without facing criminal sanctions, pending the development of safer and more efficient methods to deliver cannabinoids.**

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## 2.2 LEGAL AND REGULATORY ISSUES

### 2.2.1 ACCESS TO CANNABIS UNDER A COMPASSIONATE REGIME

The task of the Working Party was to devise a system for providing cannabis on compassionate grounds that would:

- be consistent with international agreements and Commonwealth and State laws;
- be practically feasible and easy for the police to enforce;
- respond to legitimate community concerns;
- provide access only to patients with serious illnesses who may benefit from its medical use.

Working Party considered the following regulatory options:

- medical prescription;
- government supply or licensing of the supply of cannabis;
- medical certification.

#### MEDICAL PRESCRIPTION

The Commonwealth Therapeutic Goods Administration, the NSW Attorney General's Department, and the NSW Health Department, all advised that any form of cannabis prescription or organised supply on prescription (except for clinical trials) would be illegal because cannabis has not been approved as a therapeutic good under the Commonwealth Therapeutic Goods Act (Volume II – Section 9.2). This Act, applies in NSW because it has been adopted as state law under s.31 of the NSW Poisons Act (Volume II – Section 9.2).

For the following reasons, is unlikely that cannabis as a crude plant product would ever comply with therapeutic goods legislation:

- it is unlikely that any pharmaceutical company would seek to register a natural plant product that cannot be patented and drugs cannot be registered unless such an application is made;
- there are only sparse data from controlled clinical trials on the efficacy of cannabis for treating the recommended medical conditions;
- there are serious concerns about the safety of smoked cannabis, especially in the treatment of chronic medical conditions;
- the cannabinoid content of crude cannabis varies, raising concerns about quality.

The prescription of cannabis for medical purposes, other than clinical trials, would also require the World Health Organization (WHO) to move cannabis from Schedule 1 (controlled substances having no recommended medical use) to Schedule 2 (controlled substances having some medical uses) (Volume II – Section 9.1). The WHO is unlikely to do this in the absence of evidence from controlled trials on the safety and efficacy of cannabis for medical uses. In the absence of rescheduling by the WHO, medical prescription of cannabis for purposes other than clinical trials would contravene international drug control treaties to which Australia is a signatory (Volume II – Section 9.1).

Medical prescription also raises potential medical liability issues (Volume II – Section 15). A patient who was

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prescribed smoked cannabis, and who later developed cancer or some other health problem, could sue the prescribing medical practitioner, unless they had been fully informed of the potential health risks. To remove the risk of liability medical practitioners would have to provide all the necessary information as part of the prescribing process (Volume II – Section 15.4, 15.5).

In summary, cannabis cannot be prescribed unless it is registered as a therapeutic good in Australia and, for the reasons already mentioned, this is unlikely to happen.

#### GOVERNMENT SUPPLY OR LICENSING OF SUPPLY

If New South Wales were to adopt the UK House of Lords' recommendation that the government supply cannabis for medical use the Government would have to either license manufacture in this State or ask the Commonwealth Government to import it from another country (Volume II – Section 13.1).

Cannabis could not at present be imported for routine medical use unless specific procedures under the Customs Act and regulations were complied with (Volume II – Section 9.2) and unless there was well-founded evidence of its therapeutic value (Volume II – Section 9.2). In addition, importation would have to comply with the international conventions to which Australia is a signatory, in particular the Single Convention on Narcotic Drugs 1961, and the requisite approval of the quantity to be imported would have to be obtained from International Narcotics Control Board (Volume II – Section 9.1).

The current law is being challenged by community groups who are prepared, as an act of civil disobedience, to risk prosecution by openly supplying cannabis for medical use on compassionate grounds.

The Working Party shares the concerns of the SCOST report (Volume II – Section 3.1) that the criminal law is brought into disrepute:

- if statutory provisions are seen to be harsh and lacking in compassion;
- if, for that reason, they are enforced inconsistently or not at all;
- if the laws are seen to be adversely affecting the lives of people suffering from serious and life-threatening illnesses.

A number of those who made submissions to this inquiry thought it would be prudent to leave the law as it is. After considering the matter, the Working Party concluded that this would result in the medical uses of cannabis being decided by case law and that it was preferable for public policy to be decided by the legislature, on the basis of sound information about the options available.

#### **Recommendation 10**

**That the Government consider licensing the supply, including the importation, of cannabis, but only for the purposes of the clinical trials proposed in Recommendation 5.**



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## MEDICAL CERTIFICATION

While recognising the problems related to the prescription and government supply of cannabis the Working Party concluded that these problems could be overcome if patients who had the appropriate medical certification were not prosecuted for possession, cultivation or administration of cannabis for therapeutic purposes. Certification would need to be given by an approved medical practitioner and to confirm that the patient was suffering from a medical condition that might benefit from cannabis use.

This would place the onus on the patient to establish evidence of certification. It would also remove criminal sanctions for cannabis use from those who are genuinely ill, while maintaining the proscription against the recreational use.

The Working Party was divided on whether certificates should be given to patients who met the qualifying criteria if they had already been apprehended for illegal possession. The majority view was that the medical certification should precede medical use so that patients had the opportunity to discuss the issues with their treating physician and make an informed decision after balancing the risks and benefits. The majority also considered that retrospective certification should only be available as an argument for mitigation in sentencing.

The minority view was that patients and their clinicians will often not be aware of the requirements and that many patients who are more socially marginalised may not disclose their self-medication with cannabis or other "alternative" treatments to their clinician. Also, some people, particularly those in rural areas, may not have access to a medical practitioner who is accredited to provide the necessary certification. If these people are charged by the police for possession of cannabis they should have the opportunity to obtain retrospective certification from an accredited medical practitioner. This certification would need to state that the patient met the criteria for compassionate use of cannabis *at the time they were charged*. In this way the retrospective certification would provide the same defence as prior certification.

### **Recommendation 11**

**That a person should not be prosecuted if they have the prior medical certification from an accredited medical practitioner that they suffer from a medical condition that may benefit from cannabis use.**

### **Recommendation 12**

**That the onus be placed on the medical user of cannabis plant material to establish evidence of medical certification before use.**

### **Recommendation 13**

**That the conditions included under this certification should be:**

- HIV-related wasting and cancer-related wasting;
- pain unrelieved by conventional treatments;
- neurological disorders including (but not limited to) multiple sclerosis, Tourette's syndrome, and motor neurone disease;
- nausea and vomiting in cancer patients undergoing chemotherapy which does not respond to conventional treatments.

**That, as this list may need to be amended in the light of further medical research, it should be specified by regulation rather than by primary legislation.**

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## 2.2.2 LAWFUL SOURCES OF CANNABIS FOR PERSONAL USE

Certification of a condition for which cannabis use may be of benefit does not solve the problem of supply because patients would have to obtain their cannabis from the illicit market. The extension of certified medical use to cultivation of cannabis potentially raises problems for law enforcement (Volume II – Section 13.1) and would have to be done in way that prevents exploitation by criminals who cultivate cannabis for commercial purposes.

One option would be to extend certified medical use to render lawful the possession and use of small amounts of cannabis for personal medical use (Volume II – Section 13.1). The “small” amount of cannabis for the possession and use exemption should correspond to the small amount as defined in the NSW *Drugs Misuse and Trafficking Act 1985*. At present this is 30 grams of cannabis leaf, 5 grams of cannabis resin, and 2 grams of cannabis oil.

In terms of number of cannabis plants, the “small” amount currently allowed under the Act is five. The problem is that this number of mature plants could produce a significant quantity of leaf and possibly exceed the definition of small quantity.

In seeking certification, the onus would be upon medical users to establish that the small amounts of cannabis they wish to possess, use or grow is solely for their own medical use (Volume II – Section 9.4, 13.1).

### **Recommendation 14**

**That certification be extended to the possession and use of small amounts of cannabis for medical use by patients.**

### **Recommendation 15**

**That the “small” amount of cannabis for the possession and use exemption should correspond to the small amount in the NSW *Drugs Misuse and Trafficking Act 1985*. At present this is 30 grams of cannabis leaf, 5 grams of cannabis resin, and 2 grams of cannabis oil.**

### **Recommendation 16**

**That certification be extended to the growing of small amounts of cannabis for medical use by patients in their own homes.**

### **Recommendation 17**

**That, although the “small” amount of cannabis, as defined under the *Drugs Misuse and Trafficking Act* is five plants, consideration be given to lowering this limit for medical certification by allowing cultivation of up to five plants under 25 cm but only two above that height.**

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### 2.2.3 GROWING AND SUPPLY BY ORGANISED GROUPS

Some groups who sometimes describe themselves as “compassion clubs” offer to supply cannabis to patients for altruistic reasons. The Working Party notes that such cultivation and supply of cannabis is illegal under the *Drugs Misuse and Trafficking Act 1985* (Volume II – Section 9.4).

As suppliers of commercial therapeutic goods these groups would also contravene the Commonwealth *Therapeutic Goods Act* (Volume II – Section 9.2). These groups see themselves as engaging in a form of conscientious civil disobedience and argue that they provide eligible patients with safer and better quality cannabis products than the commercially-driven criminal suppliers provide to the recreational market.

In addition to questions of legality there are other practical barriers to sanctioning such “clubs”. First, it is difficult to regulate groups such as this and to distinguish them from suppliers to the recreational market. To avoid significant law enforcement problems and make the distinction, these groups would have to be able to prove that they were only providing to eligible and certified patients and not also supplying anyone using cannabis for other reasons. This would probably require a more stringent certification regime, possibly a register of eligible individuals, and auditing of the groups’ activities. The Working Party concluded that, on balance, the administrative, policing and privacy implications of such an approach would not be sustainable.

#### **Recommendation 18**

**That no consideration should be given to altering the law to allow “compassion clubs” to operate legally.**

### 2.2.4 MEDICAL CERTIFICATION BY ACCREDITED MEDICAL PRACTITIONERS

Medical certification that a patient had one of the specified conditions could be produced to a police officer in defence of a charge of possession or use of cannabis. The certification would simply confirm that an accredited medical practitioner had certified that the patient suffered from one or more of the listed conditions. A patient who had obtained this certification, but did not have it on his or her person when apprehended, could later produce it and avoid prosecution.

In the interests of privacy, the certification document would not name the specified condition for which the patient had obtained certification (see Volume II - Appendix H). Instead, certification would simply state that the patient met criteria for one or more of the specified conditions.

Renewal of certification would occur every six months. This is the same length of time for which prescriptions for other controlled substances are made. It would mean that re-assessment of the use of cannabis for the specified condition could be made in the light of its effects on the progress of the condition and general well-being of the patient.

Doctors certifying that a patient has one or more of these specified medical conditions should be accredited medical practitioners, registered in NSW with appropriate training. This training would include guidelines on certifying, as well as training on counselling patients about the health risks of cannabis smoking.

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### **Recommendation 19**

**That the possession, supply, administration and cultivation of cannabis for personal medical use by patients with one of the specified conditions only be considered lawful if the patient possesses a certificate to this effect from an accredited medical practitioner; and that this certificate should be renewed every six months.**

### **Recommendation 20**

**That “accredited medical practitioners” be trained in the following.**

**1. Certification of patients with:**

- **HIV- or cancer-related wasting;**
- **nausea secondary to chemotherapy that is unresponsive to conventional treatments;**
- **neurological disorders such as multiple sclerosis;**
- **pain that is unresponsive to conventional treatment.**

**2. Counselling patients about the health risks of cannabis smoking.**

### **Recommendation 21**

**That legislative safeguards be established to ensure that no civil or criminal liability is incurred by any person authorised to medically certify cannabis, or assist in the proper medical certification of cannabis for recognised therapeutic purposes, if the certifier had reasonable grounds to believe that the patients had given informed consent.**

## **2.2.5 EXTENSION OF MEDICAL CERTIFICATION TO CARERS**

Given the serious nature of illnesses for which cannabis may have a legitimate medical use, some patients who might otherwise benefit are too ill or debilitated to grow their own cannabis. It may, therefore, be appropriate to extend certification which renders lawful the possession, supply, administration and cultivation of cannabis to carers of seriously ill patients who have received certification and who are too ill or debilitated to obtain cannabis or to cultivate cannabis plants themselves (Volume II – Section 13.1).

This exemption would parallel that presently found in the *Drugs Misuse and Trafficking Act 1985* (NSW) where a person with prohibited drugs in their possession has a defence if the drug is possessed for the sole purpose of administering them in the course of prescribed supply (Volume II – Section 9.4).

To avoid abuses of this system, carers would have to establish the patient’s level of disability (based on the medical opinion of the certifying doctor). They would also have to demonstrate a close and caring relationship with the ill person and that they are cultivating cannabis only to meet the direct needs of that person (Volume II – Section 8.6.1).

### **Recommendation 22**

**That certification which renders lawful the possession, supply, administration and cultivation of cannabis be extended to carers of patients who are too ill or debilitated to obtain cannabis or to cultivate cannabis plants for their own use, as long as stringent criteria for extending this certification are met.**

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## 2.2.6 EDUCATION

The Working Party also felt that it was important to ensure that the public, the medical profession and patients who could be suitable candidates for medical certification of the use of cannabis for medical purposes were well informed of the changes proposed here. To this end, the Working Party felt it was important that educational campaigns be conducted with these groups to improve awareness of the medical uses of cannabis, the risks of cannabis use, as well as the implications of any changes made by the NSW Government.

### **Recommendation 23**

**That, if the recommendations in this report are adopted, the NSW Government conduct educational campaigns to inform the following people:**

- patients who may qualify for certification;
- medical practitioners;
- the public in general.

**of the benefits and possible risks of cannabis use for medical purposes, and of the implications of any legislative changes which may have to be introduced.**

## 2.2.7 CONSULTATION AND EVALUATION

The details of proposed legislation (for example, who shall be an accredited medical practitioner) will require further consultation with patients, carers, prescribers and other interested parties to ensure that a workable form of certification is implemented.

The Working Party also believes that it is desirable to evaluate the effects of the legislation after a two year trial to see if there is any need to modify the legislation to ensure that it better meets its goals.

### **Recommendation 24**

**That the Government consult with patients, carers, prescribers and other affected parties on the proposed changes and conduct a formal evaluation of the operation of the legislation after a trial period of two years.**

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## **3 SUMMARY OF RECOMMENDATIONS**

### **3.1 MEDICAL AND THERAPEUTIC ISSUES**

#### **3.1.1 PHARMACEUTICAL CANNABINOIDS AND RELATED SUBSTANCES**

##### **Recommendation 1**

While recognising the limitations of currently available pharmaceutical preparations of cannabinoids, the Working Party recommends that they should be subject to further clinical trials of safety and efficacy as described below.

##### **Recommendation 2**

The Working Party recommends that the New South Wales Government through the Australian Health Ministers' Forum explore avenues for greater flexibility in new medication registration by the TGA based on the clinical needs of special populations.

#### **3.1.2 OTHER RESEARCH RECOMMENDATIONS**

##### **Recommendation 3**

That the Government consider funding or otherwise facilitating surveys of current medical users of cannabis and their carers to obtain an indication of how many persons are at risk of criminal prosecution for medical use of cannabis.

##### **Recommendation 4**

That the Government consider funding or otherwise facilitating surveys of potential medical users of cannabis and cannabinoids to obtain an indication of how many persons would wish to use cannabinoids for medical purposes under a more favourable regulatory regime.

##### **Recommendation 5**

The Working Party recommends that randomised controlled clinical trials, and controlled studies in individual patients, be conducted on the therapeutic efficacy of cannabis and cannabinoids.

##### **Recommendation 6**

It urges the NSW government to consider funding or otherwise facilitating research for this purpose.

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### Recommendation 7

The Working Party recommends that the NSW *Drugs Misuse and Trafficking Act 1985* be amended to ensure that there are no legal obstacles to the conduct of such trials.

### Recommendation 8

That additional research be conducted into the basic chemistry and pharmacology of cannabinoids with the aim of developing cannabinoids that have therapeutic effects and that may be delivered more safely and effectively than by smoking cannabis.

Such research could be undertaken through the following avenues:

- either investigator-initiated or requests for proposals from the National Health and Medical Research Council peer-reviewed system;
- funding from the Ministerial Council on Drug Strategy/ Intergovernmental Committee on Drugs;
- small grants provided by the State government for researchers to develop more detailed proposals to be funded through mechanisms for peer-reviewed research.

### 3.1.3 AVAILABILITY OF CANNABIS FOR COMPASSIONATE USE

### Recommendation 9

The Working Party is in sympathy with the motivation and spirit of the recommendations in the Institute of Medicine and House of Lords reports. Accordingly, it recommends the introduction in NSW of a compassionate regime to assist those suffering from the range of illnesses identified above to gain the benefits associated with the use of cannabis without facing criminal sanctions, pending the development of safer and more efficient methods to deliver cannabinoids.

## 3.2 LEGAL AND REGULATORY ISSUES

### 3.2.1 ACCESS TO CANNABIS UNDER A COMPASSIONATE REGIME

### Recommendation 10

That the Government consider licensing the supply, including the importation, of cannabis, but only for the purposes of the clinical trials proposed in Recommendation 5.

### Recommendation 11

That a person should not be prosecuted if they have prior medical certification from an accredited medical practitioner that they suffer from a medical condition that may benefit from cannabis use.

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#### Recommendation 12

That the onus be placed on the medical user of cannabis plant material to establish evidence of medical certification before use.

#### Recommendation 13

That the conditions included under this certification should be:

- HIV-related wasting and cancer-related wasting;
- pain unrelieved by conventional treatments;
- neurological disorders including (but not limited to) multiple sclerosis, Tourette's syndrome, and motor neurone disease;
- nausea and vomiting in cancer patients undergoing chemotherapy which does not respond to conventional treatments.

That, as this list may need to be amended in the light of further medical research, it should be specified by regulation rather than by primary legislation.

### 3.2.2 LAWFUL SOURCES OF CANNABIS FOR MEDICAL USE

#### Recommendation 14

That certification be extended to the possession and use of small amounts of cannabis for medical use by patients.

#### Recommendation 15

That the "small" amount of cannabis for the possession and use exemption should correspond to the small amount in the NSW *Drugs Misuse and Trafficking Act 1985*. At present this is 30 grams of cannabis leaf, 5 grams of cannabis resin, and 2 grams of cannabis oil.

#### Recommendation 16

That certification be extended to the growing of small amounts of cannabis for medical use by patients in their own homes.

#### Recommendation 17

That, although the "small" amount of cannabis, as defined under the *Drugs Misuse and Trafficking Act* is five plants, consideration be given to lowering this limit for medical certification by allowing cultivation of up to five plants under 25 cm but only two above that height.

#### Recommendation 18

That no consideration should be given to altering the law to allow "compassion clubs" to operate legally.



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### 3.2.3 MEDICAL CERTIFICATION BY ACCREDITED MEDICAL PRACTITIONERS

#### Recommendation 19

That the possession, supply, administration and cultivation of cannabis for personal medical use by patients with one of the specified conditions only be considered lawful if the patient possesses a certificate to this effect from an accredited medical practitioner; and that this certificate should be renewed every six months.

#### Recommendation 20

That “accredited medical practitioners” be trained in the following.

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- HIV- or cancer-related wasting;
- nausea secondary to chemotherapy that is unresponsive to conventional treatments;
- neurological disorders such as multiple sclerosis;
- or chronic pain that is unresponsive to conventional treatment.

2. Counselling patients about the health risks of cannabis smoking.

#### Recommendation 21

That legislative safeguards be established to ensure that no civil or criminal liability is incurred by any person authorised to medically certify cannabis, or assist in the proper medical certification of cannabis for recognised therapeutic purposes, if the certifier had reasonable grounds to believe that the patients had given informed consent.

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### 3.2.5 EDUCATION

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- patients who may qualify for certification;
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of the benefits and possible risks of cannabis use for medical purposes, and of the implications of any legislative changes which may have to be introduced.

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### 3.2.6 CONSULTATION AND EVALUATION

#### Recommendation 24

That the Government consult with patients, carers, prescribers and other affected parties on the proposed changes and conduct a formal evaluation of the operation of the legislation after a trial period of two years.