United in Compassion

Review of the Narcotic Drugs Act 1967

Submission to The Review

Foreword / Note To Review Secretariat

This submission was, for the most part, authored in January 2019 before the Secretariat published it's 'Discussion Paper' of the Review.

UIC notes the following remark within that Discussion Paper:

> *This Review is restricted to a review of the operation of the ND Act. It is not a review of cannabis regulation in Australia more broadly. Matters that do not fall directly within the scope of the review are the operation of Commonwealth, State and Territory laws dealing with:*
>
> - *patient access to medicinal cannabis – for example, under the Special Access Scheme, the Authorised Prescriber Scheme and the Personal Importation Scheme established under the Therapeutic Goods Act 1989 (Cth) (TG Act);*
> - *subsidising the cost of medicinal cannabis products through the Pharmaceutical Benefits Scheme;*
> - *scheduling of cannabis products by the Therapeutic Goods Administration (TGA) and adoption of scheduling decisions by State and Territory health departments;*
> - *registration of cannabis products as prescription medicines on the Australian Register of Therapeutic Goods (ARTG); and*
> - *decriminalisation of cannabis possession and for recreational uses.*

This we believe to be nonsensical - and an attempt by officials to limit the damage and embarrassment such a Review Process may cause by casting light upon what has been, from the outset, disastrous legislation and execrable public policy causing untold damage to sick Australians.

One of the key documents we feel the Review will have need to consider is the Explanatory Memorandum of the Narcotic Drugs Act Amendments Bill which can be viewed at the below link:
http://classic.austlii.edu.au/au/legis/cth/bill_em/ndab2016250/memo_0.html

As the Memorandum makes perfectly clear, the legislation in question was designed with all or most of the issues identified in the above bulleted list in mind, thus they absolutely *do* fall into purview and operation of the Narcotic Drugs Act Amendments of February 2106. To argue otherwise would, we feel, be tantamount to an admission that legislators were being misled when asked to consider and vote on the relevant Bill.

On this basis then, we trust every issue raised by this Submission will therefore receive due deliberation and consideration in the course of your duties.

United in Compassion
March 2019

About UIC

United in Compassion is Australia's Peak Medicinal Cannabis advocacy body which helped bring about the 2016 legislative changes this Review is tasked with exploring. Founded in 2014 by Lucy Haslam and her late son Daniel, UIC's main functions since then have been to promote education and knowledge around clinical uses of cannabis as well campaigning for improved patient access to what, for many, can be a life-saving medicine. We welcome the opportunity to contribute to this Review process.

Executive Summary

This Submission posits that the 2015 Federal Department of Health Regulation Impact Statement for Medicinal Cannabis (MC) did not meet the Standards of Best Practice as stipulated by Office of Best Practice Regulation within the Department of the Prime Minister and Cabinet (see Section 3.2 of this document).

Such a failure in turn resulted in legislative and regulatory change (the 2016 Amendments to the Narcotic Drugs Act and Re-Scheduling of cannabis in the Poisons Standard) which placed the medicine into permanent 'regulatory limbo', making it available only through a pathway designed for ‘exceptional clinical circumstances.’ This pathway moreover usually involves the support of a medical specialist (inexpert in cannabis) and comes with the additional need for additional State & Territory approval, issues explored in the Submission's Section 3.9.2.

Further, from the outset – aside from compliance to the 1961 UN Single Convention on Narcotic Drugs - no real policy aims were identified in terms of what the legislation set out to achieve, thus *no benchmark exists against which its ‘success’ or ‘failure’ may be measured.*

The result has been that only a comparatively small number of patients (out of many tens, even hundreds of thousands sourcing illicit products) have been able to access such medicine legally and then only at significant expense. Attrition among these is reportedly high.

Additionally, the Submission also points out (Section 3.5.3) that the Federal Government's intent has never been to make 'medicinal cannabis' available to sick Australians. Instead Ministers and bureaucrats have been quite clear that the only cannabis products they wish generally accessible are those that have undergone the assessment process for inclusion on the Australian Register of Therapeutic Goods (ARTG). But they have done so without acknowledging that the financial incentives are not in place for this to occur, causing a misalignment of policy and commercial objectives.

A successful and vibrant domestic industry has failed to emerge as a consequence, further hindered by lack of resource and poor management practice within the Office of Drug Control, a point also discussed

We therefore argue only a complete overhaul of the current system – which demands will at the political level – can accomplish what UIC has always had as its Mission; that being to advocate for:

'*….patient access to Full Spectrum herbal medicinal Cannabis extracts and dried herb Cannabis in a manner which is safe, effective, affordable, equitable and favourable for patients, for the dignified relief of suffering.*'

Section One: Overview

1.1 The Review & Legislation

On 14th December 2018 Greg Hunt, the Federal Health Minister, announced a Statutory Review of the operation of the 2016 Amendments to the Narcotics Drugs Act 1967 with a report to be tabled in Parliament by 29 October 2019. The public was to be consulted as part of this Review process.

As Minister Hunt said in his announcement, the Amendments in question were intended *'to provide for the regulation of cannabis cultivation and production in Australia (&) to enable a sustainable supply of safe medicinal cannabis products for therapeutic purposes*,' whilst the Terms of Reference of the Review itself were to establish:

> *'.....whether the measures implemented are working efficiently and effectively or could be improved for the benefit of affected parties (being applicants and regulated entities as well as the department administering the Act).'*

Though in and of itself a somewhat weak and equivocal policy objective (in contrast, within Section Five of this Submission) UIC proposes a minimum further *five* such objectives against which any future medicinal cannabis Framework may be more appropriately benchmarked) even this, we suggest, was never really the primary or even secondary purpose of the 2016 legislative change. Instead, we assert it set out, first and foremost, to remain compliant with the UN Single Convention on Narcotic Drugs 1961 and as a response to immense public pressure - which had continued into the start of the 2016 General Election cycle - to 'legalise medical cannabis'.

Whilst the Review may afford some advocates, members of the public and Australia's nascent cannabis Industry the opportunity to catalogue various of the many very real negative outcomes that as a matter of fact and law have their causal roots in the aforementioned 'measures', many of these, we feel are already well documented. Instead then, this document sets out to explore how and why the legislative changes of 2016 have failed - and will continue to fail - to deliver a satisfactory medical cannabis (MC) Framework for Australia, Australian patients and the country's new Industry. Suggestions on how matters might be improved will then follow.

1.2 Overlooking Actual Reality: Illicit vs Licit Medicinal Cannabis Use in Australia

UIC's focus is, and has consistently been through the lens we feel *all* discussion of this and related issues *must* necessarily be viewed: the fact that, currently, *hundreds of thousands of sick Australians needing MC are accessing black market products of unknown provenance and completely without medical supervision, criminalising themselves in the process*. [1] This highly unsafe and grossly unsatisfactory state of affairs represents – presumably - the exact *opposite* of what Governments and medical professionals would have wished to accomplish yet has become exactly the position in which Australia now finds herself, largely as a result of the legislation under review. Failing or refusing to acknowledge this reality and its significance is to overlook arguably the single most important facet of the matter at hand – the context of *things as they actually are*. Without a full appreciation and recognition of these as the circumstances in which the Review and any other discussions take place is therefore likely to render such deliberations purposeless and a misuse of labour and other resource.

1.3 In Brief: Why the Amendments to the Narcotic Drugs Act Have Failed To Deliver A Successful Medicinal Cannabis Framework

With this at the forefront then, and in broadest terms, we would argue passage of the Narcotic Drugs Amendment Act 2016 has been singularly unsuccessful in meeting what Minister Hunt claims were its original objectives (see above) - and this for three basic reasons.

First, and not least among them, is that from the outset, the legislation was based on a Regulation Impact Assessment (RIS) that *failed to meet the Government's own Standards of Regulation Best Practice* - a major factor in the scheme's evolution hitherto overlooked and to which it is hoped the Statutory Review will pay special attention. Indeed, the Government's own 'watchdog' on such matters found the Federal Department of Health's evaluation of how the legislation would play lacked '*analysis of the practical impacts of the measure*' while noting '*more extensive consultation was required*.' This issue is discussed in greater detail within Section Three.

Secondly - we believe as a direct result of this failure - the Framework as it currently stands has served to consign MC to perpetual 'regulatory limbo' destined forever to be 'quasi-approved' (via compliance with production standards like GAP/GMP and TGOs 93 & 100) yet 'unregistered' (not included on the ARTG, thus not perceived - or able to be treated - as other (conventional) medicines). Paradoxically however, exactly this state of affairs exists regardless, and even because of, the fact that, as Australian and other State Governments repeatedly point out, passage of the Narcotic Drugs Amendment Act now supposedly means:

'Medicinal cannabis products are regulated as medicines in Australia, therefore medicinal cannabis is regulated under both state legislation and the Commonwealth's Therapeutic Goods Act 1989.' [2]

Thirdly, we feel strongly that - again from the outset and by ignoring expert advice - policy-writers and legislators, whether wittingly or otherwise, badly misunderstood the nature of 'medicinal cannabis' itself and were *mistaken* in the belief it could properly be regulated - as are conventional medicines - under the Therapeutic Goods Act to begin with. And *this*, we argue, has resulted in the unsatisfactory and troubling situation Australia is now facing.

We suggest moreover a thorough assimilation of each of the above – particularly by those setting policy - is critical for a true appreciation of why the current legal and regulatory framework for MC is – as we believe it to be - irredeemably flawed in Australia for reasons this Submission discusses in detail. Only armed with this understanding, we believe, does it become apparent why a replacement system is felt necessary. Indeed, such a replacement is, we feel, the *only* real option available if cannabis is ever to be seriously and genuinely offered as a legal treatment option for Australian patients. This of course includes the 100,000+ individuals already identified as using unregulated cannabis at present.

Sections Three and Four of this document therefore explore these ‘failure points’ in more detail after having first answered what UIC sees as an equally critical question.....

Section Two: Definition: What is (and is not) 'Medicinal Cannabis'?

Much confusion abounds in the media and the minds of the public about what 'medicinal cannabis' in fact is. This is particularly true in Australia where effort is being made and emphasis placed in transforming (via the (Cth) Therapeutic Goods Act 1989) a phytochemically complex plant into a potential suite of single-molecule therapies using a regulatory system designed for conventional pharmaceutical medicines. Such laboratory-produced, highly standardised, isolated agents, of which only one – Sativex – is currently registered for use in this country, can theoretically and for the purposes of the Act, even include synthetic substances. Importantly however, such drugs are routinely conflated with all and any other cannabis-based products, especially by an ill-informed press. [3] Thus such proprietary medicines (like Sativex and others unregistered here) are (wittingly or otherwise) thrown into the catch-all basket of 'medicinal cannabis' (or 'medical marijuana') along with herbal (i.e. 'botanical') cannabis itself and whole-plant oils and tinctures made from it. Conflating these though, we would argue, is extremely misleading.

For the sake of clarity therefore, UIC proposes a definition of MC that we would hope might be commonly agreed and adopted for general use in the future, standing next to the technical and medico-legal meanings found in this country's Poison Standard (SUSMP) and in numerous items of legislation

To this end, and in the avoidance of unwarranted controversy, we commend one such definition provided by two major authorities of unquestionable credibility and repute – Associate Professor Mark Ware of Canada's McGill University and the Encyclopaedia Britannica.

The latter, we hope, needs no explanation, representing arguably the most trusted source of general knowledge anywhere in the English language. Dr Ware meanwhile is among the most prominent researchers in cannabis medicine not just within Canada but in the entire world. [4]

Thus Dr Ware's contribution to Britannica we hope offers sufficient plausibility and weight to satisfy even the most fastidious and exacting of critics and can be read in its full version here:

https://www.britannica.com/science/medical-cannabis

For the purposes of this document however, the salient and defining paragraph is this one, which describes MC as:

> *'….the use of cannabis under ongoing medical supervision, with an established diagnosis of the target symptom-disease complex. Herbal cannabis is used in conjunction with, or in consideration of, other pharmacological and nonpharmacological approaches and with the goal of reaching prespecified treatment outcomes.*'

This, Dr Ware asserts, is because '*there is no inherent difference between herbal cannabis used recreationally and that used medically*' whilst going on to imply a distinction between 'medicinal cannabis' *per se* and the '*several pharmaceutical drugs based on cannabis, in purified and standardized form, (that) have been made available for medical use.*'.

Though later in his Britannica article Dr Ware does add that cannabis '*...developed for medical use.....(is) grown under carefully controlled conditions, and the drug is standardised*' he also insists that it ceases to be 'medical' if used outside of a clinical environment:

> *'Cannabis that is used in an unsupervised manner is not considered medical cannabis. The same is true for cannabis that is authorised by a physician who has not adequately evaluated the patient, who does not prescribe the cannabis as part of a wider care model, or who does not monitor the patient for subjective and objective outcomes or adverse events,'*

Such a distinction between herbal / whole plant cannabis and '*pharmaceutical drugs based on cannabis'* is particularly important, as will become clear in due course.

Section Three: In Detail: Why the current Framework has failed and will continue to fail

3.1 Background to the Narcotic Drugs Act Amendments 2016

Some background and brief history are useful and relevant here.

In February 2016 the Australian Government passed the Narcotic Drugs Amendment Act (NDAA), replacement legislation of an earlier Bill - the Regulator of Medicinal Cannabis Bill – which itself had been passed by the Senate in October 2014.

Both pieces of legislation had been in response to huge public pressure: to make MC available to those sick Australians who needed it – and came at a time when, unlike any other medicine, the fight for access to the drug was - and continues to be - a global phenomenon driven almost entirely by patient lobbying and activism alongside a growing evidence base.

3.1.1 Two Different Bills – 2015/16

The two Bills (as at the beginning of 2016) were however very different nature and in terms of what they set out to achieve. One, (the 'Regulator' Bill) aimed to create - as the name suggests - a stand-alone, specialist Regulator for cannabis while the other sought to make it a prescription medicine governed by the (Cth) Therapeutic Goods Act 1989 and jointly overseen by the Government's Federal Medical Regulator the Therapeutic Goods Administration (TGA) and by individual State and Territory Health Departments.

3.1.2 Public Inquiry – Regulator of Medicinal Cannabis Bill

Prior to enactment of Amendments to the Narcotic Drugs Act, the 'Regulator Bill' had been the subject of an almost year-long Inquiry [5] involving hundreds of public Submissions [6] and three days-worth of Hearings, [7] culminating in a thoroughgoing Report [8] by the Senate's Legal and Constitutional Affairs Legislation Committee which sat to examine the proposal.

During this time, it became clear, the State of Victoria, having run its own 2014-15 Inquiry into MC, [9] would in any case enact its own legislation irrespective of what might occur Federally whilst the Australian Senate Committee recommended that (Cth) 'Regulator Bill' be enacted. The Turnbull Government was thus forced to move since the Victorian legislation may have put Australia in contravention of the UN Convention on Narcotic Drugs, compliance with which was felt necessary to safeguard the country's lucrative poppy straw trade. [10] The Department of Health undertook an assessment of how best to proceed, producing a Regulation Impact Statement on MC [11] in late 2015 as

is required of all Cabinet Submissions.

3.1.4 Government Response

The result was that an alternate arrangement was put forward, one that would place cannabis not in the hands of a specialist Regulator as experts had argued it should, but within TGA's existing regulatory framework by amending the (Cth) Narcotic Drugs Act 1967 so as to permit the cultivation of cannabis for medical and research in purposes in Australia for the first time in over five decades. [12]

At around the same time (with further adjustments to follow) 'cannabis' was rescheduled in the SUSMP, Australia's Poison Standard, bringing CBD products of high (98%) purity into Schedule 4 of the Standard ('Prescription Only Medicines') and those containing THC into Schedule 8 ('Controlled Substances' – requiring State authorisation for use). Non-medical – i.e. unregulated cannabis products – remained within Schedule 9 ('Prohibited Substances').

It was at this point, we would argue, that whatever (if any) plans the Australian Government may have had to make MC available to those Australian patients requiring it were de-railed, as became apparent once the 'system' for MC production and distribution in Australia took effect in November 2016. [13]

3.2 Initial evaluation process of possible outcomes of the 2016 legislative changes did not meet the Government's Regulation Best Practice Guidelines

Reasons for this failure are to be found in two key documents - the Government's own Explanatory Memorandum [14] in relation to the Narcotic Drugs Amendment Bill (later Act) of 2016 and the Regulation Impact Statement referred to above, which itself became incorporated into the Explanatory Memorandum.

As we have noted, producing Statements like these are standard (and compulsory) procedure in Government whenever significant regulatory developments are planned - a process is overseen by the 'Office of Best Practice Regulation' (OBPR) which sits in the Department of the Prime Minister and Cabinet.

As one would expect from an organisation tasked with administering Regulatory Impact Analysis requirements, the OBPR has its own handbook - the 'Best Practice Regulation Handbook' [15] - which sets out the standards and demands placed on Government Departments where the framing of regulation and assessment of its impacts are concerned. Meet those requirements (per the Handbook) and a Department will have achieved the expected Best Practice; failure to do so means it will not.

Unfortunately, the Regulation Impact Statement for Medicinal Cannabis *did not* meet

those standards, with the OBPR commenting that:

> *'The Office...assessed the RIS prepared by the Department Health as compliant with the Government's requirements but not best practice. To achieve best practice more detailed analysis of the practical impacts of the measure and more extensive consultation was required.'* [16]

To this it should be added, the Narcotic Drugs Amendment Act was passed by Parliament in record time making it possible the majority of members of both houses may not have had time to read or fully understand the Explanatory Memorandum or the Regulation Impact Statement it contained. With this in mind, it becomes easy to see why United in Compassion and many others believe Australia's current MC system has floundered: *the 'system' does not, nor ever has, adhered to the Government's own guidelines and prescriptions for achieving best practice in regulation and policy-making*.

It should also be noted in the year 2015-16 when the Regulation Impact Assessment was created, 78% of all such documents submitted to the OBPR achieved the designated Best Practice standards, [17] placing the Department of Health's exercise well into the bottom quartile of Assessments appraised by that Office and among a minority of 'fails'.

Thus from the outset, far from setting any meaningful policy objectives such as those UIC identifies in Section Five and then devising a strategy to meet them, individuals responsible for this country's MC 'system' as it is currently seem to have sought only to keep as tight a rein on the medicine as possible – ostensibly to comply with the UN Convention – and to have had little regard for all else.

3.3 System 'A Basket Case' – RACGP President

The result, which for over two years has been widely discussed and criticised both in the media and within medical advocacy circles, has been – from the patients' perspective – a disaster, one the now-immediate past President of the RACGP Dr Bastian Seidel described (while in post) as a 'basket case'. [18]

3.4 Case Proven: ODC Internal Audit 2017

Such a view of the extent to which substandard management practices have contributed to this present unsatisfactory situation was amply borne out by an Internal Audit of the ODC from 2017 [19] obtained by The Australian Newspaper [20] under a Freedom of Information request this January and seen by UIC.

The Audit and accompanying Report were undertaken and prepared by Protiviti, a Management Consultancy firm, and dealt with the ODC's handling of applications for MC cultivation, manufacture and research licences in Australia, of which there was at the time and remains a considerable backlog.

3.4.1 Findings of Audit, ODC Under-resourced etc.

Among other things, Protiviti found the ODC to be substantially under-resourced, an observation to which the Department of Health replied: '*Given the present financial situation of the Department it is unlikely that the effort in closely mapping the resourcing required would lead to an increase in resources for the medicinal cannabis program*.'

Notwithstanding that comment, the RIS being discussed in this Section originally identified an initial cost of running an MC programme of $407,000 - clearly a gross underestimate subsequently bolstered when '*last month, however, (December 2018) the government quietly allocated a further $4.4 million over two years for "assessment and compliance activities"*,' according to The Australian. In mid-January 2019 the ODC posted advertisements for an extra six staff. [22]

3.4.2 ODC lacking objectives, leadership etc.

Unsurprisingly, given the RIS never met the Government's own Best Practice Standards, Protiviti's Report also appears to identify the fact that the ODC - at the time, and one suspects currently - had no clear policy objectives so was provided with guidance by the Consultancy which identified thirteen characteristics it felt '*effective regulatory arrangements (and regulators) should demonstrate'.* These included having '*clearly defined objectives and a defined regulatory philosophy and approach*' as well as an understanding of '*the complexity of regulation (while striving) to undertake its mandate in the most efficient and effective manner possible*.'

Tellingly, the Consultancy also pointed out such tasks should '*embed the principles of regulatory best practice in all of (their) activities*,' which as we have already established, from the outset they manifestly did not.

3.4.3 Characteristics & Principles of Best Practice in Regulation

Equally, the other twelve 'characteristics' highlighted by Protiviti are precisely what UIC believes Australia's MC 'Framework' lacks as a whole - not just in terms of the administration of licensing matters. Besides these and those of the Office of Regulation Best Practice, Protiviti additionally specify out a further framework also exists for managing regulatory performance – those of the Australian National Audit Office (ANAO) which suggests such practice should focus on:

1. Defining regulatory outcomes and administrative priorities;
2. A risk-based approach to regulatory administration;
3. Effective stakeholder relationships;
4. Effective information management;
5. Transparency and accountability;
6. Managing regulatory capability; and
7. Measuring, reporting and reviewing regulatory performance.

UIC questions whether any evidence exists to suggest those drafting and enacting the Narcotic Drugs Act Amendments now or in the past succeeded or even made efforts to ensure points 1-7 were effected in the course of their work – since we contend they were not. Assuming this to be the case however means *Australia's MC 'Framework' neither currently has - nor has ever had - a clear set of objectives against which progress could or can realistically be benchmarked.*

And such a failure to meet the Government's Best Practice Guidelines on Regulatory Impact or the ANAO framework when creating Australia's cannabis 'policy' was, we feel, the first – and arguably most significant – of many additional errors and provides the context for all else that followed.

With this in mind, it is hardly surprising that the current 'system' has been criticised – and we suggest any future changes in policy, legislation or regulation are undertaken only *after an analysis of their possible impact has met with Government's own Best Practice Guidelines* per the OBPR and the ANAO frameworks.

3.5 An 'Approved Unapproved Medicine': Australia's current Framework consigns cannabis forever to 'regulatory limbo'

In November 2018 the TGA announced that 568 approvals of MC prescriptions had been granted that month, [23] bringing the total number to 2339 for an estimated (though unconfirmed) 2,000 patients. The November approval rate was, the TGA said, its highest ever, though, despite requests, no breakdown of figures on a State-by-State basis has been forthcoming (perhaps unsurprising; in Tasmania, for example, the number of patients in November 2018 totalled seven). [24]

Almost all of the MC products made available had (and have always) been imported from overseas since to date (at time of writing – January 2019) only one Australian company (The Little Green Pharma Co) has succeeded in bringing a domestic product to market. [25] Whilst the apparent inertia and lack of activity in this country's embryonic (legal) cannabis industry may speak volumes about the success or otherwise of the current Australian 'system', perhaps the most significant point to be made concerns the regulatory status these medicines 'enjoy'.

3.5.1 How Cannabis Products Are Currently 'Approved'

The TGA and its recent (2015) offspring the Office of Drug Control have in place (quite correctly) various standards relating to the cultivation and production of cannabis and cannabis medicines whether originating in Australia or overseas. Hence imports and (so far mostly theoretical) locally sourced goods alike must be grown using Good Agricultural Practices (standards laid out by the Food and Agricultural Organization of the United Nations), Good Manufacturing Practice (as stipulated by the PIC/S Guide to GMP) as well as the Therapeutic Goods Orders #93 & #100 – the TGA's 'Standard for Medicinal Cannabis' - and 'Microbiological Standards for Medicines' respectively.

To the extent that *every* cannabis product available here *must* comply with these standards, they can clearly be said, in one sense, to be 'approved for use in Australia' yet none (save for Sativex, already mentioned) has been evaluated for inclusion on the Australian Register of Therapeutic Goods (ARTG) which lists products that can be legally supplied in this country. Thus, in an equally substantive and highly consequential way, are these medicines simultaneously '*unapproved* for use in Australia', leaving them, as we've already argued, in an incoherent state of 'regulatory limbo' – quite literally, simultaneously *'approved unapproved medicines'*.

At this juncture we must turn to the two documents cited earlier – the Explanatory Memorandum of the Narcotic Drugs Amendment Bill 2016 and the Regulatory Impact Statement for MC the Memorandum contains – and which comprises the analysis upon which the Bill's purpose and intent for the most part was fundamented.

3.5.2 By Its Own Admission: How 'Regulatory Limbo' was planned from the start

From the outset, it appears, the Department of Health was not only *aware* that cannabis would be designated 'neither fish nor fowl' from an 'approved medicines' perspective - it purposely designed a system that would ensure that exactly this happened, as the below two quotes from the (non-Best Practice compliant) RIS attest (our emboldenment):

> ***'The option (of regulating MC Federally) will not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term,*** *but will facilitate further clinical trials that may support such a registration in the future. Cannabis material cultivated and manufactured in Australia would be able to be used to conduct clinical trials and* ***develop therapeutic products to be used in accordance with the Therapeutic Goods Act.'***

And:

> *'Assuming there is a suitable source of cannabinoids available; pathways for lawful access to cannabinoids for medicinal use are:*
>
> 1. *Medicines registered on the Australian Register of Therapeutic Goods (ARTG);*
> 2. *Clinical trials (such as the trials being conducted in New South Wales and Victoria); and*
>
> 3. *The Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).*
>
> ***Access to cannabis for medicinal purposes through the first pathway, such as occurred for Sativex, requires a robust dossier of clinical trial and other data and is commonly submitted after some years of significant***

commercial investment.' (Our emboldenment).

3.5.3 The Australian Register of Therapeutic Goods: Of no use to cannabis or cannabis products

Leaving aside for now the matter of '*pathways for lawful access to cannabinoids for medicinal use*' other than the ARTG; as the above statements make clear, whilst the *intent* of the legislation has always been to encourage the development of '*therapeutic products to be used in accordance with the Therapeutic Goods Act*', even in 2015 the Government realised this could (and then only might) occur after '*some years of significant investment*'. Thus by its own admission and even in its exact words, the option of regulating MC Federally would '*not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term.'*

At the same time however, and crucially, policy-writers had ignored advice handed them by many experts and by the Senate's Legal and Constitutional Affairs Legislation Committee during and after the Public Inquiry into the Regulator of Medicinal Cannabis Bill discussed in Section 3(A). Instead they decided to favour the views of organisations like the Australian Medical Association and others [26] long opposed to the use of medicinal cannabis as such, arguing rather for the development and use only of '*pharmaceutical drugs based on cannabis'.*

3.5.4 Opponents of MC shape policy and legislation

Indeed, quoted within the same Regulatory Impact Statement already cited, the AMA makes its position explicitly clear on the matter, saying:

> *'Smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes and other appropriate ways of delivering cannabinoids for medical purposes should be developed.'*

For 'risky' 'completely unacceptable' is actually meant, yet, save for the element of 'smoking' (no clinician in the world known to us recommends ingesting cannabis in such fashion) it needs to be stressed the above statement is factually wrong in several respects – issues discussed in Section Five**.**

Just as importantly though, it is at this point the definition of 'medicinal cannabis' itself takes on appreciable importance, since the Mark Ware/Britannica view of the matter described earlier (and which UIC suggests be adopted as a commonly agreed meaning) differentiates and distinguishes between 'medicinal cannabis' *per se* ('*there is no inherent difference between herbal cannabis used recreationally and that used medically'* Ware says*)* and '*pharmaceutical drugs based on cannabis'.*

3.6 Legislation (2016) never intended to make MC readily available to sick Australians

The reason we go to such considerable pains to emphasise this is that it is our contention the Amendments to the Narcotic Drugs Act 1967 were *never* intended to make *actual* 'medicinal cannabis' (per the Ware/Britannica definition) available and were *always* in order to create an environment in which pharmaceutical products made from it might be developed. Indeed, these, in practice are the *only* types of product the Therapeutic Goods Act 1989 is capable of regulating save from those within the quite separate realm of complementary medicines (and from which cannabis is excluded because of its Scheduling in the Poisons Standard).

To the counter-argument - that this was always the intention and nothing is wrong since it is done for all other drugs and medicines - we would point out, as discussed further below, neither the commercial incentive nor practical means exists to regulate cannabis in this manner.

3.7 Legislation (2016) enacted against the majority of expert advice after *six* Public Inquiries

Such an intent also flies in the face of the vast majority of evidence presented at the ***six*** Public Inquiries into MC that have occurred in Australia to date [27-32] – including the large Federal Inquiry into the Regulator of Medicinal Cannabis Bill 2014.

A review of these half-dozen Inquiries in general and the Federal Inquiry in particular would, we argue, overwhelmingly demonstrate that, if the Government had been (or is) *genuinely serious about making cannabis available for medical purposes to Australian patients* it would regulate the drug *outside* of the Therapeutic Goods Act 1989.

Such a view was propounded by (among others) Emeritus Professor Laurence Mather of Sydney University in both his Public Submission to that Inquiry [33] and in the oral evidence he provided to the Inquiry's Public Hearing in Sydney (one of three day's-worth of such events that were integral to the proceedings). [34]

Here Professor Mather made clear:

> *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 label.'*

3.8 Additional reasons current Framework unsuitable for Medicinal Cannabis: 'Enourage Effect/Personalised Medicine

In addition to this, many clinicians and scientists experienced in cannabis medicine as well as their patients consider that precisely *because* cannabis itself cannot properly be considered a 'single drug' but is rather a natural product composed of a plethora of

disparate compounds, the 'whole plant' is superior in its efficacy to any single-agent derived from it. [35] This is known as the 'entourage effect' meaning, in simple terms, its chemical components act synergistically and perform as a whole – the combined effects of which appear to be greater than the sum of its parts.

As Dr Ethan Russo – among the world's foremost cannabinologists and a recognised expert in this matter in particular recently put it:

> *Although the single molecule synthesis remains the dominant model for pharmaceutical development (Bonn-Miller et al., 2018), the concept of botanical synergy has been amply demonstrated contemporaneously, invoking the pharmacological contributions of "minor cannabinoids" and Cannabis terpenoids to the plant's overall pharmacological effect.'* [36]

While this Submission does not seek, nor is designed to offer any clinical commentary or opinion of its own, next to this we would nevertheless additionally note that many experienced clinicians insist a personalised approach both to the patient and the drug itself is desirable. [37] This is because its effects may vary between individuals while different cannabis cultivars are said to possess quite different qualities. In short, with cannabis medicine one size may not fit all – while products regulated by the Therapeutic Goods Act and which are included on the ARTG absolutely *demand* that they do. Put next to the fact that cannabis is extraordinarily versatile and effective in an uncommonly wide range of clinical settings [38] and two problems more are added as to why, at this stage, attempts, to regulate the drug 'like other conventional medicines' will not deliver good outcomes to patients. They also help explain why the approach has been rejected in all jurisdictions with well-functioning MC programmes. [39]

3.8.1 UIC's Position on the above

None of this is to suggest however that UIC does not advocate further investigation into cannabis or the eventual creation of new, proprietary cannabis-based products. Over 80 years of continued international prohibition have meant research into the plant's therapeutic uses has been exceedingly difficult. It is thus possible – highly likely even – that an entire array of extremely promising and effective new medicines will one day find their way into the market – and onto the ARTG. Herbal cannabis on the other hand cannot and never will join the Register - for reasons touched on above. We contest in the meantime that the latter – *actual* medical cannabis in other words – *should and must* be made available to patients while being *regulated in a logical and reasonable way*. It should not, and never should have been, placed - as it is now - within what is at best an inelegant, self-contradictory legal and regulatory position within which it appears destined to remain in perpetuity unless significant legislative and/or regulatory change is forthcoming.

The above having been said, UIC recognises and fully predicts the TGA and some in the medical profession will argue that the system in place currently is adequate and in fact

working well. They will refer, in all probability, to the approval figures cited at the top of this sub-section and argue this apparent month-on-month increase testifies to the growing success of Australia's existing cannabis 'Framework'.

To such arguments – recalling the entire system and legislation behind it was predicated on an assessment the Government itself said required '*more detailed analysis of the practical impacts of the measure'* and about which *'more extensive consultation'* was needed – UIC would take strong exception: *since no policy objectives appear to exist currently, nor were ever devised to begin with, no benchmark exists against which success or failure may be measured.*

In short then, the regulatory position we describe has created - and will continue to cause - such negative outcomes for any presumed MC 'programme' in Australia that, where patients at least are concerned, in practice, no real or properly designed 'programme' to speak of is actually in operation at all.

The consequences of such a regime on the other hand are readily identifiable.

3.9 Inadequate Pathways to accessing cannabis – the consequences of a failed MC programme

Firstly, the current 'system' ensures access to MC is *only* available (legally) through the 'pathways' outlined above and identified in the Explanatory Memorandum of Narcotic Drugs Amendment Act 2016 and in the Regulation Impact Statement it contains - both cited previously. As a reminder, these pathways are comprised of the following - meaning access to cannabis products can be via:

1. Medicines registered on the Australian Register of Therapeutic Goods (ARTG);
2. Clinical trials; and
3. The Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).

Looking at each in turn, although doctors are largely unhindered when prescribing drugs listed on the ARTG, issues already highlighted demonstrate a complete absence of any utility for this as a 'pathway' for cannabis or cannabis products now or in the foreseeable future. And where herbal/whole plant cannabis is concerned this is ***forever*** an impossibility, in part because of its scheduling within the SUSMP.

3.9.1 'Pathway' One: ARTG

Thus the ARTG's current (completely aspirational) role in the drug's regulation (the *hope* that 'cannabis-based pharmaceuticals' will one day appear) the Register in fact serves to *impede* access to the products patients have been demanding: that is, herbal cannabis and 'whole-plant' products made from it.

As the primary and official repository of legally available drugs in Australia, the ARTG speaks to how such medicines are evaluated, sold, obtained, perceived, marketed and subsidised so its role and importance cannot be overstated, nor, *in the absence of any alternative*, the ramifications for products *not* listed within it.

While these facts alone should be sufficient to raise serious concerns about the suitability and adequacy of instruments like the Therapeutic Goods Act 1989 and the ARTG properly to regulate cannabis, the other three pathways referred to we find equally unsatisfactory and problematic. This, we argue, is the case *irrespective and regardless* of the TGA's citing of modestly upward-moving approvals figures for November 2018 and onward. These, we would claim, represent little more than an attempt to convey a sort of 'Australian cannabis success story' while – to some extent anyway – bowing to the considerable and unremitting public pressure characteristic of the MC debate in this country since at least 2014.

3.9.2 'Pathway' Two: Special Access Scheme, 'Record Approval Levels' and use of an unsuitable system

The 'record November figures' mentioned earlier are themselves in reference to Federal (TGA) cannabis prescription approvals, all accomplished via use of the second form of 'pathway' identified: the TGA's Special Access Scheme – which, we must begin by making clear, was and is in this instance *being employed in a role for which it was never intended*. The SAS, according to the TGA website, was created ***'for health practitioners who wish to access therapeutic goods that are not in the Australian Register of Therapeutic Goods (ARTG) and are not otherwise exempt from being in the ARTG'***. [40]

This however – and in the TGA's own words – is pathway designed and intended only '***for exceptional clinical circumstances***' (TGA's emboldenment). [41]

As an organisation advocating for medical cannabis, UIC is acutely aware – as we have already made clear - there are currently many thousands of individuals using the drug solely for medical purposes across Australia (and millions doing so worldwide). [42] Whilst it remains true almost all domestic users are obliged to source their medicines from the illicit market for use without clinical supervision (including of children with complex conditions, often rare forms of intractable epilepsy) it cannot realistically be argued these circumstances are remotely 'exceptional'. This situation of course remains true regardless of the extent to which politicians, bureaucrats and elements within the medical profession would like to believe or insist otherwise. The reality is that cannabis *is* widely used and its use (as a medicine) is growing in both popularity and ubiquity. [43]

Thus, regardless of how much the Government and elements within the medical profession wish to view and proclaim use of MC products as appropriate only for these

'*exceptional clinical circumstance*s' the truth of the matter is that they are clearly and obviously far from it – as vast and growing data from across the globe increasingly illustrate. [44] *Any* 'pathway' to a legal MC supply therefore that is for use only in these 'exceptional circumstances' is, we believe, *inherently and, by definition, unfit for purpose*.

Thus, regardless of how much the Government and conservative forces within healthcare wish to view and proclaim the use of MC products as appropriate only for these 'exceptional clinical circumstances', the truth of the matter is that clearly and obviously far from it- as vast and growing data from across the globe increasingly illustrate.

We would further add the SAS pathways were specifically devised for use on a one-off, patient-by-patient, case-by-case basis - each unique (or 'exceptional') and each requiring its own, unusual, distinct and sparingly used type of medicine, usually those registered for use overseas. Cannabis and cannabis patients clearly do not fall into this category, yet (as we discuss below) their treatment *does* require a high degree of personalisation to determine the most effective protocol. [45] This is extremely difficult, time-consuming and inefficient using the SAS since every product being appraised for its suitability requires a separate, long-winded application, to say nothing of repeat applications for obtaining more of the same medication.

It thus remains our contention that accessing cannabis and cannabis products via the SAS pathways offers a makeshift solution at best. It seeks to stuff the 'square peg' of MC into the 'round hole' of whatever existing regulatory apparatus happened to be to hand at the time. Such a regulatory 'stop-gap' not only flies in the face of the Quality Use of Medicines (QUM) requirements [46] but suggests little in the way of compassion and nothing in the way of wanting a truly useful or innovative solution on the part of policy-writers and lawmakers alike. The number of 'illicit' users compared to those doing so legally is testimony enough to this fact.

In addition to the use of this inappropriate 'access pathway' contorted to perform functions for which it was never designed is the fact that the 'Framework' as it currently stands requires ***two*** levels of approval or sanction, one Federal - the Special Access Scheme just discussed - the other from State or Territory Departments of Health. This, again, is due to the medicine's Scheduling in the SUSMP, since Schedule 8 substances are controlled by State Governments. And while UIC acknowledges and has seen evidence of efforts by the Federal Health Minister to 'streamline' this two-tiered procedure and - via the introduction of an online 'single application' portal – harmonise the process across all S&Ts, such an initiative, we believe, *has failed in conspicuous fashion.*

Notwithstanding the TGA's withholding a breakdown of the number of SAS approvals on a State-by-State basis this assertion is based on the fact that at least two - Tasmania and Western Australia - have refused to participate in the 'portal' project altogether [47]

and in the Northern Territory UIC understands not a single medical practitioner has been prepared to write a prescription for cannabis. [48]

Problems are aggravated further by a general insistence on the part of most State Health Departments and often by the TGA that 'specialist' doctors are required to endorse or authorise a GP's prescription for MC or undertake such prescribing themselves. It is therefore assumed a knowledge of cannabis and cannabis medicine is presumed- which is (somehow) greater than that of their counterparts in General Practice - and we know from direct experience this categorically is not the case.

The result, in any event, has been the creation of a 'postcode lottery' in Australia in which the comparatively small number of patients that can afford it are relatively likely to be able to access some cannabis product or another in certain States (we believe mainly Victoria and NSW) whilst being almost completely unable to do so in others (such as Tasmania). This creates what have been termed (in the US) 'cannabis refugees' involving patients having to move from States where MC is unavailable to those where it is not.

3.9.2.1 Minimal approval levels compared to overseas jurisdictions

Moreover, the approvals figures in Australia are unimpressive when compared to other jurisdictions in which MC is legally available. Hence, we find Canada with c. 300,000[49] patients, The Netherlands with c. 40,000 patients, [50] Germany (which legalised the drug for medical use a year later than Australia) also with c. 40,000 patients [51] and Israel with a similar number. [52] *What all of these jurisdictions have in common however are regulatory models established to deal with cannabis* **outside** *of those used for conventional medicines.*

3.9.3 'Pathway' Three: Authorised Prescribers (APs)

The 'Authorised Prescribers' (AP) scheme meanwhile – a further purported 'pathway' granting a medical practitioner the authority to prescribe a specified, unapproved medicine to multiple patients (in this instance cannabis products) – was ostensibly (and according to the Explanatory Memorandum of the Narcotic Drugs Act Amendments) implemented in order to overcome what the TGA itself admits is the '*cumbersome and costly exercise*' [53] of using the SAS pathway, discussed above and neither do these figures reflect well om Australia when adjustments for population sizes are factored.

Becoming an 'Authorised Prescriber' however requires medical practitioners to have their applications approved by a Human Research Ethics Committee (HREC) or endorsed by a specialist college, and none of these Colleges are prepared to do so in Australia. [54] Thus to the best of our knowledge and to date, almost all Ethics Committee approvals have been granted to those undertaking or involved in clinical trials, with just a single HREC alone (that of NIIM – the National Institute of Integrative Medicine) approving GPs or doctors outside of these trial settings. We understand only around ten

GPs have thus far been approved by the NIIM HREC [55] and in any case as of December 2018 the TGA's own figures confirm only 54 APs have been created in total out of a population of around 100,000 doctors, [56] 38,000 of them GPs. [57] This method of access too then, we would argue, has been wholly and glaringly ineffectual.

3.9.4 'Pathway' Four: Clinical Trials

The final 'pathway' to accessing MC and cannabis products available as a result of the 'Framework' ushered in by the Narcotic Drugs Act Amendments are the clinical trials themselves, which, we suggest, do not and should not merit the descriptor of 'access pathway' at all.

UIC naturally welcomes research into the cannabis plant and its derivatives and recognises that a number of trials are currently underway in Australia with more to follow in 2019. Common sense however dictates that exercises such as these are open to a limited number of individuals only and are absolutely *not* designed to facilitate general access to medicines among the wider population. Additionally, we are particularly critical of the attitude expressed by at least one researcher who is quoted as saying she opposed cannabis being made readily available to patients because of the adverse effects this might have on research funding. [58]

3.10 Consequences of the 2016 Legislation

We have, we hope, made the case that the 2016 Amendments to the Narcotic Drugs Act serve to place medicinal cannabis into a permanent state of what we have termed 'regulatory limbo'. Additionally illustrated has been that this predicament has forced upon it so-called 'access pathways' that are – to understate matters appreciably-sub-optimal if not completely inadequate. There are however several more serious consequences the legislation (intentionally or otherwise) has precipitated.

3.10.1 Stifling of Domestic Cannabis Industry

Of these, we believe one of the most serious is the fact that it (the legislation) and its attendant regulatory apparatus has severely retarded the growth (or even, in practice, any real commencement) of a (legal) cannabis industry in Australia, and hence an affordable supply.

Whilst it is true several companies have obtained Government Cultivation, Research and Manufacturing Licences and some are now publicly listed on the Australian Stock Exchange just three have managed – to the best of our knowledge – to put 'seeds in the ground' and only one to create any locally produced medicine for sale (Little Green Pharma Co as previously mentioned).

Ample evidence exists to suggest this is partly due to poor management practices and under-resourcing within the ODC but we would also argue, it is also because the current regulatory and legislative model has – for reasons already explained - kept the market

for (licit) MC and cannabis products artificially and unrealistically minuscule (while the unregulated market continues to blossom).

3.10.2 Distortion of market/unaffordable prices

Concurrently, demand for these products is huge. Thus, by creating a scenario in which such demand is not matched by the ability to access the medicine more readily the market has become badly distorted. Development of a local cannabis industry - which would have the effect of decreasing prices - is hamstrung because of a seemingly modest demand while the growth of 'specialist clinics' (their 'expertise' not in cannabis medicine itself but negotiating the bureaucracy involved in accessing it) is ensured.

These establishments in turn prescribe imported products sold at grossly inflated prices, [59] placing them well out of reach of most patients so that, three years after the NDA Amendments were enacted, almost the only products currently available (in so far as they are available at all) are those obtained from overseas, mainly Canada. 'Licensed Producers' in the meantime are presumably adapting their business models accordingly and seeking the bulk of their custom from abroad – indeed a number are known to be doing so. [60] It is not within UIC's remit or this document's to speculate as to their likely success, nor is it of particular interest. But it does illustrate nevertheless how *millions of dollars in domestic business is being gifted to illegal operators despite cultivation and production of cannabis being perfectly permissible by Australian law under licence*.

The cost of these imported medicines – in all but one State (Tasmania, which we have discussed) is borne by the patient – which we find equally untenable. And we categorically refute the 2018 claim by a business operating one of the above-mentioned 'clinics' (happy to prescribe cannabis and cannabis products for a $300 consultation fee to individuals it believes 'qualify') that prices for such items are plummeting. [61]

In fact, we know the exact opposite to be true; on an almost daily basis UIC hears directly from sick Australians or their carers or read in the press about the preclusively high cost of such products *if* they can be accessed at all (hundreds of dollars per month – much more for medicines for epilepsy - is not an uncommonly cited figure.) [62]

3.10.3 Causes black market to flourish

The net effect has been that for most people – despite very substantial risk – the black market remains by far the most economical and realistic option for obtaining their medicines. In fact, we are aware of many dozens of illicit 'dispensaries' every one of which individually services more 'clients' than there are patients accessing legally prescribed cannabis products in the whole of Australia. This is an absurd and dangerous state of affairs in a country professing to have made MC available, placing people in harm's way from what might be poorly manufactured and / or contaminated products which are by definition used outside of the care of a doctor.

3.10.4 Prevents medical professionals accessing critical information

A further effect of the legislation – by ensuring that MC and cannabis products remain 'approved yet unapproved' medicines (i.e. meeting the high production and other standards stipulated by the TGA yet not listed on the ARTG) - has been to prevent lawful suppliers from 'marketing' (in other words providing information about) their goods to the public and doctors alike.

Subject to legislation and the Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG), the TGA makes the position explicitly clear on its website:

> *'The advertising of prescription only medicines (including medicinal cannabis preparations) to the public is prohibited.*
>
> *Prescription medicines not included on the ARTG are considered unapproved therapeutic goods and cannot be advertised in Australia to consumers or health professionals.*
>
> *Medicines accessed through the approved therapeutic goods pathways generally are, or are likely to meet the requirements for scheduling as, prescription medicines. In any case, such goods cannot be advertised to consumers.'* [63]

Since doing so is unlawful under both civil and criminal law, instead, healthcare practitioners interested in prescribing MC and cannabis products must first find a supplier's identity (provided on the ODC website) then contact the business directly before particulars may be finally provided.

This obstacle to knowledge flowing between doctors and MC suppliers, at a time when medical education is desperately needed in this sphere is unacceptable. UIC is contacted on a regular basis by medicos seeking product details where the sharing and dissemination of such information should clearly be permissible for the cannabis Industry itself. The current position therefore represents a highly inadequate and haphazard means for clinicians to acquire what is often critically important data and information enabling practitioners to assess whether MC or cannabis products may be suitable (or otherwise) for their patients.

3.10.5 Cannabis & cannabis products impossible to subsidise for the less well off

Inclusion of cannabis in this country's Pharmaceutical Benefits Scheme (PBS) is also currently out of the question since a prerequisite is that all products to be considered must be ARTG-registered. Such a subsidy therefore will never be possible for medicinal cannabis without comprehensive regulatory or legislative change.

Only an abundant and varied source of domestically cultivated product grown to the high standards already specified, readily accessible in straightforward fashion to all those who need it can possibly address these and other concerns raised within the Submission. In practice this means a decision must be taken at the political level as to whether sick Australians deserve a *genuine* programme for *actual* medical cannabis since we believe unequivocally this currently does not exist.

3.10.6 Policy-writers and legislators misled?: A misunderstanding of 'medicinal cannabis' - why the Therapeutic Goods Act is an inappropriate mechanism for its regulation

When amending the Narcotic Drugs Act in 2016 only two perceptions of the medicine and access to it were practically possible, meaning at the time legislators must have been of the belief either that:

> a) It was somehow possible for whole-of-plant cannabis itself (per the Ware/Britannica definition) to be regulated like 'conventional' medicines OR
>
> b) 'Cannabis' when used as a medicine is best (hence should only be) administered – at some unidentified future point – as a suite of proprietary single-agents derived (or not) from the cannabis plant and delivered in pharmaceutical form.

UIC's position is that neither of these propositions is currently true yet innumerable hours spent discussing the matter with politicians indicates to us that many (not all) simply fail to grasp fully the issues at stake.

Further, for reasons this Submission attempts to set out, if the two statements (a & b above) were presented to lawmakers as fact then we feel they (the politicians) were badly misled.

Section 4 Review of the arguments, notes on evidence selection and privilege, further obstacles to availability of MC

Almost all of the discussions and disagreements around this subject were, as we have said, aired fairly exhaustively, in the six Public Inquiries into MC held in Australia to date, most especially the Federal Inquiry into the cross-bench 'Regulator of Medicinal Cannabis Bill 2014'.

We strongly recommend therefore, as context and for background purposes, re-visiting (or visiting for the first time) the Public Submissions and Oral Evidence given to the Inquiry as well as the Final Report of the Senate's Legal and Constitutional Affairs Legislation Committee all of which are available at the below link:

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill

4.1 Argument for separate Regulator made, won, then rejected

From these documents, it is clear, sufficient evidence was provided to satisfy the Senate Committee that 'medicinal cannabis' should indeed be made available to patients and furthermore, for this to occur, a stand-alone Regulator would be required necessarily operating outside of the Therapeutic Goods Act 1989.

4.2 Minority against separate Regulator win policy battle

Conversely, and just as importantly, opponents of the idea (essentially, conservative elements within the medical profession together with the pharmaceutical companies with which they are frequently allied [64] were not so convincing in their objections as to persuade the Committee to think otherwise. Yet, as the below (Australian Medical Association) position cited in the Regulation Impact Statement for MC demonstrates, such views were the *only* ones seriously taken into account by the Department of Health when framing the Narcotic Drugs Act Amendments: [65]

> *'While the AMA acknowledges that cannabis has constituents that have potential therapeutic uses, it argues that:*
>
> *1. Appropriate clinical trials of potentially therapeutic cannabinoid formulations should be conducted to determine their safety and efficacy compared to existing medicines, and whether their long-term use for medical purposes has adverse effects;*

2. *Therapeutic cannabinoids that are deemed safe and effective should be made available to patients for whom existing medications are not as effective;*
3. *Smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes and other appropriate ways of delivering cannabinoids for medical purposes should be developed; and that*
4. *Any promotion of the medical use of cannabinoids will require extensive education of the public and the profession on the risks of the non-medical use of cannabis'*. [66]

4.3 'Medicinal cannabis' *not* to be made readily available

Thus, regardless of the Public Inquiries' findings and the Senate Committee's Recommendations to the contrary, the Amendments did indeed ensure that 'medicinal cannabis' itself would *not* be made readily available and would instead be subjected to the (demonstrably inappropriate) regulatory processes undergone by conventional, pharmaceutical medicines.

4.4 Results of the legislation

The result, as we have argued, is that Australia has been left with a chaotic and profoundly unsatisfactory situation that - to review some of the points already raised and highlight a number of others - comprises:

- Tens if not hundreds of thousands of sick Australians continuing to be forced to use illicit products and being criminalised as a result;
- A medicinal cannabis 'programme' based on an assessment of regulatory change that did not meet the Government's Best Practice requirements at the time and leading to legislation that was hopelessly flawed from the outset;
- 'Medicinal cannabis' itself forever consigned to the void of 'regulatory limbo' (i.e. an 'approved unapproved medicine');
- 'Access pathways' which are wholly inadequate;
- Untenable and obscenely high prices of the limited choice of imported cannabis products available (if and when they can be accessed at all);
- An Australian 'Postcode Lottery' where such access is concerned;
- No (legal) Australian cannabis Industry to speak of thus almost no domestic product grown or available;
- Patients having move to States to source their medicines or even doing so by going overseas, sometimes relocating there;
- Patient deaths, including those of children.

4.5 'Cherry-picking' of 'experts' to assist & support Government position

To help defend and justify these otherwise unconscionable circumstances, the TGA enlisted the services of a carefully selected group of academics, clinicians and public health 'experts' almost all with known prohibitionist stances on cannabis and antagonistic toward its use as a medicine. Many of the same individuals have either built their careers demonising the plant or have received drug company funding or both. [67] They were set to work producing documentation ('Systematic Reviews' and 'Clinical Guidance Documents' [68, 69] which - as predicted by advocates a full twelve months earlier [70] – supported the position taken by opponents of MC that 'not enough evidence' exists as to its safety and efficacy. Their publication prompted one eminent medico (Associate Professor David Caldicott of the Australian National University - who created the most thoroughgoing of the three RACGP-accredited 'Medical Cannabis Courses' available in Australia) to criticise this work publicly. The week the 'Guidance Documents' mentioned above were released Dr Caldicott noted:

> *'In just a decade's time, they (the Guidances) will be mocked as an example of the abuse of science. (They are) political, designed to arrive at conclusions that suit parties other than patients. The sad reality is these documents ...will do next to nothing to change the status quo – an illicit market of uncertain provenance, accessed by desperate people. They don't tally with the experience of tens of thousands in Australia – millions worldwide - and so will simply be ignored, even by doctors who choose to educate themselves, overseas and online, about the 'actual' pros & cons of medicinal cannabis.'* [71]

In addition to this, UIC has gathered evidence and examples of how these opponents of cannabis medicine rather than cannabinologists and clinicians expert in its use have been positioned to lead Journal debate and regulatory review and routinely disseminate misinformation in evidence synthesis. [72] This includes failure to consider the synergistic action of cannabis for therapeutic benefits and the massively reduced side effects when MC is compared to other drugs - a matter that rarely crops up in the literature. Such efforts also ensure the lower costs of MC against other drugs when used as a whole plant-based therapy are also omitted from consideration. Meanwhile reviews that take a public health perspective and allow for practice and epidemiological evidence or calls for public health and health economic evidence synthesis are excluded from the discussion or suppressed altogether. [73] Factually inaccurate 'danger messages' about cannabis are at the same time unrelentingly forced home to non-experts and the general public. [74]

Passage of the Amendments to the Narcotic Drugs Act therefore, along with a clear collaboration of forces antithetic to MC, have together served to create a plethora of obstacles – many of them believed dealt with and overcome by the Federal Public Inquiry into the 'Regulator' Bill. These, in our view, if left unaddressed, will effectively prevent any form of genuine or meaningful medical cannabis programme ever from existing in Australia yet, practically and as a matter of policy, they help underpin the

current, highly unacceptable position in which the country finds itself in respect of this issue.

4.6 Summary of current obstacles to a functioning MC Programme for Australia

A number of these obstacles are as follows; some already addressed by this Submission:

- A refusal by the Government and 'medical establishment' to consider any evidence as to the efficacy of MC other than that of Randomised Controlled Trials (RCTs) – often expressed in shorthand as 'not enough evidence';
- An apparently unshakeable ambition to treat and regulate cannabis like other conventional medicines;
- The belief (more a policy position) that 'a crude plant product' is 'a risky way' (i.e. impermissible way) to 'deliver cannabinoids for medical purposes' and that 'other appropriate ways of delivering cannabinoids for medical purposes must be sought' – e.g. the creation of pharmaceutical products made from them, and this despite permitting overseas products that themselves are based on or comprise 'crude plant';
- Generally a regulatory framework that was neither designed for nor is able to cope with a medicine like cannabis;
- A patchwork of State and Federal regulation which has the net effect of interfering with the doctor/patient relationship while creating a 'postcode lottery';
- An assumption that medical 'specialists' are better qualified and have a greater understanding of medicinal cannabis than do GPs;
- No concessions made for patients subjected to Roadside Drug Testing while using even legally prescribed cannabis products. The RDTs do not test for impairment but for the presence of THC, which is fat soluable and thus may remain in the body for days – sometimes weeks – after use. Meanwhile no such testing is done or required for the use of equally intoxicating drugs such as benzodiazipines and other products even when these are likely to cause impairment, creating a wholly discriminatory situation where MC is concerned. [75]

4.7 The matter of 'Acceptable Evidence' & a note on Randomised Controlled Trials (RCTs)

Of these, one issue in particular is of considerable importance – and which we have not thus far examined in detail. Its absence from the discussion however would render any such exercise incomplete and is the first of the above-listed points: the matter of what constitutes 'acceptable evidence'.

For policy-writers, drug companies and the medical 'establishment' the only acceptable form this may take is that of the Randomised Controlled Trial (RCT) – the 'Gold Standard' of 'Evidence Based Medicine'.

On this matter, UIC accepts the relative paucity of RCT data where MC is concerned – the result of decades of complete prohibition – although the UK's Centre for Medical Cannabis reports over 700 RCTs investigating the medical benefits of various cannabis products have been published in the last 10 years. [76] Nor do we consider this Submission an appropriate platform from which to engage in debate (which exists) [77] over whether RCTs are indeed the most effective means of assessing the medicine. Still a though a significant issue arises.

When the Department of Health experts conducted their 'Literature Review' and concluded only that 'insufficient' or 'low quality' evidence could be found for the drug's safety and efficacy they failed to include any material outside of RCT data. Such an approach we consider to be a significant oversight given increasingly large volumes of information that are becoming available from around the world, particularly from those jurisdictions where MC is accessible legally. [78]

4.7.1 All other evidence disregarded

Any thoroughgoing and truly disinterested exercise of this nature we therefore suggest should and must consider a range of evidence, not just RCTs - though we acknowledge the summarising of evidence is where most of the skill is required and that the potential for bias is a threat.

Disregarding huge demographic data however (involving millions of people using the medicine with remarkable degrees of success) along with countless clinically conducted observational studies and prescribing know-how and scholarship on the part of innumerable clinicians worldwide is certain to be partial at best and unscientific and dishonest at worst. It is also detrimental to the interests of patients and insulting to those thousands of sick Australians currently making use of MC illegally, many to maintain a basic quality of life that would otherwise be unavailable. In some of these instances its use is a life or death matter. [79] Discounting this extensive 'lived experience' among patients furthermore in effect brands them as liars.

4.7.2 UIC's Position on the above

UIC finds such a stance unacceptable, particularly since, at time of writing, our organisation is in the process of producing a fourth 'Medicinal Cannabis Symposium (in March 2019). [80] This world-class, international event will feature - as have its predecessors [81] - some of the best and most celebrated scientists and medical practitioners working with cannabis globally. We continue to be dismayed and perplexed therefore that the individuals and work being showcased – not to mention the events themselves - are all but ignored by those whose opposition to MC has been of most hindrance to its re-introduction. In particular we refer here to those Governmental advisors and organisations such as the AMA and other medical bodies which persist - in the face of such expertise - with the argument that 'not enough evidence' exists in

relation to the drug's safety and efficacy.

Here it is worth returning once more to Professor L. Mather cited earlier, who argued in his Submission to the Federal Inquiry into the Regulator of Medicinal Cannabis Bill that:

> '*the present complications of cannabis as a medicine are not due to a lack of evidence, as some would claim'* since *'hard-backed' peer-reviewed published evidence supports the use of cannabis.'* This had, he said, *'been reported and analysed in various places, including Australian parliaments, the British House of Lords and the US Institute of Medicine.'*

And crucially, Prof. Mather went on to add:

> '...*there are many drugs in current use, including some supported by PBS listing, for which the evidence of therapeutic efficacy is not as strong as that for cannabis, and this is reinforced when anecdotal evidence is admitted into the argument.'*

This somewhat disturbing fact too we believe needs to be taken into account when considering the availability cannabis and cannabis products and the effects of the 2016 legislative change.

And whilst UIC is certainly not arguing RCTs are faulty by design, or that other forms of evidence are equally valid, we do challenge what we consider to be the difficult-to-understand rationale behind a 'Framework' that is denying patients legal access to MC essentially because of a lack of the supposedly highest levels of evidence. This has directly left thousands of people with the only option of tackling complex health problems alone and without appropriate clinical oversight by a licensed medical practitioner. Such policy, we argue, is contradictory at best and risks the health and safety of patients by subjecting them to illicit, unregulated products. We suggest it is safer and in fact within the scope of duty of care to clinically monitor patient use of an easily accessible, affordable and better regulated medicinal cannabis product - *even if with sub-optimal scientific evidence* - than it is to subject them by default to using unregulated products, unsupervised by a healthcare professional, via illicit use.

4.7.3 Hierarchy of Evidence: A possible solution

Moreover, according to the National Health and Medical Research Council (NHMRC) [82] evidence comes in the form of systematic reviews (Level I), randomised controlled trials (Level II), pseudo-randomised controlled trials (Level III-1), comparative studies with concurrent controls (Level III-2), comparative studies without concurrent controls (Level III-3) and case series with either post-test or pre-test/post-test outcome measures (Level IV). This 'hierarchy of evidence' underpins the clinical decision-making process of government departments, research institutes and universities as well as individual medical practitioners making informed clinical judgements for the health and well-being of their patients on a day-to-day basis.

Of particular relevance to this discussion therefore is the N of 1 clinical trial, which fits within the hierarchy of evidence framework. This level of evidence considers an individual patient as the sole unit of observation in a study investigating efficacy or side-effect profiles of different interventions, with the goal of determining the optimal intervention for an individual patient using objective data driven criteria and outcome measures. Results of such studies can be collected and collated to ascertain proof of concept and establish a scientific rationale for treatment of a particular condition, which can then lead to more rigorous forms of evidence as required. This approach, we suggest, should be made genuinely available to all patients currently using unregulated (i.e. illicit) products.

Finally, before turning to our conclusions in this Submission's final Section – which provides a number of recommendations for better policy and regulation around MC in Australia – we note alongside the obstacles listed above, a disturbing lack of knowledge about cannabis and cannabis medicine among healthcare professionals.

As Professor Mather has additionally pointed out, despite widespread use, and possibly because of it, there lies a marked gap in medical expertise – partly, he says:

> '*a consequence of the bias in research support (and consequent publication bias) arising from the intentional promotion of research into the harms of 'recreational' cannabis and the dearth of research into the benefits of 'medicinal' cannabis*.'
> '*Evidence in support of this viewpoint*,' Prof. Mather continues, *'lies in the volumes of publications in the 'drug abuse' literature compared to those in the 'applied therapeutics' literature*.

4.8 Poor/limited knowledge of cannabis & cannabis products & medicine among healthcare professionals

As if proof of these assertions were needed, last year the Lambert Initiative at Sydney University produced a 'cross sectional survey' of Australian GPs in relation to MC published in the British Medical Journal. [83] It showed only 28.8% felt comfortable discussing the matter with patients and the paper concluded there was a '*need for improved training of GPs around medicinal cannabis, and the discrepancy between GP-preferred models of access and the current specialist-led models*.'

Yet only three RACGP-accredited training courses exist for healthcare professionals across the whole of Australia (one of them UIC's) even as the Federal Government repeatedly lays the slow take-up of this medicine at the feet of medicos [84] – while failing to assist with or fund these or any other learning or knowledge-sharing initiative.

These, and many more issues, we hope give an indication of some of what currently troubles Australia's MC 'Framework' and why it remains our view that, in its current form,

it is irredeemably unfit for purpose.

Section Five: Further Comments & Recommendations

This Submission has set out to argue and demonstrate that, for numerous reasons explained, the 2016 Amendments to the Narcotic Drugs Act have resulted in a messy, ill-considered and ultimately unworkable Framework for medicinal cannabis in Australia.

Though its architects may (and likely will) attempt to argue that the current 'system' was designed to - and indeed does - meet patient need and ensure best outcomes for them by restricting access to untested cannabis products by individuals who could be harmed from their use, UIC refutes this position entirely.

5.1 In Summary

To summarise once again why this is our view:

- Australia still has a significantly sized black market for medicinal cannabis and cannabis products which are supplied without provenance or quality assurance, dwarfing the licit market by orders of magnitude. Results of the legislation have obliged sick Australians to rely on this source with no clinical supervision available to them, necessarily placing themselves in harm's way;
- No real objectives in terms of what of the 2016 legislation set out to achieve (other than compliance with the UN Single Convention on Drugs) were ever identified making it impossible to determine whether it (the legislation) has 'succeeded' or 'failed';
- The NDA Amendments have caused medicinal cannabis and other cannabis products to fall into a state of permanent 'regulatory limbo' – quite literally '*approved unapproved medicines*' - a situation we find highly illogical if not completely nonsensical;
- The above regulatory position has resulted in an access pathway to cannabis and cannabis products that ensures they are treated and viewed only as medicines of last resort, for use in 'exceptional clinical circumstances'. This is notwithstanding the ineliminable fact that in excess of 100,000 individuals are already using such products illegally.

5.1.1 Moving forward – remedy needed at political level

Faced with this reality, UIC believes the only genuine solution available is a root and branch overhaul of this country's entire MC Framework, beginning with and requiring the political will to make medicinal cannabis and cannabis products genuinely available to patients and far more coherently regulated.

5.1.2 Judiciary might solve the problem

Without such resolve at the political level, we anticipate little progress will be made outside of (possibly) the Judiciary - which we predict will continue to take an increasingly lenient view of individuals caught in possession of cannabis and cannabis products purely for medical purposes. [85] Pleas of 'not guilty on grounds of medical necessity' could well become more frequent and acquittals from these charges not uncommon, setting increasingly firm legal precedent (as in the November 2018 instance of *R v Katelaris* in Sydney). [86] It is thus possible such cases, over time, will bring into effect a *de facto* decriminalisation of cannabis possession but outside of political or regulatory control. In any event, we believe a 'do nothing' approach will, in the immediate and longer terms, be entirely counter-productive.

5.2 Five Policy Objectives for the Future

In our consideration therefore, UIC is here suggesting **five** *minimum required policy objectives* we feel should be placed at the heart of any revised scheme or Framework for MC in the future. These could and should then serve as benchmarks for further Review processes against which the success or otherwise of policy can be evaluated. These five 'objectives' are as follows:

Australian MC regulation should, going forward:

- Assess and meet patient need as well as ensure best outcomes for patients based on the reality of the situation across the country;
- Create an MC programme that optimises net clinical and health system benefits;
- Provide a serious and better alternative to the black market as well incentivisation of patient migration from black market products;
- Deliver legal, accessible, and affordable products domestically;
- Optimise the financial and economic benefits offered by a regulated and vibrant local cannabis industry.

With these aims placed at its centre UIC believes a far better solution for regulating and delivering MC should be possible.

5.3 Immediate Actions Required

In the meantime however, and as a matter of urgency and absolute priority, we call on all Governments in Australia **immediately** to:

1. Recognise demonstrably medicinal use of cannabis and cannabis products (per a note of confirmation from a practising doctor) to be an *absolute defence* against arrest and charges for cannabis possession;
2. Ensure every MC user has the opportunity to transition from unregulated to regulated products;

3. Provide resource and support in the sphere of training for healthcare practitioners in the use of medicinal cannabis.

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