



United in Compassion Ltd.



Re: Submission for Inquiry into Improving Access to Medicinal Cannabis Bill 2023

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Medicinal_cannabis

My name is Lucy Haslam. I am the Co-Founder and Director of United in Compassion Ltd (UIC). I am also Co-Founder and Chair of The Australian Medicinal Cannabis Association (AMCA), and a founding member of The Society of Cannabis Clinicians Australian Chapter (SCCAC). I believe that AMCA will be providing a separate submission.

All three organisations have been founded to try and support the various aspects of the medicinal cannabis sector, recognising that the whole of sector needs to function well in order to best serve the needs of patients.

UIC has long advocated for the rights for Australian patients to access safe and affordable cannabis products for the treatment and/or management of symptoms of a wide range of debilitating medical conditions. I am proud to say that it was our lobbying, that resulted in a change in the legal status of medicinal cannabis in February 2016, one the first anniversary of my son Dan's death from stage 4 bowel cancer.

However, it is clear, that many are still regularly sourcing cannabis products on the illicit market due to numerous barriers to legal access as were highlighted in the Senate Community Affairs Reference Committee inquiry into the current barriers to patient access to medicinal cannabis.(March 2020) This was an inquiry which was strongly opposed by the previous Government and disappointingly, many of the recommendations of that inquiry went unaddressed by the previous Government and remain unaddressed today.

I would therefore like to first and foremost applaud Senator Pauline Hanson and One Nation for seeking to address what have been longstanding problems that heavily impact thousands of Australian patients, on a daily basis, seven years since legalisation.

One of the benefits of being a member of the AMCA, is that we have access to the specialist legal and regulatory advice provided by our Secretary Dr Teresa Nicoletti and her staff at Mills Oakley Law Firm, Level 7, 151 Clarence Street, Sydney NSW 2000. Dr Nicoletti is qualified both as a lawyer and as a scientist with many decades of experience in the Pharmaceutical Industry across both her fields of qualification.

When this The Improving Access to Medicinal Cannabis Bill 2023 was made public, Dr Nicoletti was tasked with providing an assessment of the merits of the Bill and the likelihood that it would achieve its objectives to improve access to medicinal cannabis for all Australians and additionally, for animals.

I therefore refer to the expertise of Dr Nicoletti and her team who have a thorough understanding of the purported amendments.

Unfortunately, their assessment of The Bill is that it ***will not achieve its objectives***. I am sure that Dr Nicoletti and Mills Oakley will make this opinion available to the Committee as a submission. I attach the article she provided to AMCA with this submission with full disclosure that any opinion expressed by myself as Director of UIC and Chair of AMCA is made with direct reference to this professional and very specialised advice.

Driving some amendments to the National Health Act to facilitate the listing of medicinal cannabis products on the Pharmaceutical Benefits Scheme (PBS) to make them more affordable for patients may reflect well acknowledged need, however, significant overhauling of the legislation would first be required, as the Minister of Health may or may not decide to list something on the PBS based on advice received from the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC assesses the cost and effectiveness of a medicine compared with other therapies that are currently listed on the PBS. **However, there is nothing in the legislation that states that a medicine has to be on the ARTG to be listed on the PBS.**

The key issue is that other than the two registered products (Sativex and Epidiolex), medicinal cannabis products do not yet have the data that is required to support listing.

Whilst I have been critical in the past of the Amendment to the Narcotic Drugs Act that transpired in 2016 to make medicinal cannabis available, (because the processes appeared very inferior and less flexible than the original Regulator Of Medicinal Cannabis Bill of 2014,) it is appreciated that a regulatory scheme was created that allowed the supply of medicinal cannabis products as unapproved goods, in circumstances where really safety and efficacy has not been properly established (as would be expected for registered goods). Safety and efficacy data underpin applications to the PBAC, because it is those data that are used to compare the drug to be listed, with existing drugs, and to show no worse a value proposition than drugs that are already listed on the PBS.

We believe that based on conversations that have been held with various MPs that most show a total misunderstanding and that a whole new listing regime would be required. Using Dr Nicoletti's expertise again, she reiterates that the key issue is not whether a drug is registered, but whether a company seeking to list a medicinal cannabis product on the PBS will ever have the necessary data to do that; clinical trials would be required to generate the data that is needed, and those data could be used to submit an application for registration, as well as listing.

The upcoming Therapeutic Goods Order 93 (TGO93) is all about quality. It has nothing to do with safety and efficacy and cost effectiveness, which are what you need to demonstrate to the PBAC if you're ever going to have a chance of listing. PBAC requires not just randomized controlled trials for a particular product for a particular indication, but also cost-effectiveness data built into the trials. Just collecting and collating observational data would be unlikely to satisfy PBAC.

In conclusion, I would like to add that it is very important that the Government and all Members of Parliament across all political persuasions, not give up on trying to improve the current problems that

inhibit access. Perhaps the solutions to removing some of the barriers to patient access to medicinal cannabis lie in other considerations. For example:

- Finding other means of subsidising products for patients.
- Conducting a Parliamentary inquiry into the obvious price gouging and closed loop arrangements that add costs to almost every step of the supply chain and that seem to be becoming endemic in the sector.
- And revising existing State and Territory drug driving laws being the most obvious of these issues.

As time passes, the other emerging problem that will require addressing, is the situation that sees some legally prescribed medicinal cannabis patients who are also employees across a range of industries, being sacked because of equally discriminatory and archaic drug regulations that endure across some workplaces.

Indeed, many areas within the community, including many health care professionals and employers have not kept up with the legal status of medicinal cannabis and the fact that it improves the capacity for many to work and to do so with enhanced work safely.

Referring once more to the recommendations of the Senate Community Affairs Reference Committee inquiry into the current barriers to patient access to medicinal cannabis. (March 2020) the Government would do well to invest in independent education and public awareness to drive down stigma and better inform policy in the many areas that require reform.

Toward that end UIC, AMCA and The SCCAC support this action toward regulatory reform and would welcome any opportunity to work with Government.

Yours sincerely

Lucy Haslam
Director UIC

Referenced Attachment:

Document titled Pauline's Puzzling Proposal: Does it achieve its intended purpose.

Dr Teresa Nicoletti (Partner), Ella Adams (Lawyer), Rebecca Pecovski (Lawyer)