Chapter 4

Key Issues

4.1 Submitters and witnesses to the inquiry raised various issues relating to the regulation of medicinal cannabis.

4.2 The first part of this chapter examines the issues associated with the way medicinal cannabis is currently regulated in Australia, drawing on evidence from academics, organisations and individuals who contributed to the inquiry.

4.3 The second part of this chapter explores comments made by submitters and witnesses in relation to the specific reforms proposed by the Bill.

Issues arising from Australia's current regulatory approach to medicinal cannabis

4.4 Submitters and witnesses presented evidence that the current regulatory environment in Australia is not conducive to the proper evaluation and implementation of medicinal cannabis products. Issues raised over the course of the inquiry included: the lack of information available about the current use of illicit cannabis in Australia for medicinal purposes; the inability of state and territory governments to implement reforms in this area without Commonwealth assistance; and the difficulties associated with gaining approval for medicinal cannabis products through the Therapeutic Goods Administration (TGA).

Information about the use of cannabis for medicinal purposes in Australia

4.5 One issue complicating the debate surrounding the regulation of medicinal cannabis in Australia is the absence of any clear data in relation to current usage of illicit cannabis for medicinal purposes. Professor Allison Ritter, Director of the Drug Policy Modelling Program at the National Drug and Alcohol Research Centre (NDARC), confirmed that there is currently no data available or independent researchers trying to objectively assess this issue in Australia.[1] Despite this lack of official data, the committee did receive information from various groups that help illuminate, at least partially, the level of use of medicinal cannabis in Australia.

4.6 Medicinal cannabis advocacy user groups that contributed evidence to the inquiry included the Medicinal Cannabis Users Association of Australia, which claims to represent over 6,000 Australians currently involved in the production or use of cannabis for medicinal purposes.[2]

4.7 Mr Lance Feeney, Policy Analyst at the National Association of People Living with HIV Australia, stated that recent survey data from HIV-positive

1 *Committee Hansard*, 31 March 2015, p. 40.

2 *Submission 145*, pp 1 and 18.

individuals in Australia indicates that approximately 20 per cent of respondents use cannabis for therapeutic and symptom relief.[3]

4.8 Epilepsy Action Australia commented on the current usage of medicinal cannabis products for epileptic conditions:

> We understand from social media and other sources that a number of consumers (parents) in Australia are gaining access to cannabis derivatives to treat seizures in the form of tinctures and oils. Given the catastrophic and debilitating nature of their children's epilepsy conditions it is not difficult to understand their desperation. These parents report immense improvement in the severity and frequency of their children's seizures and overall quality of life.[4]

4.9 Throughout the course of this inquiry, the committee received evidence from many individuals who relayed how medicinal cannabis products had assisted them or their family members in alleviating the symptoms associated with a range of medical conditions, many of extreme severity. Two of their stories are included here as case studies.

4.10 The first case study is of Mrs Lucy Haslam, who gave evidence at the committee's public hearing in Sydney about her son Daniel's use of medicinal cannabis to provide relief during chemotherapy treatment for bowel cancer, from which he sadly passed away in early 2015.

Case Study 1 – Mrs Lucy Haslam

Daniel was diagnosed with stage 4 bowel cancer when he was 20. He had three years of treatment, which involved a lot of major surgeries but also a lot of chemotherapy. He was three years into chemotherapy and he was told basically that for as long as he lived he would require chemotherapy.

But for him chemotherapy was not just something that you slotted into your routine; it was a major issue for our whole family because he became so violently ill from the chemotherapy. Daniel developed what is called anticipatory nausea, which is quite common in young people who are on very strong chemotherapy. Just the thought of chemotherapy would actually make him vomit. So, the day before chemotherapy, he would start being unwell. He would initiate all sorts of stalling tactics on the day of chemotherapy, because he would start vomiting, and he would usually vomit on the way to chemotherapy. He would vomit all through chemotherapy. He would vomit on the way home. And usually, invariably by midnight that night, after hours of vomiting, it would be an emergency trip to Accident and Emergency to have some fluids and to have more IV antiemetics. He tried literally every antiemetic that was available pharmaceutically…They worked to a degree, but this became such a psychological issue as well—a bit like Pavlov's dog, I guess. We tried to seek help for this in all number of ways, and nobody really was equipped to help us deal with it.

3 *Committee Hansard*, 31 March 2015, p. 17.

4 *Submission 31*, p. 1.

At the point where Daniel tried cannabis, he was three years into this treatment. The chemotherapy was not working. They were saying he needed to go back to the original chemotherapies that they had tried, which did not last very long with him because the side effects were so severe… [The next time Daniel had chemotherapy], he had a couple of puffs on a cannabis joint, and it was amazing. I really cannot understate that. It was as near to a miracle as I have ever seen… He would come home with a chemotherapy pump on, so he would be out of the clinic but effectively still hooked up to chemotherapy, and he would be [extremely white] for days. He had a couple of drags; the colour came back into his face, and he just went: 'Wow! I'm hungry. Mum, can I have something to eat?' We just went: 'What is going on here? This has never happened'—because this kid would lie in a hospital room for days and days not eating. This was just such an incredible change. It was life-changing for all of us. We just looked at each other and thought, 'Well, if this is what it takes, this is what it takes.'[5]

4.11 The second case study is of Mrs Joelle Neville, who gave evidence to the committee at its Brisbane public hearing in relation to using cannabis oil as a last resort treatment for her daughter's severe seizures.

Case Study 2 – Mrs Joelle Neville

I am the mother of a ten year old child that was diagnosed with Tuberous Sclerosis at the age of five months. As a result of the genetic condition she has been severely epileptic since birth. Prior to starting medication she was having 15-20 seizures a day.

Over her short life she has trialled over twenty anti-epileptics, had two brain surgeries and trialled various diets/ supplements. Other than a six month period when she was 18 months old, when we briefly managed to find the perfect balance of medication and brain development, she has never been seizure free. As a result of her epilepsy, she has an intellectual disability diagnosis and currently attends a special needs school. She has also never slept more than a four hour period. She has needed constant care and supervision all her life. As you can imagine, this has placed a huge strain on our family and massive limitations on our lives.

August of 2014 saw us hit a particular low point when Ava's seizures became worse despite being on maximum doses of four anti-epileptics, one of which we were trialling off-label and was costing us almost $4000 a month. Each of the drugs have horrible, potential side effects. At this time, Ava was having 6-8 seizures a day, some of which were lasting up to ten minutes and sending her back to sleep for hours.

I was able to obtain a few syringes of 18% CBD Hemp Oil and began her at a tiny dose (approx. 1/6ml twice a day). Within a week Ava's seizures completely stopped. Now, six months later, we have completely weaned Ava off of all her medications and she is currently on approx. 1/3ml twice a day. She has the occasional, very small seizure that probably only my husband or myself would notice. A month ago she started sleeping 9-10 hours a night, unbroken.

5 Mrs Lucy Haslam, *Committee Hansard*, 31 March 2015, pp 26-27.

> As you can imagine, this has been absolutely life changing for all of us. We have been able to explore normal lives and realise the potential in our child…I don't have a specific dollar amount that Ava's prior medication regime was costing the government but I would imagine (especially if you take into account surgeries, doctors and therapies) that it was in the hundreds of thousands per year.[6]

Reliance on unrefined cannabis products in the illicit market

4.12 A significant problem for individuals currently using medicinal cannabis is the fact that, as an unregulated and illicit activity, there is little control over the quality or standardisation of the products being used. The University of Sydney academics group noted in its submission:

> Medicinal cannabis use is widespread in Australia despite the prevailing regulatory framework. Vulnerable patients source cannabis preparations from the black market. These preparations are unregulated with potential for inappropriate cannabinoids for certain indications (e.g. high THC for paediatric epilepsy), contamination with pesticides or heavy metals, tinctures with no cannabinoids sold as medicine, and poor understanding of appropriate dosing schedules.[7]

4.13 Their submission confirmed that black market cannabis available in New South Wales is not generally optimised for therapeutic applications:

> In 2013, in conjunction with the NSW Police and the National Drug and Alcohol Research Centre (NDARC), our group preformed the first ever chemical analysis of street cannabis seized by the police at various sites in NSW…Our results showed that typical street cannabis (more than 200 samples were analysed) was high in THC and very low in the therapeutically useful, non psychoactive cannabinoids such as CBD and THCV. This illustrates a major potential problem with the current regulatory environment whereby person seeking to use medicinal cannabis are likely to end up with illicitly obtained, high THC preparations, that may be devoid of the phytocannabinoid ingredients that would best treat their condition... At present, consumers have no ability to determine the type or strength of cannabinoid products they are consuming, and it remains illegal for analytical laboratories to even test these products. These are major impediments to the safer use of medical cannabis, and may more than likely be exacerbating the harms experienced by consumers.[8]

4.14 Professor Iain McGregor of the University of Sydney expanded on this argument in evidence to the committee:

> [In the illicit market] there is no quality control. We have had parents of epileptic children get in touch and say: 'Suddenly the new tincture is not working. The old one was fine and controlled the seizures. Now my child is

6 *Submission 70*, p. 1.

7 *Submission 52*, p. 2.

8 *Submission 52*, pp 5 and 6.

> fitting again with this new bottle that we got, and we don't know why. Can you help? Can you tell us what has changed and why it is not working anymore?' These are desperate people that should be helped.[9]

4.15 Several patient groups that gave evidence also commented that concerns about quality control were a significant issue for individuals seeking to use cannabis products for therapeutic purposes.[10] These concerns were echoed in written submissions by other individuals currently using medicinal cannabis.

4.16 Several submitters and witnesses expressed the view that a regulated medicinal cannabis industry would be better than the current situation in which many individuals access cannabis products illegally. The University of Sydney academics group stated:

> A regulated industry is far preferable to the existing situation of consumers relying on unregulated and illegal products, no authoritative consumer information from health professionals, and researchers being restricted to pharmaceutical products – of which there remain a very limited number of cannabinoids available from a small number of pharmaceutical companies.[11]

Difficulties associated with getting TGA approval for cannabinoid products

4.17 Several submitters and witnesses commented on the process and difficulties associated with gaining approval for a cannabis-based product through the TGA. As noted in chapter 2, getting a product listed on the Australian Therapeutic Goods Register (ARTG) involves a sponsoring organisation presenting a dossier of evidence including clinical trial data to the TGA, which then assesses the application in an iterative process that can take up to a year to complete.[12] The TGA informed the committee that costs for an application for a new chemical entity are around $250,000.[13]

4.18 Emeritus Professor Laurence Mather noted that the herbal nature of the cannabis plant means that it is difficult for pharmaceutical companies to gain patent protection in relation to cannabis-derived products:

> When used as a medicine, cannabis cannot be regarded as a single drug, and therein lies an issue. Conventional regulatory bodies have no framework for examination and approval of potentially variable mixes of drugs. Conventional pharmaceutical companies have little to gain from investing in natural products that cannot be patented or bear an illegal drug level.[14]

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9 *Committee Hansard*, 31 March 2015, p. 9.

10 Mr Lance Feeney, National Association of People Living with HIV Australia, *Committee Hansard*, 31 March 2015, pp 17-18; Ms Carol Ireland, Epilepsy Action Australia, *Committee Hansard*, 31 March 2015, p. 18.

11 *Submission 52*, p. 8.

12 See evidence from the TGA at paragraphs 2.44-2.49.

13 Dr Lisa Studdert, TGA, *Committee Hansard*, 30 March 2015, pp 36-37.

14 *Committee Hansard*, 31 March 2015, p. 11.

4.19 When questioned on why more companies were not sponsoring cannabis-based products for registration with the TGA, Dr Lisa Studdert of the TGA agreed that patent protection is an issue:

> [T]he economics of medicine registration are such that companies need some patent protection to recoup costs over a period of time. We know that many of the development costs of new medicines vary but they can be in the hundreds of thousands if not up to billions of dollars.[15]

4.20 Professor Philip Morris of the Royal Australian and New Zealand College of Physicians agreed that:

> with cannabis…I do not think there is any big commercial organisation that will be coming forward to sponsor this drug's application, and we will have to think about ways of having the drug's pros and cons presented to the TGA so that it can be assessed in that way.[16]

4.21 Associate Professor Lintzeris observed that the relatively small pharmaceuticals market in Australia is another factor that means companies are unlikely to invest significantly in getting new cannabinoid medications listed through the TGA.[17]

4.22 Professor Hall stated that, in additional to regulatory barriers, pharmaceutical companies have not developed new cannabinoids or methods of delivering them because 'it is costly to develop and test new cannabinoids and difficult to recoup these costs when the conditions for which they may be medically used are uncommon'.[18]

Difficulties associated with conducting research into medicinal cannabis products

4.23 Several of the academic groups in Australia conducting research into medicinal cannabis noted that undertaking research in this area is extremely difficult. The University of Sydney academics group submission stated:

> Over the past decade there has been immense international growth in this area of research as the significance of the endocannabinoid system in human health and disease becomes increasingly apparent. Despite this, we conduct our research in a tight regulatory environment that makes sourcing, holding and administering cannabinoids extremely difficult and expensive. Cannabinoid preparations typically have to be imported from the USA or Europe at great expense, and with time consuming paperwork and processes imposed by the TGA and state regulatory authorities. This is despite the fact that the vast majority of cannabinoids we research have no psychoactive or addictive properties in humans.[19]

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15 *Committee Hansard*, 30 March 2015, p. 37.

16 *Committee Hansard*, 31 March 2015, p. 53.

17 *Committee Hansard*, 31 March 2015, p. 5. See also: Professor Wayne Hall, *Committee Hansard*, 1 April 2015, p. 26.

18 *Submission 4*, p. 6.

19 *Submission 52*, p. 2.

4.24 Dr Alexander Wodak of the Australian Drug Law Reform Initiative (ADLRI) commented that research restrictions have been problematic overseas as well as in Australia:

> In the United States cannabis is still on schedule 1, which means it is as dangerous as heroin and more dangerous than cocaine, which is on schedule 2. That gives you an idea of how serious the obstacles are. But getting funding, getting approval from an ethics committee and, most importantly of all, getting supplies of lawful medicinal cannabis in Australia, the United States and many other countries at the moment is virtually impossible.[20]

4.25 Professor Iain McGregor, an academic at the University of Sydney, elaborated on the practical challenges associated with conducting cannabinoid research in Australia:

> We are involved in everything from cellular studies through animal studies through to clinical trials, and all we encounter along the way is hurdles imposed by state and federal legislation. For example, I am interested in the mechanism whereby CBD affects epilepsy, but to get CBD I have to fill in dozens of forms, deal with New South Wales Health, deal with the TGA and often wait six to 12 months and spend thousands of euros to bring that into Australia. Yet the industrial hemp manufacturers that are currently present in New South Wales could easily extract CBD from their plants and give it to me for research purposes.[21]

4.26 In relation to the current clinical trials in Australia of the nabiximols Sativex, Associate Professor Lintzeris commented:

> [I]t is a very long, difficult process to do this kind of research and there is only one pharmaceutical company in the world from which we can access these medications. So we are beholden to GW Pharmaceuticals' board decisions. These are financial interests that they have, just like any other drug company…In the studies that we are doing, GW Pharmaceuticals have been supportive of us…We have estimated that the medication that GW Pharmaceuticals will be providing us for the research [costs the company] well in excess of half a million dollars…That is comparable to the total grant we received from NHMRC to do this research. That really puts in perspective just how expensive it is to do this kind of research and, at this point in time, how beholden we are upon the drug company to provide us these medications.[22]

Supply-specific issues

4.27 Professor McGregor noted that supply of cannabis for research purposes at the current time is entirely dependent on overseas suppliers, stating that researchers 'are really at their mercy with our clinical trials at the moment because we have no local

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20 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, p. 47.

21 Professor Iain McGregor, *Committee Hansard*, 31 March 2015, pp 1-2.

22 *Committee Hansard*, 31 March 2015, pp 2-3.

supply of cannabinoids'.[23] He also explained, however, that if regulatory restrictions were relaxed in Australia it would be relatively straightforward for existing industrial hemp producers to start growing cannabis strains for specific research purposes:

> [T]here is quite a vibrant industrial hemp industry in Australia…In discussions with industrial hemp manufacturers, I have said to them, 'What would it take for you to switch over to different plants that will express some of the therapeutically important cannabinoids and extract them?' Basically, they could do that this year…[T]hey have more than 200 strains of cannabis plants available that express different levels of these cannabinoids. So, if we wanted to, say, have a plant that was very high in THCV that might be good for obesity or diabetes, that is certainly doable within their existing stocks and strains.[24]

4.28 The committee received evidence from companies and individuals involved in the production of industrial hemp in Australia, who confirmed that it would be possible for existing growers to produce cannabis plants with specific cannabinoid profiles, including low-THC strains, and controlled for contaminants in order to advance the use of and research into medicinal cannabis products.[25]

Inability for state and territory governments to progress the issue

4.29 Several submitters and witnesses noted that state and territory governments are currently unable to progress bringing medicinal cannabis inside a legal regulatory framework, due to the *Therapeutic Goods Act 1989* (TG Act) 'covering the field' in relation to the regulation of cannabis as a therapeutic good. The ADLRI stated:

> All State or Territory based initiatives to allow, or trial, medical cannabis come up against the jurisdictional supremacy of the Commonwealth law, in particular the [TG Act].
>
> The central problem is that the [TG Act] covers the field – that is, the Commonwealth has sole jurisdiction for therapeutic goods and the States have no (or very little) authority in this area. Further, the [TG Act] applies to any substance that is marketed and/or traded as a therapeutic good. Therefore, as soon as cannabis is provided as a therapeutic good, any affect of State laws is overridden by the [TG Act]…Given this, it is essential that the Commonwealth pass legislation allowing States to have self-determination over their medical cannabis policies. The simplest way for this to happen is for legislation that clearly states that the [TG Act] does not apply to medical cannabis.[26]

4.30 Mr Ben Mostyn of the ADLRI expanded further on how this issue currently plays out in New South Wales:

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23 *Committee Hansard*, 31 March 2015, p. 2.

24 *Committee Hansard*, 31 March 2015, pp 5-6.

25 See: Mr Paul Benhaim, *Committee Hansard*, 1 April 2015, pp 30-31; Mr David Gillespie, *Submission 47*.

26 *Submission 36*, p. 2.

> We have the perverse situation in New South Wales at the moment where every party has expressed support for medical marijuana; there seems to be very strong support in the community, where 75 or 80 per cent of people do not want to see people who use medical marijuana facing prosecution; and unfortunately the New South Wales parliament just seems to not have the authority or the jurisdiction to do anything about it. Any attempt that they make to try medical marijuana will have to be a very laissez-faire trial…because it will have to try and completely avoid the [TG Act]. They will have to be doing something completely outside that therapeutic framework.[27]

Comments on the regulatory model proposed in the Bill

4.31 Many submitters and witnesses expressed support for the intention of the Bill to provide a national framework for the regulation of medicinal cannabis that facilitates the acceleration of research in this area and increases access to medicinal cannabis products where these are show to be effective.[28]

Broad comments on the regulatory approach taken by the Bill

4.32 The evidence presented to the inquiry by submitters and witnesses, including cannabis researchers and drug policy experts was that the two extremes in terms of approaches to regulating medicinal cannabis are:

- approaches which legalise or decriminalise medicinal cannabis, providing high availability to patients but limited quality control and greater risk of leakage into the illicit market; and
- approaches which only allow for pharmaceutical-grade medicinal cannabis products subject to stringent testing regimes, with supply being tightly controlled.[29]

4.33 Several submitters and witnesses commended the Bill's attempts to strike a middle ground between these two extremes of regulation. For example, Associate Professor Lintzeris commented:

> This legislation, the way we see it, provides at least a framework. It does not have all the answers on how we are going to do it but it provides a framework and, importantly, it is somewhat independent of direct government roles. It allows appropriate experts and community players to

27 *Committee Hansard*, 31 March 2015, p. 50.

28 See, for example: Palliative Care Australia, *Submission 23*, p. 3; Public Health Association of Australia, *Submission 26*, p. 4; Australian Medical Association, *Submission 44*, p. 1; ACT Government, *Submission 147*, p. 2; Emeritus Professor Laurence Mather, *Submission 17*, p. 8; National Centre for Education and Training on Addiction, *Submission 66*, p. 1.

29 See: Associate Professor Nicholas Lintzeris, *Committee Hansard*, 31 March 2015, p. 3; Professor Allison Ritter, National Drug and Alcohol Research Centre, *Committee Hansard*, 31 March 2015, pp 38-39.

> drive this agenda moving forward. So we see it as striking a fairly useful and important balance between those two competing poles of the debate.[30]

Views on the necessity of a standalone regulator

4.34 Some stakeholders to the inquiry argued that the current system of regulation in Australia is adequate and does not require significant change. The Australian Medical Association (AMA), for example, argued that the necessity for any medicinal cannabis products to be of pharmaceutical quality means that an alternative scheme to regulate medicinal cannabis would be detrimental:

> The public discourse on the use of medicinal cannabis for a limited number of health conditions ignores the fact that consuming cannabis for recreational purposes is harmful…This is why medicinal cannabis should be subject to the [TG Act] and not regulated separately.
>
> While this stance may be seen as conservative in the context of the current debate on the merits of medicinal cannabis, it is critical that medical practitioners have confidence in the integrity of the pharmaceutical products that are available to treat patients. Similarly, all patients including those being treated for terminal illness, must be confident in the quality of the therapeutic products that are prescribed to them by their treating medical practitioner.[31]

4.35 The Australian and New Zealand Society for Palliative Medicine similarly argued:

> With patient safety paramount, Medicinal Cannabis use should be evidence-based and as a prescribed medication, regulators should establish the use of pharmaceutical quality products only, which are managed in the same way as other prescribed medications, via the existing mechanisms established by the [TG Act].[32]

Role of the proposed Regulator versus the current role of the TGA

4.36 Discussion about whether a new standalone regulator for medicinal cannabis was justified focussed on the question of whether the functions proposed to be granted to the new Regulator could already be performed by the TGA.

'Duplication' of regulatory functions with the TGA

4.37 Some submitters and witnesses argued that creating the proposed regulator, as envisaged under the Bill, would generate a duplication of regulatory functions with the TGA. The Pharmacy Guild of Australia argued that the creation of a new regulator solely to regulate medicinal cannabis 'has the potential to fragment the regulation of medicines in Australia as well as lead to confusion and unnecessary duplication of

30 *Committee Hansard*, 31 March 2015, p. 3.

31 *Submission 44*, p. 1.

32 *Submission 42*, p. 6.

regulatory processes'.[33] Medicines Australia agreed that a new regulator would 'introduce an additional level of regulation that is unnecessary'.[34]

4.38 Cancer Voices Australia stated its concern that the Bill would circumvent and add complexity to the current process of listing and approving medical drugs by the TGA.[35]

4.39 Representatives from the TGA presented the view that the TGA would be able to perform some but possibly not all of the functions proposed for the Regulator to perform under the Bill. Dr Lisa Studdert of the Market Authorisation Group within the TGA stated:

> Certainly for the approval of a product for therapeutic use, [the TGA does] have that expertise...there is a precedent with the product Sativex, which is a cannabis based product which has been approved for market registration in Australia. For that function there is the expertise, but I think the scope of the bill and perhaps what is being anticipated goes much beyond what is covered in the [TG Act].[36]

4.40 Ms Philippa Horner, Principal Legal Advisor at the TGA, continued:

> [The TGA] really only gets involved in terms of pharmaceuticals like Sativex in that bit about approving the medicine. Before that and after that there are the customs prohibited imports regulations, which determined whether drugs can come into Australia to be manufactured in Australia, and there are then the states and territories who have all the rules about what pharmacists and wholesalers can do with drugs that have got schedule 8 substances in them. So we are just a kind of slice of a whole system that is set up already.[37]

4.41 The Pharmacy Guild of Australia argued that any expanded regulatory powers in relation to medicinal cannabis should be granted to the TGA through amendments to the TG Act, rather than the creation of a new regulator:

> [P]owers and responsibilities [relating to medicinal cannabis] should be delegated to the relevant regulatory area within the Therapeutic Goods Administration (TGA) and any required amendments to the law should be made to the *Therapmtic Goods Act 1989*…[The TGA's] key roles include classifying medicines based on their risk, implementing appropriate regulatory controls for manufacturing of medicines and the monitoring of medicines which includes a comprehensive adverse event reporting programme. Therefore, the TGA is the most appropriate regulatory body to

33 *Submission 18*, p. 1.

34 *Submission 24*, p. 2.

35 *Submission 10*, p. 2.

36 *Committee Hansard*, 30 March 2015, p. 34.

37 *Committee Hansard*, 30 March 2015, p. 36.

> oversee the supply and export of medical cannabis as they possess the necessary experience and expertise in this area.[38]

4.42 By contrast, Emeritus Professor David Penington expressed the view that the TGA does not have the experience required to handle the complexities associated with coordinating the issue of medicinal cannabis across Australia:

> [T]he TGA traditionally has dealt with clear-cut proposals which lead to drugs which can be commercialised and so on. It would not be a body that would be able to liaise with other state health departments and the like in the way that I believe is going to be essential to get effective control of medical cannabis. The control will need to be at a state level with programs that are flexible and can be adjusted as more knowledge emerges as to which particular forms of disease would benefit from treatment. I think the TGA wants clear-cut proposals that are all supported by factual evidence of trials and the like. But it is not likely to be able to handle the complexities of production of the appropriate cannabis product, nor is it likely to be in a position to handle the liaison that will be needed between the various state programs.[39]

4.43 Professor Penington argued further that this national coordination would require a body other than the TGA to implement, regardless of whether the Regulator proposed by the Bill was to eventuate:

> I think it is very important that there be tight regulation—that is, regulation which needs to be implemented by the states, in my view, rather than a national regulation. That regulation hopefully ought to be consistent, so that even under COAG it is possible that you could have a special group established that could handle these sorts of issues with the Commonwealth agreeing to operate it. It may not have to be an agency comparable to the TGA in any sense. But it may need to be an agency or committee or structure that has the authority to coordinate activities for the various programs that would be advised, medically as well as legally, on the sorts of conditions that it is agreed should commonly be used and the sorts of ways in which the new trials of emerging new things can be tested…I do not think [the TGA] can be the body that will persuade the states to come together and have sensible, ongoing agreement as to what are the conditions that should apply and so on.[40]

'Parallel' operation of the TGA and the Regulator

4.44 Professor Wayne Hall expressed caution in relation to creating a parallel system of regulation for one particular class of medicinal product:

> I would be wary of creating special regulatory systems for one drug. I think we should try and do what we can to deal with it within the existing pharmaceutical structure. It might need bit of tweaking, but I think creating

38 *Submission 18*, p. 1.

39 *Committee Hansard*, 30 March 2015, p. 21.

40 *Committee Hansard*, 30 March 2015, p. 23.

> a parallel system for distribution, a special access scheme, adds to the expense. One could easily imagine other people coming along making similar demands about other products that they want to see introduced in a medical practice, so I think one has to worry about precedents.[41]

4.45 Conversely, the Public Health Association of Australia stated:

> PHAA fully supports the approach of having the Regulator operate in parallel to the TGA. We note the intention to have its processes align with the TGA insofar as that is appropriate, particularly as new cannabis-based therapeutic products that meet TGA standards come onto the market.[42]

4.46 The University of Sydney academics group stated its support for an independent regulator being able to operate synergistically with the existing TGA system:

> We believe that a dedicated medical cannabis regulator can coexist in parallel with the TGA's existing procedures and processes but provide a much more lean, efficient and specialized approach to regulation. While there is a role for medical cannabis products as identified in this bill, it does not obviate the role of the TGA in the development of medical cannabinoids as pharmaceutical products. Pure pharmaceutical grade products will be an inevitable result of the current research trajectory in the medicinal cannabinoid area and may be the most desirable end product for certain patient populations. The new regulator can explore alternate yet parallel and synergistic policy models for the regulation of research into medical cannabis products, as well as their use.[43]

4.47 Dr Wodak expressed the view that a dedicated regulator would allow the difficult issues surrounding the regulation of medicinal cannabis to be worked through and address concerns raised about the prospect of using cannabis medicinally:

> There are a lot of people in the community and in the professions who would welcome [the introduction of medicinal cannabis], but there are some people who are very nervous about that, and I think we should try to allay their fears, and say that this is going to be done seriously and properly. I think an office of medicinal cannabis would do that. It is a very difficult area…and I think that having a dedicated office that does this and does not do other things would allow them to focus and concentrate and sort out some of the thorny issues.[44]

4.48 Dr Wodak argued that a standalone regulator would be required for the time being, but may later be able to be subsumed within the TGA as the science of

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41 *Committee Hansard*, 1 April 2015, p. 24.

42 *Submission 26*, p. 4.

43 *Submission 52*, pp 6-7.

44 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, p. 47.

medicinal cannabis becomes better understood and the regulatory processes for medicinal cannabis are firmly established.[45]

Applications made both to the Regulator and the TGA

4.49 The Bar Association of Queensland questioned whether the Bill would result in 'forum shopping' from companies seeking to list medicinal cannabis products:

> It appears from the [EM] to the Bill that pharmaceutical companies will have a choice as to which regime they apply to for approval to sell medicinal cannabis products.
>
> It is unclear if two separate applications may be submitted concurrently to these authorities (the TGA and the…Regulator). It is also unclear if an application is rejected by one Regulator that fact and reasons for that rejection are required to be disclosed to the other Regulator should the company make a subsequent application pursuant to the alternative scheme. This should be clarified.[46]

4.50 The Pharmacy Guild noted that 'if the majority of companies elect to have their products registered through the TGA, then the proposed new regulator becomes redundant'.[47]

4.51 On the issue of the high costs of listing products through the TGA, the Pharmacy Guild argued:

> If the cost of registering a cannabis product through the TGA is deemed to be a potential barrier to market entry, consideration should be given to reducing the application fees for these types of products. This approach will ultimately be a more efficient option than establishing a new separate regulator.[48]

Application of the TG Act and Narcotic Drugs Act 1967 to activities undertaken in accordance with the Bill

4.52 Evidence presented to the inquiry by the Department of Health (department) and the TGA raised concerns that the system of regulation envisaged under the Bill could create legal uncertainty in relation to whether the TG Act would apply to activities purportedly taken in accordance with the Bill in certain circumstances.

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45 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, pp 47-48.

46 *Submission 53*, p. 3.

47 *Submission 18*, p. 1.

48 *Submission 18*, p. 2.

An opt in/opt out system?

4.53 The department questioned how the "opt in/opt out" system proposed in the Bill might work, stating that it was unclear when the Bill would apply versus the TG Act:

> The…Bill appears to operate in parallel with the TG Act on the basis of choice by a person to opt into the [Bill's] Scheme and opt out of the TG Act scheme. The implication of the opting in and opting out mechanism could be significant. This is particularly the case in relation to the application of the TG Act, as the definitions of "medicinal cannabis" and "medicinal use" are not clearly articulated in the [Bill] and it is not clear how they would not be caught by the definition of "therapeutic goods" in the TG Act. The complexity of this opting in and opting out system can be confusing for the regulated persons, the regulator and other agencies such as the TGA. Without a clear definition, it is not clear to consumers, health professionals, the industry and the regulators which law applies and what their legal obligations and responsibilities would be. It would be difficult for the regulators to determine what their powers are and whether they have the right to take regulatory action in relation to a particular product or activity.[49]

4.54 The TGA shared similar concerns. The TGA argued that, while licensees granted authorisations under the Bill's schemes would be exempt from the operation of the TG Act so long as they complied with their licence or authorisation, any activity outside the scope of their license may then come under the coverage of the TG Act. Ms Phillipa Horner, Principal Legal Advisor at the TGA, stated:

> The way we understand the bill works is that it fundamentally says that if you are acting in a way that is compliant with a licence or authorisation you have been given under this legislation then, for instance, the [TG Act] does not apply…[W]here it becomes complicated is where someone does something that is not in conformity with a licence—whether or not it is a breached condition, it is an offence under this Act. Then every provision of the [TG Act] would come into play, so that a person would be committing an offence under the [TG Act] in relation to that. Until you know whether someone has committed an offence you do not know whether you have got jurisdiction to investigate them. So you might be in this rather difficult position of purporting to use powers that you do not know you are able to use. It is a bit of a catch-22 position, because…the provisions come in and out, depending on whether you are compliant or not. It makes it quite difficult.[50]

4.55 When asked whether this potential difficulty could be overcome, Ms Horner suggested:

> I do not know that this would work in every situation, but another way you might do it is to make it so the [TG Act] applies whether the drug you are

49 *Submission 67*, p. 2.

50 *Committee Hansard*, 30 March 2015, pp 34-35.

> talking about is regulated under this Act or not; but that would [then] require a whole suite of offences to be in [the Bill] when the person did not behave.[51]

4.56 The department argued in its submission that a similar issue would arise in relation to the interaction between the Bill and the Narcotic Drugs Act, whereby license holders under the Bill would be exempt from the operation of the Narcotic Drugs Act when acting in accordance with that licence. However, where a licensee is non-compliant with licence conditions and the activity in which a licensee is engaged is not accordance with the medicinal licence they would be, based on the current wording of the Bill, subject to the Narcotic Drugs Act again.[52]

4.57 Accordingly, the department questioned whether under the Bill there could be 'several offence provisions from different legislative schemes potentially applying to the same activity', and concluded:

> Further consideration should be given to the interrelationship between the…Bill and the [Narcotic Drugs Act] and whether there is value in dealing with the regulation of medicinal cannabis by amendments to the [Narcotic Drugs Act] rather than creating a completely separate and free-standing regime. Building on the existing legislative framework may assist in ensuring consistency, achieving clarity and avoiding duplication of regulation due to several applicable laws.[53]

Register of regulated medicinal cannabis products

4.58 The TGA also questioned what would happen if the Regulator made a decision to take a product off the proposed register of regulated medicinal cannabis products:

> [I]f a drug were taken off the register…that would immediately mean that everybody down the line who was using that drug would immediately be committing offences under the therapeutic goods legislation and probably under the state legislation as well—that means the people who had an authorisation—because suddenly the drug is no longer the defined drug; it is a drug that has been removed. I am not sure how that would work and whether people would have an opportunity to appeal against that decision, but you can imagine that could create a fair degree of legal uncertainty.[54]

Interaction with other Commonwealth legislation

4.59 The department also raised concerns about the Bill's interaction with the Customs (Prohibited Imports) Regulations 1956 and Customs (Prohibited Exports) Regulations 1958 (together the Customs regulations) and the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*.

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51 *Committee Hansard*, 30 March 2015, p. 35.

52 *Submission 67*, p. 4.

53 *Submission 67*, pp 4-5.

54 *Committee Hansard*, 30 March 2015, p. 35.

4.60 The department highlighted that the Bill appears to overlap with some aspects of the Customs regulations with regard to the importation and exportation of cannabis and other cannabis products.[55] The department stated that the Bill 'does not appear to override the prohibition on importation or exportation of cannabis products under the customs legislation' and that '[f]urther consideration on the best way to achieve consistency and avoid duplication between the…Bill and the customs legislation with respect to import and export licences' would be required.[56]

4.61 The department indicated that the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*, which contains offences relating to the cultivation, import and export, and possession of controlled plants and drugs including cannabis, may also interact with the operation of the Bill. The department stated that further consideration needed to be given to whether amendments to this Act are required in relation to the production of cannabis for medicinal or experimental use sanctioned under the Bill.[57]

Adherence to Australia's international treaty obligations

4.62 Several submitters and witnesses commented on whether the functions and powers of the proposed Regulator were sufficiently articulated in the Bill to satisfy Australia's obligations under the *Single Convention on Narcotics Drugs* (the Single Convention), the *Convention on Psychotropic Substances* and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*.

4.63 The Penington Institute noted that other signatories to the international narcotics treaties have already approved the use of cannabis for therapeutic purposes through various regulatory structures.[58]

4.64 The department expressed the view that there are aspects of the Bill 'which may not adequately implement Australia's obligations under the drug control conventions, in particular the Single Convention'. In particular, the department argued that the Regulator's functions in relation to fulfilling Australia's obligations under the Single Convention should be more clearly defined:

> [C]lause 30 of [the Bill] provides that the Regulator has the functions of the Agency referred to in Article 23 of the Single Convention. However, [the Bill] does not specifically provide that the Regulator will be the sole agency that can authorise and licence cultivation of cannabis plants in Australia, nor that it is required to purchase and take physical possession of cannabis crops, as required by Article 23.
>
> Article 23 also requires that the Agency must have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers, of medicinal cannabis or cannabis

55 *Submission 67*, pp 3–4.

56 *Submission 67*, p. 4.

57 *Submission 67*, p. 5.

58 *Submission 75*, p. 1.

> preparations. To ensure clarity of the functions of the Regulator and to ensure that Australia meets its international obligations, it would be preferable if the functions and powers of the proposed Regulator were drafted in a way that more clearly conforms with all the requirements of Articles 28 and 23, rather than simply referencing relevant articles of the Single Convention, and generally requiring that the scheme operate in accordance with the Single Convention.[59]

4.65 The department further argued that the ability for Australia to prevent excess accumulation of cannabis and limit the total quantities of cannabis manufactured in or imported to Australia, as required under the Single Convention, may be compromised 'by the potential existence of more than one agency under Commonwealth and State and Territory law that can grant authorisations and licences with regard to dealings in cannabis'.[60]

4.66 The department also noted that Australia is required under the Single Convention to provide the United Nations International Narcotics Control Board (INCB) by 30 June each year with statistical returns in relation to of production, manufacture, consumption, stocks and seizures of narcotic drugs, and stated that 'it is unclear from [the Bill] whether the Regulator would be responsible for meeting these obligations' in relation to cannabis.[61]

Application of the Bill to participating states and territories

4.67 Another significant issue discussed throughout the inquiry was whether the Bill would be able to improve the current arrangements between the Commonwealth and states and territories in relation to the regulation of medicinal cannabis products.

4.68 Emeritus Professor Mather highlighted that several states are advancing the regulation of medicinal cannabis, and that the existence of a single, federal regulator as proposed under the Bill would be preferable to individual states and territories advancing their own schemes:

> Various of the state and territory governments are presently examining the evidence concerning medicinal uses of cannabis, and how it should be dealt with by legislation. This includes whether and how it should be lawfully prescribed and dispensed as a pharmaceutical preparation, or at least lawfully allowed to be used, with the patient and/or carer being responsible for its acquisition and quality. However, it is proceeding in a state-by-state or territory basis, with notable differences, and this will inevitably lead to problems, unforeseen and otherwise.
>
> How to permit and regulate cannabis and cannabis preparations for medicinal use has been a major stumbling-block to present state and territory governmental inquiries. If this Bill will allow a mechanism for the

59 *Submission 67*, p. 3.

60 *Submission 67*, p. 3.

61 *Submission 67*, p. 3.

> Federal production, regulation and permission of cannabis use as a medicine, including production and research, and to allow State and Territory governments to adopt the code of regulation afforded Federally, then surely this seems a beneficial way of precluding inharmonious local legislation and the errors of the past. A nation-wide code seems both sensible and economical.[62]

4.69 Medicines Australia agreed that the current federated model of regulation is unsatisfactory, but did not support a new regulator as proposed by the Bill:

> [T]he foremost barrier that Medicines Australia members have experienced in attempting to supply medicinal cannabis products in Australia have arisen from state and territory poisons legislation. In particular, differences in permit, prescription and risk-management plan requirements. These issues would not be overcome by the introduction of the [Bill] without appropriate changes to state and territory legislation…[T]he focus should be placed on harmonising state and territory legislation, rather than introducing a new level of national regulation, where appropriate and functional regulation already exists.[63]

4.70 The National Centre for Education and Training on Addiction (NCETA) cautioned that implementing a regulatory scheme in conjunction with participating states and territories would be complex:

> This will likely require States and Territories to amend legislation and undertake activities on behalf of the Commonwealth. These cooperative arrangements will be complex and will vary between jurisdictions due to differences in jurisdictional…[law] enforcement approaches to illicit cannabis [and regulatory] structures and approaches in place for Schedule 8 drugs.
>
> It will be important not to underestimate the complexities of these legislative and regulative arrangements in establishing the Regulator.[64]

4.71 The Law Institute of Victoria argued that it was unclear to what degree states would be required to reform existing legislation to incorporate the parallel system of regulation proposed by the Bill.[65]

Comments from state and territory governments

4.72 The committee received submissions to the inquiry from both the Victorian and ACT governments.

4.73 The Victorian Government confirmed its commitment to investigating legislative reform options to allow people to be treated with medicinal cannabis in exceptional circumstances, noting that 'the use of medicinal cannabis is a matter of

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62 *Submission 17*, pp 7-8.

63 *Submission 24*, p. 2.

64 *Submission 66*, p. 2.

65 *Submission 61*, p. 2.

high sensitivity and complexity'.[66] It stated that the Victorian Law Reform Commission's (VLRC) final report into these issues, due to be completed in August 2015, would inform its deliberations on the matter of legislative reform in relation to medicinal cannabis:

> The Victorian Government is committed to working collaboratively with the Commonwealth Government and other states and territories, to share information on issues relating to the use of appropriate therapeutic products derived from cannabis.
>
> The Victorian Government will consider the recommendations made by the VLRC before forming a final position on the proposed Regulator of Medicinal Cannabis Bill 2014.
>
> If the Regulator of Medicinal Cannabis Bill 2014 progresses, the Victorian Government will seek to further engage with the Commonwealth Government regarding issues raised in the Bill. In particular, consideration will need to be given to the scope of the Regulator's proposed functions and the interaction between the operation of Victoria's legislation and any new proposed national regulatory framework.[67]

4.74 The ACT Government stated its belief that a national approach to the regulation of the medicinal use of cannabis is required, and expressed support for the compassionate intent of the Bill.[68] It noted that if the ACT agreed to enter into an arrangement with the Commonwealth to participate in the scheme, it would need to amend its laws relating to the unlawful possession and administration of cannabis.[69]

Appropriateness of the rule-making power in the Bill

4.75 Several submitters and witnesses commented on the nature of the Bill as a 'framework' piece of legislation, with many significant features of the regulatory structure in relation to medicinal cannabis to be determined by the Regulator through the proposed rule-making power.

4.76 Ms Phillipa Horner of the TGA suggested that the proposed broad discretion of the Regulator to create rules relating to its operation is uncommon:

> [I]t is very unusual I think for an agency to be set up that makes its own rules—and you can see a lot of the detail of this is going to be in the rules—grants licences, enters into contracts with people in licences…[a]nd then it presumably does some enforcement and presumably prosecutes people if they breach. It also would then take things off the register—it would take licences away. That is a pretty unusual kind of set up.[70]

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66 *Submission 69*, p. 1.

67 *Submission 69*, p. 1.

68 *Submission 147*, p. 2.

69 *Submission 147*, p. 3.

70 *Committee Hansard*, 30 March 2015, pp 35-36.

4.77 In relation to the rule-making power, the ACT Government submitted that the absence of draft or indicative principles or processes for the development of the rules 'creates uncertainty about the efficacy of the scheme to prevent or minimise diversion and threats to public health and safety'.[71] It argued that consideration could be given to including principles in the Bill to serve as a guide for the development of the rules, and that the rules should be made by executive government rather than the Regulator.[72]

4.78 The AGT Government further commented that, should the Bill be enacted, it would 'be eager to participate in the development of the rules', with a view to ensuring that the relevant issues and perspectives are satisfactorily addressed and incorporated.[73]

4.79 Some stakeholders expressed the view that the flexibility afforded by the rule-making power in the Bill was a positive feature. For example, Professor Ritter of the NDARC stated:

> [An] advantage, from my reading of this draft bill, is that it has the capacity to be flexible and the regulator can then change over time. One of the problems with public policy is that decisions get made and then there is no ability to then change those decisions once one starts to see either very positive consequences or unintended negative consequences. It seems to me that there is the opportunity for enormous flexibility. If you look at the United States experience, many of the states have changed and resharpened some of their regulatory approaches over time. You really want to have that ability, and I think the bill gives that.[74]

Proposed register of medicinal cannabis products

4.80 In relation to the Regulator's proposed role of approving and registering medicinal cannabis products, various submitters and witnesses argued that the Regulator would need to maintain similar standards in relation to these products as apply to other medicines. For example, the Cancer Council Australia & Clinical Oncology Society of Australia in a joint submission stated that 'any product for medicinal purposes must be evaluated against objective criteria to ensure a high standard of safety, efficacy and quality for a particular use or uses'.[75]

4.81 NCETA, which supported the creation of the Regulator, submitted that the Regulator should maintain similar standards to the TGA in its decision-making on medicinal cannabis products:

> It will be critical to ensure that an appropriate level of rigour is maintained in the Regulator's decisions concerning the ways in which medicinal

71 *Submission 147*, p. 3.

72 *Submission 147*, p. 3.

73 *Submission 147*, p. 4.

74 *Committee Hansard*, 31 March 2015, p. 41.

75 *Submission 37*, p. 9.

> cannabis is made available and used. Given that pharmaceutical companies will also be able to apply to the Therapeutic Goods Administration to sell medicinal cannabis products under the TGA's legislation, it will be important to ensure the new approval mechanisms established under the Bill are both complementary to, and as rigorous as, those that currently apply to the TGA. Any short cuts to obtaining regulatory approval should be avoided at all costs.[76]

4.82 In arguing against the necessity for a new regulator, the AMA stated:

> Medicinal cannabis should be held to the same standards of evidence, safety, quality, and efficacy as other therapeutic narcotic products. This will ensure that medicinal cannabis can be standardised and regulated in its pharmaceutical preparations and administration, thereby reducing the harm to potential users.[77]

Process for the Regulator to approve products as 'suitable for medicinal use'

4.83 Under paragraph 13(2)(b) of the Bill the Regulator would be required to be 'satisfied that the cannabis product is suitable for medicinal use' in order to include a cannabis product on the proposed register of medicinal cannabis products.

4.84 Cancer Council of Australia & Clinical Oncology Society of Australia noted in a joint submission:

> This subjective assessment does not acknowledge any process undertaken by an applicant in seeking a product to be registered, including responding to specific criteria such as clinical outcomes and patient safety. The absence of a structure to objectively evaluate the application should also be noted. A rigorous review process is critical, for example, the review of therapeutic products prior to registration on the Australian Register of Therapeutic Goods. In the context of the Bill this is essential as people will be exposed to the product either through access (medicinal license) or research (experimental license). Assessment determines whether any risks associated with the product outweigh the benefit to the patient.[78]

4.85 Painaustralia expressed the view that the proposed Regulator should adhere to the principle that substances intended for therapeutic purposes be fully characterised chemically, pharmacologically and toxicologically, and argued that providing a clear definition of 'medicinal cannabis' in the Bill would address this concern:

> Painaustralia believes that in this context "medicinal" should refer to cannabinoid preparations of sufficient and consistent quality to be capable of being tested for efficacy and safety, and calls for a *specific definition of medicinal cannabis* to be incorporated into the Bill.
>
> It is not clear that [paragraph 13(2)(b)]…satisfies this requirement.[79]

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76 *Submission 66*, p. 1.

77 *Submission 44*, p. 1.

78 *Submission 37*, p. 7.

79 *Submission 56*, [pp 3-4].

4.86 Bedrocan, a medicinal cannabis producer responsible for supplying medicinal cannabis products in the Netherlands and Canada, commented that scientific findings in relation to different strains of cannabis should underpin listings by the Regulator:

> [Under the Bill] it is not clear what scientific evidence may be required to market specific cannabis products as effective for different indications.
>
> Claims are often made connecting certain cannabis strains with specific indications. While anecdotal reports of patients are useful and necessary, these claims are often not supported by scientific evidence. Such claims become particularly problematic in referring to cannabis that is non-standardized, as a claim of efficacy may be made for products that are marketed under the same name, but which may vary significantly in their chemical composition batch-to batch.
>
> The marketing of different strains of cannabis for specific indications, without proper evidence to support those claims, may create confusion among patients and doctors. Care should be taken that the evidence required to make claims of efficacy of a medical product for a certain indication should remain at a high level of quality.[80]

4.87 Palliative Care Australia called for the Bill to provide further details about the evidence that would be required by the Regulator in approving products.[81]

4.88 In contrast to these stakeholders, the Cannabis Policy Project contended that the current wording of paragraph 13(2)(b) 'gives the regulator the option to place a very narrow definition on the suitability of a cannabis product', and argued it is 'conceivable that as it currently reads the regulator could refuse all products'.[82]

Cost of medicinal cannabis products

4.89 Cancer Council Australia & Clinical Oncology Society of Australia noted that the cost of medicinal cannabis products made available by the Regulator may be an issue:

> By not requiring registration by the TGA, a product cannot apply to the Pharmaceutical Benefits Advisory Committee for reimbursement. Therefore a product cannot be available to a patient at a reduced price. Pricing of products on the register for regulated medicinal cannabis products must be public and transparent with an aim to provide products at a reasonable price.[83]

80 *Submission 48*, p. 11.

81 *Submission 23*, p. 8.

82 *Submission 43*, [p. 3].

83 *Submission 37*, p. 9.

4.90 Mrs Joelle Neville, whose daughter is currently being treated with high-CBD cannabis oil, expressed concern that pricing would need to be considered in order to make medicinal cannabis products affordable:

> [W]e are currently out of pocket about $6,000 a year. If we got to the point where it was being grown in Australia being produced here I would hope that that would bring the cost down slightly, but my fear is that if it was regulated to such an extent that government needs to recoup that cost somehow it would then become unviable for an average family to purchase. That is certainly a concern at the moment for most families. I know many families that would like to be on hemp oil, or cannabis oil, but financially it is not available to them, which leads, unfortunately, to shopping around on the internet.[84]

Medicinal cannabis licensing scheme

4.91 Some submitters commented on the processes proposed to be undertaken by the Regulator when granting licenses. NCETA expressed the view that ensuring the integrity of the licensing scheme proposed under the Bill would be of significant importance:

> The Regulator will…have an important role in ensuring that only fit and proper individuals are involved in the production, distribution and dispensing of medicinal cannabis. This will involve ensuring that appropriate probity checks are undertaken to ensure that those involved in the industry have no significant relevant criminal history or links to organised crime.[85]

4.92 On the issue of the criminal history of licensees, Palliative Care Australia opined that the Bill should clarify whether a person with previous convictions around cultivating or supplying cannabis would be able to gain a licence to cultivate or manufacture medicinal cannabis under the proposed medicinal cannabis licensing scheme.[86]

4.93 Cancer Council Australia & Clinical Oncology Society of Australia stated that the Bill was not clear about how a license application would be made and assessed, including against what selection criteria a license application would be evaluated, and recommended:

> Specific application processes, conditions of a license and the obligations of a license holder for each area of approval (e.g. distribution, cultivation etc.) must be clear and transparent to the applicant and general public. It is essential that post license monitoring and reporting be enforced especially the licensee's responsibility to report any adverse events.[87]

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84 *Committee Hansard*, 1 April 2015, p. 15.

85 *Submission 66*, p. 2.

86 *Submission 23*, p. 8.

87 *Submission 37*, p. 11.

Authorised patients and carers scheme

4.94 Several issues were raised in relation to the proposed authorised patients and carers scheme, including:

- processes for determining what kinds of medical conditions would qualify patients to access the scheme;
- the requirement under the Bill for access to the scheme to be subject to the prescription of a medical professional;
- implications for prescribing medical professionals, including liability issues; and
- means of ensuring that authorised patients and carers are sufficiently protected from law enforcement activities.

Determining access to the scheme for different conditions

4.95 Stakeholders to the inquiry presented varying views about how the Regulator should determine which patients, or classes of patients, should qualify for access to regulated medicinal cannabis products.

4.96 Emeritus Professor David Penington argued that the legislation should allow for the listing of recipient groups in line with emerging research and clinical trial results:

> Legislation will need to designate processes for approval of further recipient groups, which will no doubt emerge. It is suggested that the initial categories of pain in cancer, nausea and distress with cancer chemotherapy, painful neurological conditions and refractory juvenile epilepsy also provide for further categories when strongly recommended by two or more recognised specialists with a commitment to data collection and reporting or formal clinical trials.[88]

4.97 Professor Wayne Hall argued that the government should not be involved in supplying medicinal cannabis to patients outside of the context of clinical trials:

> If that were to happen, I think it would make clinical trials harder to do because people could get the drug without participating in trials, and we are talking about relatively small numbers of some of these cases, which would make it difficult to recruit patients into trials. There are also equity issues that are raised by governments supplying an unapproved, unevaluated substance at substantial cost when the pharmaceutical regulatory process decides not to fund drugs for which there is evidence of efficacy and safety because they are too expensive.[89]

88 *Submission 9*, p. 4.

89 *Committee Hansard*, 1 April 2015, p. 22.

4.98 Professor Hall stated that if medicinal cannabis was made available outside of clinical trials, this 'should be for registered patients and for a time limited period (e.g. 5 years) rather than an open ended commitment'. He further argued:

> Governments should fund long term follow-up studies of patients who use cannabis preparations and medical cannabinoids over periods of years to assess: the risks of developing cannabis dependence; exacerbating cardiovascular disease; precipitating psychotic disorders; and developing cancer.[90]

4.99 The Royal Australian and New Zealand College of Psychiatrists (RANZCP) was concerned that, given the link between cannabis use and psychiatric illness in some individuals, the Bill does not have a provision to identify patients who have experienced negative psychiatric consequences as a result of cannabis use:

> Without such a register, there would be the potential for medical practitioners to prescribe something that - while it may be the appropriate treatment for a medical concern - could have a significant detrimental impact on a person's mental health and would not be in the best interests of both patients and prescribers.[91]

Necessity for a doctor's prescription

4.100 As noted in chapter 3, under subclause 19(2) of the Bill, the proposed authorised patients and carers scheme (to be established by the rules) must stipulate that authorisations to patients or carers must only be given on request by a medical practitioner.

4.101 Submitters and witnesses commented on how 'medical practitioner' should be defined for these purposes, with the main three options being considered to be:

- allowing all doctors and some allied health professionals (for example, physiotherapists or occupational therapists) to prescribe medicinal cannabis;
- allowing all doctors to prescribe (but excluding allied health professionals); or
- allowing only some doctors to prescribe through a registered scheme.

4.102 Dr Alex Wodak suggested that all doctors should be given the ability to prescribe medicinal cannabis under the scheme, but that allied health professionals should be excluded from the initial scope of the authorisation scheme.[92]

4.103 Professor Ritter from the NDARC considered that it would be appropriate to allow health professionals other than doctors to prescribe products under the scheme, as long as they had access to appropriate accreditation, training and support.[93]

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90 *Submission 4*, p. 13.

91 *Submission 51*, p. 1.

92 *Committee Hansard*, 31 March 2015, p. 48.

93 *Committee Hansard*, 31 March 2015, p. 43.

Issues for prescribing medical professionals

4.104 The AMA did not support the establishment of an authorised patients and carers scheme as proposed by the Bill, nor the requirement that a medical practitioner should be required for a patient authorisation:

> [T]he requirement that patients and their carers be authorised to use medicinal cannabis at the request of their medical practitioner, is problematic. This may see undue pressure being put upon doctors to support applications for authorisation, purely as a means of access to cannabis products. There is a risk that if a doctor does not support a patient's application for authorisation it may undermine the doctor/patient relationship.[94]

4.105 RANZCP noted that the issue of individuals seeking cannabis for non-medical reasons was an issue that needed to be considered:

> It is the experience of many psychiatrists that patients who express a wish to obtain cannabis lawfully are motivated more by experience of its 'recreational' use than by reputed target symptoms that they may have, or claim to have. The alleged benefits of cannabis (some of them unproven) have been widely promulgated, and for doctors, the problems of assessment and control will probably be comparable to those associated with the prescription of opioids.[95]

4.106 Professor Philip Morris, of the Royal Australasian College of Physicians (RACP), claimed that doctors would be unwilling to prescribe medicinal cannabis products unless those products had been assessed to the standards required by regulators such as the TGA:

> You are going to be asking doctors to prescribe this medication for certain conditions. Once you start doing that, the physicians that are doing this need to know that the medication has been appropriately approved and that the pros and cons and the safety versus effectiveness in that particular condition have been assessed adequately. Anything less than that means that basically you are using a form of regulation which does not meet the usual medical standards. Now, if you are going to have medication or the thing prescribed by people other than doctors, then perhaps you could use a different standard. If you are going to ask doctors to be responsible for patients and to prescribe medication, then you need to go through the TGA experience.[96]

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94 *Submission 44*, p. 2. See also: Australian and New Zealand Society for Palliative Medicine, *Submission 42*, p. 8.

95 *Submission 51*, [p. 5].

96 *Committee Hansard*, 31 March 2015, pp 53-54.

4.107 The Australian and New Zealand Society for Palliative Medicine (ANZSPM) queried what would occur in the event that one only practitioner operating as part of a treatment team obtained a licence to be able to prescribe medicinal cannabis products:

> Issues of ongoing supply may be problematic. Should one clinician within a palliative care service decide to support the use of cannabis and apply for a licence, there would need to be consideration by the greater team as to issues of responsibility for ongoing care and support, particularly at times of recreational leave for the licensee, etc. This adds another level of complexity to patient care when one clinician holds the licence but is not available to care for the client.[97]

Exposure to liability for prescribing medical practitioners

4.108 The ANZSPM raised concerns relating to the potential liability of medical practitioners licensed to prescribe medicinal cannabis products:

> The medico-legal ramifications with being responsible for the outcomes associated with the use of this drug, particularly if there are breaches of the rules such as drug diversion, may also be of great concern to many ANZSPM members.
>
> The Regulator would be yet another body which doctors, who apply for a licence, will be answerable to, with possible serious legal ramifications if breaches occur.
>
> It is not known how Medical Indemnity Societies will support clinical members if there are legal implications arising, especially as the use of these drugs is not supported by good practice guidelines within a medical setting.[98]

4.109 The RACP echoed these concerns, arguing that the authorised patients and carers scheme as currently proposed offers medical practitioners insufficient protection from liability.[99]

Education for prescribing medical practitioners

4.110 Several submitters and witnesses discussed the need for education in relation to medicinal cannabis for prescribing medical practitioners. NCETA argued that clear guidelines would need to be developed for doctors:

> If medical practitioners are to have a role in prescribing cannabis it will be crucial that they have access to evidence informed guidelines about its appropriate medicinal uses. Such guidelines will need to be developed in consultation with relevant medical colleges and experts and supported by an extensive educational program to support practitioners in their prescribing decisions.[100]

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97 *Submission 42*, p. 8.

98 *Submission 42*, p. 9.

99 *Submission 29*, p. 1.

100 *Submission 66*, p. 2.

4.111 ANZSPM expressed similar views:

> Expanded teaching of health professionals who will be dealing with patients that have access to the drug will need to be considered. Patients are not isolated to one health professional (the licencee), and general education will be required to enable pharmacists, nursing staff and medical practitioners who have clinical responsibilities of patients using the medicinal cannabis, to ensure ongoing safety and good clinical practice. This will be important particularly for Palliative Care and Mental Health Specialists where many of the drugs used for symptom control have additive properties to the effects of cannabis.[101]

4.112 The ANZSPM stated that if the Bill was passed, health professionals would need guidance on the use of medicinal cannabis in practice, and argued that such guidelines would need to consider 'assessment criteria for prescribing, monitoring patient response, monitoring any potential misuse and for identifying possible drug interactions' as well as the relevant licensing arrangements.[102]

4.113 Palliative Care Australia noted that some medical bodies have developed guidelines for the use of medical cannabis, including in countries such as Canada where mechanisms for the use of medical cannabis have been introduced. It argued that these guidelines may be worth considering by the Regulator in the development of guidance materials for Australia.[103]

4.114 The Pharmacy Guild suggested that, rather than a new regulator providing standards and guidelines in relation to medicinal cannabis:

> The National Health and Medical Research Council (NHMRC) could…develop clinical guidelines to assist health professionals in determining the suitability of medicinal cannabis treatment for individual patients as well as ongoing management of symptoms and side effects.[104]

Ensuring protection for authorised individuals

4.115 ADLRI stated that practical safeguards would be needed to ensure that authorised patients and carers were not unwittingly targeted by state and territory law enforcement:

> Whilst a class of people will be created who are free from prosecution, it may be hard to ensure this freedom is absolute. There may be a need for strong policy to be drafted for State police forces giving direction on how to deal with people found with cannabis, who claim to be authorised under the Commonwealth scheme to use medical cannabis.[105]

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101 *Submission 42*, p. 8. See also: Bedrocan, *Submission 48*, p. 12.

102 *Submission 42*, p. 9.

103 *Submission 23*, p. 7.

104 *Submission 18*, p. 2.

105 *Submission 36*, p. 3.

4.116 ADLRI noted that while various options could be considered to help identify authorised patients and carers, including a patient register or a card system, none of these options were ideal:

> Although a card may be issued to people within the defined class, this is no guarantee that such people will be safe from search, arrest, and detention. A registry may need to be created that Police can check before arresting people, however significant thought will have to be given to how such a registry is constructed and maintained to avoid concerns about accuracy and patient privacy.[106]

4.117 Epilepsy Action Australia expressed concern that authorised persons carrying regulated medicinal cannabis products may not be protected whilst transiting through or temporarily visiting any Australian states and territories not participating in the scheme implemented by the Bill.[107]

4.118 The Bar Association of Queensland argued that it should be made clear that medicinal use of approved cannabis products by registered patients is a complete defence against any criminal charges relating to the possession or use of those products in participating states and territories.[108]

Experimental cannabis licensing scheme

4.119 Many submitters and witnesses expressed support for the intention of increasing access to cannabis for research and experimental purposes in Australia, in order to establish a broader evidence base in relation to the efficacy of medical cannabis.

4.120 The University of Sydney academics joint submission, which highlighted the difficulties in obtaining cannabis strains for research purposes in Australia, expressed strong support for the Bill's intention to allow for cultivation of cannabis for research purposes:

> [The Bill's] proposed mandate of setting up a system for the cultivation and production of cannabis for medical use and research in Australia, based on the Tasmanian poppy industry for opioids, would greatly accelerate basic, clinical and translational research in the cannabinoid area. This not only has the potential to facilitate access to medicinal cannabinoids for the research and broader community, but also may help position Australia as a global leader in the fast moving area of cannabinoid therapeutics... As we develop a greater understanding of the role of different "big 10" cannabinoids (e.g. CBD, THCV) for different medical indications (e.g. epilepsy, chronic pain, neurodegenerative conditions, PTSD, obesity, cancer), we will need to grow strains of cannabis that maximize the content of these cannabinoids to

106 *Submission 36*, p. 3; *Committee Hansard*, 31 March 2015, pp 49-50.

107 *Submission 31*, p. 2.

108 *Submission 53*, p. 1.

> facilitate therapeutic efficacy and the extraction and purification of these compounds for high quality medications.[109]

4.121 Emeritus Professor Mather lauded the inclusion of the proposed experimental cannabis licensing scheme in the Bill as a means of furthering research and development activities in the field of cannabis science.[110] NCETA agreed, stating that by enhancing access to cannabis for research purposes, the proposed regulatory arrangements would assist researchers address a number of knowledge gaps concerning the potential role of medicinal cannabis.[111]

Research standards

4.122 The joint submission from Cancer Council Australia & Clinical Oncology Society of Australia noted that the Bill does not acknowledge any requirement to comply with Australian guidelines or policies for proposing or conducting research on humans, or mention the need to fulfil a formal assessment process or seek authorisation from a Human Research Ethics Committee to commence cannabis product research on humans.[112] The submission argued:

> The Bill must promote research integrity and ethical compliance within the conditions of granting an experimental medicinal cannabis license. This must include: the *Australian Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*, including approval from a Human Research Ethics Committee to undertake the proposed research.[113]

Composition of the Regulator and membership requirements

4.123 Cancer Voices Australia supported the mandatory inclusion of a consumer (patient) representative as part of the Regulator's membership.[114] This proposal was also suggested by the Public Health Association of Australia in its submission.[115]

4.124 Palliative Care Australia argued that the inclusion of palliative care expertise in the composition of the Regulator was important, and stated that strong medical representation would be important to ensure that issues such as who may use medicinal cannabis, the impacts of long term use and the level of use were addressed properly.[116]

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109 *Submission 52*, pp 5 and 6.

110 *Submission 17*, p. 8.

111 *Submission 66*, p. 1.

112 *Submission 37*, pp 10-11.

113 *Submission 37*, p. 11.

114 *Submission 10*, p. 2.

115 *Submission 26*, p. 5.

116 *Submission 23*, p. 6.

4.125 The department stated that the establishment of the Regulator as a separate statutory entity with a CEO and staff 'is not in keeping with the Government's policy on a smaller and more rational government'. Further:

> [The Bill] also proposes that the CEO of the entity be the Chair of the regulator. It is not clear whether there may be any potential conflicts for a person to hold these dual statutory positions, [or] whether the person would be entitled to remuneration for each role. Further consideration should be given to whether existing government agencies could support the work of the Chair and members of the regulator.[117]

Appropriateness of the monitoring and investigatory powers of the Regulator

4.126 ADLRI expressed concern about the monitoring and investigatory powers of the Regulator proposed under the Bill:

> While we accept the argument that law enforcement and the public must be able to be confident about the security of the scheme, extending these powers to a new office, the Regulator, with no experience in police investigative powers may be ill-advised. The Committee must give serious consideration to whether a new agency should be given police powers or whether it is appropriate for police to monitor medical users.
>
> The preferred approach is to confine the use of powers of entry, search and seizure to police organisations that are trained and experienced in exercising these powers and that have appropriate oversight and accountability...It may be simpler for the office of the regulator to report concerns to local Police. Creating another investigative force may lead to over-policing of sick people.[118]

4.127 Mr Ben Mostyn of the ADLRI suggested that local police may already have adequate powers to deal with suppliers licensed by the Regulator who breach the terms of their licence:

> It would seem that…those monitoring and investigative powers [in the Bill] may not be necessary in the sense that either people who are licensed suppliers will be supplying it in accordance with their licence or they will not be…It would appear that, once they overstep the powers of the licence, they would quite clearly then come within the jurisdiction of the local police because they would be supplying cannabis without lawful authority. So it may be simpler and preferable to just leave any of that unlawful supply to the current systems in place.[119]

117 *Submission 67*, p. 5.

118 *Submission 36*, p. 3.

119 *Committee Hansard*, 31 March 2015, p. 50.

Impact on state and territory law enforcement agencies

4.128 Both the ACT Government and ADLRI expressed concern about the implications of the Bill for state and territory law enforcement agencies. The ACT Government argued that the Bill 'does not consider the impacts on law enforcement':

> Law enforcement agencies will be responsible for dealing with instances involving the diversion of authorised medicinal cannabis products to the illicit market, and to enforce other associated ACT legislation (for example, the *Road Transport (Alcohol and Drugs) Act 1977*).
>
> While the…Bill proposes to give the Regulator powers to monitor compliance with the Act and the rules (including powers to investigate breaches), there is no way to assess the possible impact on other law enforcement agencies.[120]

4.129 Similarly, ADLRI acknowledged that the Bill could place state and territory police in a difficult situation:

> …because they are the ones who need to enforce the regular cannabis laws whilst not overstepping the boundaries in any Commonwealth system. Unfortunately…we can point to the problem, but we do not necessarily have the solution.[121]

Review of decisions by the Administrative Appeals Tribunal

4.130 The TGA questioned whether the lack of definition of 'medicinal cannabis' in the Bill may create a large number of applications for decisions of the Regulator to be reviewed by the Administrative Appeals Tribunal (AAT):

> In the AAT, any person with an interest in a decision can come along and apply to have the decision overturned—not just the person who has the licence. Whether that is going to result in thousands and thousands of people wanting to go to the AAT, because either they have been refused an authorisation or the drug that they were getting has been taken off the register, will depend on how we define 'medicinal cannabis'. That is not very clear, so it is a bit hard to know whether it is a practical problem or not…If it mirrored the [TG Act], though perhaps not at the pharmaceutical level of prescription medicines, then presumably the drugs you are talking about would not be very many. But, if you are talking about a much wider group of drugs that would be approved, then I suspect you would have some practical issues about people wanting to appeal against any decisions about, or if any changes were made to, accessibility.[122]

Other issues

4.131 Stakeholders raised several other issues relating to the impact of the Bill that did not relate to its specific provisions, including resourcing, reporting requirements and the need for community education.

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120 *Submission 147*, p. 3.

121 *Committee Hansard*, 31 March 2015, p.

122 *Committee Hansard*, 30 March 2015, p. 35.

Resourcing issues for the proposed Regulator

4.132 NCETA noted that in order to be effective, the Regulator would need to be adequately resourced:

> It will be necessary to financially compensate States and Territories for activities related to the medicinal cannabis system. The Regulator's activities and those to be undertaken by States and Territories will need to be fully costed and appropriately resourced. Given that the Bill contains no appropriation, funds will need to be allocated by the Parliament for this purpose. Failure to ensure full and sufficient funding to the Regulator will result in regulatory gaps and inconsistency in approaches as are currently seen the regulation of Schedule 8 drugs across jurisdictions.[123]

4.133 The NSW Bar Association argued that it would also be important that adequate resources were devoted to law enforcement in order to prevent the diversion of 'licit' cannabis to the illicit market.[124]

Reporting requirements of the Regulator

4.134 The Cannabis Policy Project noted that there are currently no reporting requirements imposed on the Regulator, and that in order to enhance transparency and good governance, the Regulator should be required to provide an annual report to Parliament detailing its activities and decisions.[125]

The need for community education and measures to prevent 'commercialisation'

4.135 NCETA argued that, should the Regulator be established as proposed by the Bill, community education in relation to the changes would be important:

> The introduction of arrangements such as those outlined in the Bill will also require an extensive community education process. In particular, the introduction of medical cannabis should not come at the expense of cannabis coming to be regarded as a harmless, natural product. The adverse effects of cannabis use have been well documented…Any move to enhance the medicinal use of cannabis should not leave the broader community with the impression that cannabis use (particularly smoking) is a health promoting activity or not associated with a range of potential significant risks.[126]

4.136 A joint submission from Australian Federation of AIDS Organisations, the National Association of People With HIV Australia, ACON and Positive Life NSW also highlighted the importance of community education:

> The provision of information and education to communities that are likely to utilise and benefit from the medicinal use of cannabis would also be valuable. This should include the engagement of community, service

123 *Submission 66*, p. 2.

124 *Submission 3*, p. 2.

125 *Submission 43*, pp 3 and 6.

126 *Submission 66*, p. 3.

> providers and doctors to ensure that reliable information is available to consumers and doctors.[127]

4.137 The NSW Bar Association argued that if the Bill was successful in increasing access to regulated medicinal cannabis products, measures would need to be taken to prevent the commercialisation of the cannabis industry:

> A concern often expressed is the potential for the 'commercialisation' of cannabis use that could flow from regulated availability of medicinal cannabis (similar to the commercialisation of tobacco and alcohol). If a regulatory scheme for medicinal cannabis was introduced, it would be necessary to have very strict restrictions on advertising, to ensure that some of the mistakes in America are not replicated here.[128]

127 *Submission 30*, p. 2.

128 *Submission 3*, p. 2.