



NSW Industrial Hemp Association
INC 9892530
21st May 2020

Consultation: Proposed amendments to the Poisons Standard - Joint ACMS/ACCS meetings, June 2020

2.2 Cannabidiol CAS Number 13956-29-1

ATTENTION: Advisory Committee on Medical Scheduling

Via email: medicines.scheduling@health.gov.au

Dear Sir/Madam,

I am writing in my capacity as the President of the NSW Industrial Hemp Association (<https://www.ihansw.org.au/>). We were incorporated in 2010 and have been one of the most active hemp associations in Australia. We were one of the key drivers in forming the Australian Industrial Hemp Alliance and are currently an Associate Member, represented on the AIHA Executive Committee.

This submission will address the reasons for the proposals as outlined on the TGA website (<https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-acmsaccs-meetings-june-2020#how>).

As well as mandatory elements to the submission there are optional elements: -

Submissions might also include:

- *Suggested improvements; and/or*
- *An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.*

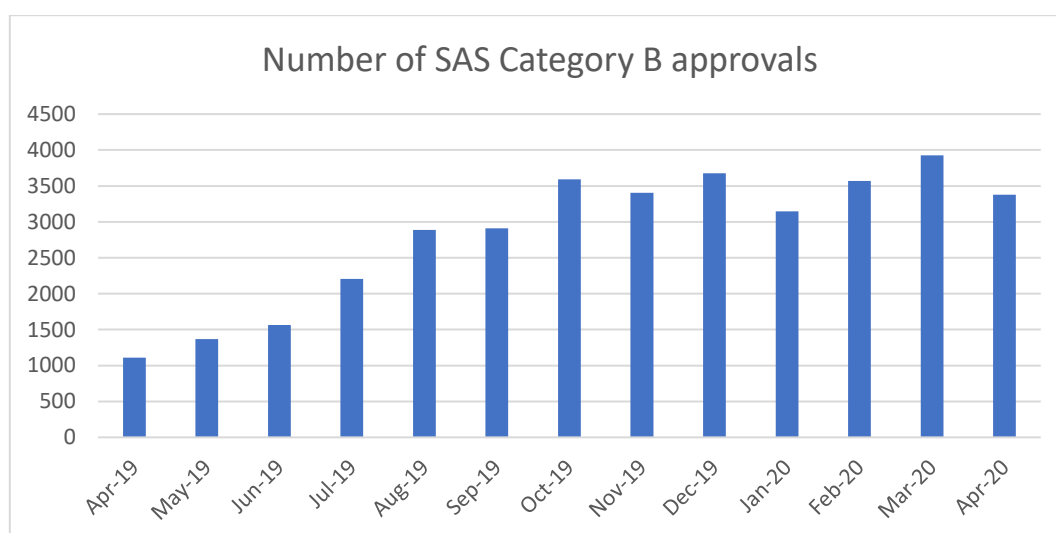
These will be addressed in this submission, as it is our opinion that CBD should be de-scheduled, readily available, and affordable. Australia has the capacity to produce large quantities of CBD for the domestic market at affordable prices.

Response to the proposed amendments

The proposal to reschedule CBD from S4 to S3 will have a positive impact on access to CBD products bypassing the need to see a General Practitioner or visit a specialist Cannabis Clinic. This removes a time-consuming process and a cost that many consumers cannot afford. This is borne out by the relatively small numbers of patients currently accessing licit medicinal cannabis.

As of April 30th, 2020, as stated on the TGA website, there were 63 Authorised Prescribers and approximately 42,000 cannabis prescriptions have been written under the SAS-B since 2016. This figure does not equate to patients as there would be repeat prescriptions.

The number of SAS Category B approvals has levelled or fallen in 2020. The chart below is based on current data from the TGA.



Sativex (nabiximols), an approved medicinal cannabis product included in the ARTG, is also available in Australia and its use is not included in these statistics.

These figures are not for CBD only preparations, as many prescriptions are for CBD: THC, and a minor amount for THC only. Regardless, the data does show that supply has plateaued and is falling far short of the potential demand.

The White Paper produced by the University of Sydney in Partnership with MGC Pharmaceuticals (2016) contained data on the numbers of Australians with conditions that could be treated with medicinal cannabis. In some cases, these are children suffering from rare and extremely dangerous forms of epilepsy. Some children suffer hundreds of seizures per day and these do cumulative damage to the developing brain.

According to this paper, it has been estimated that 101,250. Australians are living with epilepsy. 22,842 Australians have pharmacoresistant epilepsy. 3,814 Australians have not responded to at least four anti-epileptic medicines. These figures show that the current scheduling, and number of applications, is not allowing people with epilepsy to access medicinal cannabis.

Although there is some evidence to suggest that CBD could be used for treating pharmacoresistant epilepsy, most medicinal cannabis research is particularly concerned with using CBD to treat severe pharmacoresistant childhood epilepsy, specifically Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS).

These are the most serious epileptic conditions and require the supervision of medical professionals. However, downscheduling or de-scheduling will make medicinal cannabis cheaper and more affordable for DS/LGS patients, as well as the those with less severe forms of epilepsy. A poll conducted on Epilepsy Action Australia (<https://www.epilepsy.org.au/>) showed that 96.93% of respondents agreed that medicinal cannabis should be readily available as a treatment for people living with epilepsy.

To date, the TGA has approved SAS applications including, but not limited to, the following indications:

- chemotherapy-induced nausea and vomiting
- refractory paediatric epilepsy
- palliative care indications
- cancer pain
- neuropathic pain
- spasticity from neurological conditions
- anorexia and wasting associated with chronic illness (such as cancer)

it is difficult to quantify the total number of people with the conditions approved by the TGA. In 2013-2014, there were 621,239 treatment sessions (or 'events') for radiation oncology in Australian hospitals. In 2012-2013, Australian patients underwent a total of 374,588 'treatment days' for chemotherapy.

As far as anorexia is concerned, according to the government website, <https://www.eatingdisorders.org.au/>, The number of people in Australia with an eating disorder at any given time is estimated to be 913,986, or approximately 4% of the population (Butterfly Foundation, 2012). In comparison to the general population, mortality rates are almost twice as high for people with eating disorders; this rises to 5.86 times higher for people with anorexia (Arcelus et al., 2011). Suicide has been identified as a major cause of death for people with an eating disorder (Pompili et al., 2006). The prevalence of eating disorders is increasing amongst boys and men (NEDC, 2012a). Approximately 15% of women will experience an eating disorder at some point during their life (Wade, 2006). An estimated 20% of females have an undiagnosed eating disorder (NEDC, 2012b). Eating disorders are the 3rd most common chronic illness in young women (Yeo & Hughes, 2011). It is our contention that the current scheduling of CBD is not serving the total numbers of people with the conditions listed above.

Suggested improvements and impacts of proposed changes

Having addressed the mandatory elements there are some changes the optional elements will be addressed: -

- *Suggested improvements; and/or*
- *An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.*

Suggested improvements

It is our position that a rescheduling of CBD from Schedule 4 to Schedule 3 does not go far enough in addressing all the conditions for which medicinal cannabis can be an effective treatment. The numbers of people with the conditions listed below run into many millions and the cost to the healthcare system using conventional treatment practices is in the many billions of dollars per annum.

The list of conditions is partial and other conditions can be treated with medicinal cannabis.

- Autism
- Fibromyalgia
- Anxiety
- Depression
- Post-Traumatic Stress Disorder (PTSD)
- Addiction (including opioids/tobacco)
- HIV/Aids
- Multiple Sclerosis
- Parkinson's Disease
- Diabetes
- Crohn's Disease
- Colitis
- Rheumatoid Arthritis
- Tourette's Syndrome
- Insomnia

It is our contention that these groups represent a significant proportion of the Australian population that need ready access to CBD that will not be met by S3. It is not our contention that CBD will "cure" these conditions but that it will provide relief for some individuals. It is the view of our association that de-scheduling CBD is the most logical and humane way for giving affordable access to CBD. It will also bring the greatest benefit to the Australian economy through job creation and commerce.

Many of the conditions listed above relate to mental health. Depression, anxiety, insomnia, and addiction are common conditions. PTSD is also a mental health condition related to a traumatic incident or prolonged periods of heightened stress. Mental health is something that affects many Australians and 4.3 million Australians received mental health prescriptions in 2018/2019. Inflammatory conditions can also be caused by stress and exacerbated by a deterioration in mental health.

Mental illness refers to a clinically diagnosable disorder that significantly interferes with an individual's cognitive, emotional, or social abilities (COAG Health Council 2017). The term covers a spectrum of disorders that vary in severity and duration (Slade et al. 2009). Mental illness can have damaging effects on the individuals and families affected, and its influence is far-reaching for society. Social problems commonly associated with mental illness include poverty, unemployment, reduced productivity, and homelessness. Those with mental illness often experience problems such as isolation, discrimination, and stigma (WHO 2016). The terms mental illness and mental disorder are often used interchangeably. Forty-five per cent of Australians will have a common mental disorder in their lifetime, according to data from the 2007 National Survey of Mental Health and Wellbeing (NSMHWB) of adults (aged 16–85). That equates to about 8.7 million people who will experience a common mental disorder in their lifetime, based on the estimated 2017 population. Each year, 1 in 5 Australians in this age range (20% or about 3.9 million Australians in 2017) are estimated to experience a mental disorder (ABS 2008). Anxiety disorders (for example, Generalised Anxiety Disorder and Social Phobia) were the most common types of disorder reported in the NSMHWB, with 14.4% of Australian adults experiencing an Anxiety disorder in the previous 12 months (ABS 2008). This was followed by Affective disorders (for example, Depression, 6.2%) and Substance use disorders (for example, Alcohol dependence, 5.1%).

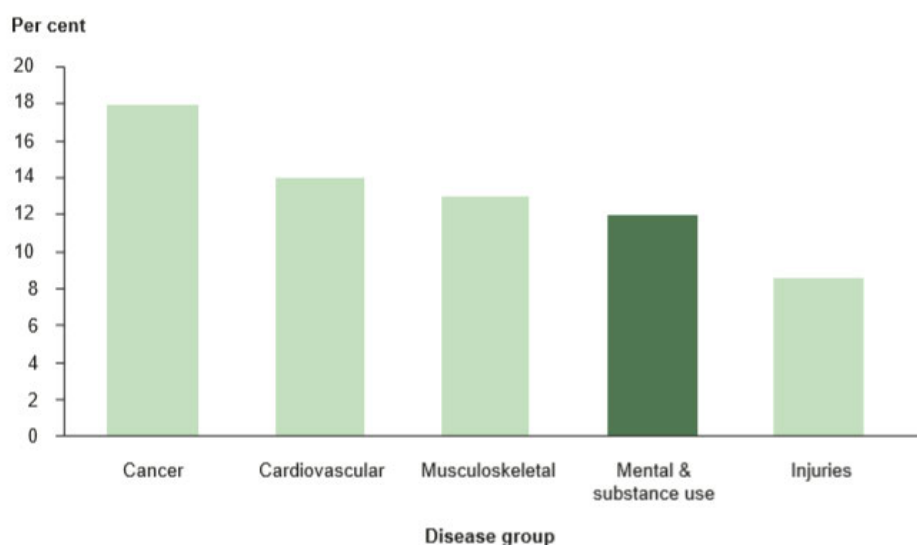
Expenditure on mental health.

- \$9.9 billion, or \$400 per person, was spent on mental health-related services in Australia during 2017–18, a real increase from \$382 per person in 2013–14.
- 1.1% annual average increase in the real per capita spending on mental health-related services from 2013–14 to 2017–18.
- 7.6% of government health expenditure was spent on mental health-related services in 2017–18.
- \$6.0 billion was spent on state/territory mental health services in 2017–18; \$2.6b on public hospital services; \$2.3b on community services.
- \$1.3 billion, or \$51 per person, was spent by the Australian Government on benefits for Medicare-subsidised mental health-specific services in 2018–19.
- \$541 million, or \$21 per person, was spent by the Australian Government on subsidised mental health-related prescriptions under the PBS/RPBS during 2018–19.

The treatment of mental health has a huge impact on the economy and ready access to over the counter CBD preparations would be effective in reducing these sums. Many sufferers self-medicate with illicit drugs and alcohol, which further reduces quality of life.

In addition, Australian sourced CBD can reduce dependence on conventional pharmaceuticals, a large proportion of which are either imported or foreign owned.

Australia's top 5 burden of disease groups, 2015 (Mental health Services in brief 2019/AIHW)



Mental and substance use disorders (24%) were the second largest contributor to non-fatal burden, behind Musculoskeletal conditions (25%) (AIHW 2019a).

CBD has been found to help patients with mental disorders ranging from mild anxiety to clinically diagnosed schizophrenia. CBD is well tolerated and has shown no side effects in clinical trials. It is not being suggested that CBD is the solution to all mental health issues, but rather that it can alleviate some symptoms and aid recovery of some individuals.

There is evidence that people with mental health issues are turning to CBD where it is readily available and affordable. A Gallup poll published in August 2019 showed that 14% of Americans said that they used CBD products. Whilst 40% utilised CBD for pain, 20% used it for anxiety and 11% for sleep, <https://news.gallup.com/poll/263147/americans-say-cbd-products.aspx>.

In Australia, the Alcohol and Drug Foundation published an insight piece in September 2019. Their review of multiple trials looking at the therapeutic effects of CBD concluded that CBD is a promising treatment.

In summary: -

- some improved symptoms for individuals who have schizophrenia
- reduced anxiety in some people with anxiety disorders
- some reductions in craving for people with a tobacco dependence
- improved symptoms in people experiencing withdrawal from cannabis.

The full study is available here: <https://adf.org.au/insights/medical-cannabis-mental-illness/>

In Australia the Lambert Initiative for Cannabinoid Therapeutics in collaboration with the University of New South Wales is currently conducting a trial of CBD for anxiety. They see great potential for clinical trials of cannabinoids for mental health disorders, thanks to its ability to reduce anxiety and psychosis.

The Lambert Initiative research

Cannabidiol for adolescent anxiety (CAPS)

This study is a single-centre, 12-week open-label trial of CBD for anxiety disorders. Participants are young people aged 12 – 25 years with a DSM-5 diagnosis of an anxiety disorder who do not respond to evidence-based standard treatment (e.g. CBT or CBT plus SSRIs/SSNRIs). CBD is administered on a fixed–flexible schedule adjusted up to a maximum dose. Each participant will be offered biweekly CBT for 12 weeks (5 sessions). The trial is being conducted at the Headspace Glenroy facility according to Good Clinical Practice guidelines, overseen by the trial sponsor, Orygen – The National Centre of Excellence in Youth Mental Health study service unit.

This is a collaboration between the Lambert Initiative for Cannabinoid Therapeutics at the University of Sydney; and Orygen, The National Centre of Excellence in Youth Mental Health.



The following is taken from a study that is a very balanced assessment of recent clinical trials.

The therapeutic role of Cannabidiol in mental health: a systematic review

Journal of Cannabis Research volume 2, Article number: 2 (2020)

<https://jcanabisresearch.biomedcentral.com/articles/10.1186/s42238-019-0012-y>

The cannabis plant has more than 140 cannabinoid compounds, with Δ^9 -tetrahydrocannabinol (Δ^9 -THC) and cannabidiol (CBD) attracting significant interest (Citti et al., 2018). Δ^9 -THC is the primary psychoactive ingredient, and CBD is a non-intoxicating ingredient (Zuardi, 2006; Citti et al., 2018). Evidence from preclinical studies suggested that CBD had potential therapeutic benefits ranging from anti-inflammatory to neuroprotective, antipsychotic, analgesic, anticonvulsant, antiemetic, antioxidant, antiarthritic, and antineoplastic properties; for a review, see (Pertwee, 2006). CBD has several receptors and molecular targets. This compound antagonizes the action of CB₁ and CB₂ receptor agonist (Blessing et al., 2015; Peres et al., 2018). The CB₁ and CB₂ receptors are coupled negatively through G-proteins to adenylate cyclase and positively to mitogen-activated protein kinase (Pertwee, 2006). In addition to CB₁ and CB₂ receptor activity, CBD is an agonist of vanilloid receptor TRPV₁. It also acts as an agonist of serotonin receptor 5-hydroxytryptamine (5-HT_{1A}), an antagonist of G-protein-coupled receptor GPR55, and an inverse agonist of GPR3, GPR6, and GPR12 (Peres et al., 2018). Data from single-photon emission computed tomography showed CBD to exert anxiolytic effects by acting on paralimbic and limbic pathways (Crippa et al., 2011). The agonist effect of CBD on 5-HT_{1A} also supports its anxiolytic and antidepressant properties (Russo et al., 2005). CBD inhibits enzymatic hydrolysis and anandamide uptake through its agonist action on CB₁, CB₂, and TRPV₁ receptors (Peres et al., 2018). In addition, CBD indirectly enhances endogenous anandamide signalling by inhibiting the intercellular degradation of anandamide (Leweke et al., 2012). This endogenous neurotransmitter exerts antipsychotic effects in patients with schizophrenia (Leweke et al., 2012).

CBD is postulated to improve cognitive performance in psychosis through the mediation of CB₁ and CB₂ receptor agonism at lower concentrations (Hallak et al., 2010; Solowij et al., 2018; Manseau & Goff, 2015). This cognitive improvement has been hypothesized due to the higher concentration of

cannabinoid receptors in the hypothalamus, suggesting a role in superior cognitive functioning (Hallak et al., 2010). Naturalistic studies of CBD report better cognitive performance including memory, increased grey matter in the hippocampus, and fewer psychotic symptoms in patients given higher doses of CBD (Solowij et al., 2018).

The therapeutic benefits for psychosis is hypothesized due to the inhibition of anandamide re-uptake and degradation, resulting in increased anandamide levels in the brain (Manseau & Goff, 2015). Increased anandamide levels and improvements in the symptoms of psychosis were reported in another 4-week-long RCT comparing the efficacy of CBD to amisulpride for the treatment of schizophrenia (Leweke et al., 2012). Interestingly, anandamide levels were elevated in patients with acute schizophrenia compared to chronic schizophrenia, indicating a compensatory increase in an acute state (Giuffrida et al., 2004).

It is fair to say that there is already a need for CBD to made more widely available to treat mental health conditions. What is also clear is that the current Covid 19 outbreak will increase the incidence and severity of mental health issues. There are many media reports of increases in suicides and people contacting counselling services and crisis centres. The effects of the current pandemic are wide reaching. Loss of employment is leading to increases in stress. The effects of isolation and quarantine are also deleterious to mental health.

Australia is facing a pandemic of unknown proportions with uncertain outcomes. One factor that can be assessed is the effect of quarantine and isolation on mental health. The Lancet produced a study in response to the outbreak of Covid 19 in December 2019.

The psychological impact of quarantine and how to reduce it: rapid review of the evidence
([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30460-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30460-8/fulltext)).

The December 2019 coronavirus disease outbreak has seen many countries ask people who have potentially come into contact with the infection to isolate themselves at home or in a dedicated quarantine facility. Decisions on how to apply quarantine should be based on the best available evidence. The researchers did a review of the psychological impact of quarantine using three electronic databases. Of 3166 papers found, 24 are included in the review. Most reviewed studies reported negative psychological effects including post-traumatic stress symptoms, confusion, and anger. Stressors included longer quarantine duration, infection fears, frustration, boredom, inadequate supplies, inadequate information, financial loss, and stigma. Some researchers have suggested long-lasting effects.

Researchers undertook a Review of evidence on the psychological impact of quarantine to explore its likely effects on mental health and psychological wellbeing, and the factors that contribute to, or mitigate, these effects. These studies were done across ten countries and included people with SARS (11 studies), Ebola (five), the 2009 and 2010 H1N1 influenza pandemic (three), Middle East respiratory syndrome (two), and equine influenza (one). One of these studies related to both H1N1 and SARS.

Most quantitative studies only surveyed those who had been quarantined and generally reported a high prevalence of symptoms of psychological distress and disorder. Low mood (660 [73%] of 903) and irritability (512 [57%] of 903) stand out as having high prevalence.

People quarantined because of being in close contact with those who potentially have SARS 25 reported various negative responses during the quarantine period: over 20% (230 of 1057) reported fear, 18% (187) reported nervousness, 18% (186) reported sadness, and 10% (101) reported guilt. Few reported positive feelings: 5% (48) reported feelings of happiness and 4% (43) reported feelings of relief. Qualitative studies also identified a range of other psychological responses to quarantine, such as confusion, fear, anger, grief, numbness, and anxiety-induced insomnia.

Two studies reported on longer-term effects of quarantine. Three years after the SARS outbreak, alcohol abuse or dependency symptoms were positively associated with having been quarantined in health-care workers. In a multivariate analysis, after controlling for demographic factors, having been quarantined and having worked in a high-risk location were the two types of exposure significantly associated with these outcomes.

Having a history of psychiatric illness was associated with experiencing anxiety and anger 4–6 months after release from quarantine. Health-care workers who had been quarantined had more severe symptoms of post-traumatic stress than members of the public who had been quarantined, scoring significantly higher on all dimensions. Health-care workers also felt greater stigmatisation than the general public, exhibited more avoidance behaviours after quarantine, reported greater lost income, and were consistently more affected psychologically: they reported substantially more anger, annoyance, fear, frustration, guilt, helplessness, isolation, loneliness, nervousness, sadness, worry, and were less happy. Health-care workers were also substantially more likely to think they had SARS and to be concerned about infecting others.

In cases where there was an underlying mental health condition quarantine and post-quarantine mental health will be affected more dramatically and for a longer period.

How the proposed changes will affect the NSW Industrial Hemp Association members

The NSWIHA represents members that range from farmers, to retailers, and health professionals. Prior to making this submission their views have been canvassed. The overall conclusion is that CBD should be de-scheduled. This would have many benefits. Many of our members who have, or will, enter the medicinal cannabis industry have business models that are vertically integrated. Their models cover the whole supply chain from cultivation and manufacturing to sales to the end consumer. These models have a strong online component. If CBD is moved to schedule 3 these companies will not be able to sell direct to the consumer but will have to sell wholesale to pharmacists. Wholesale to retail involves a 100% mark-up. This means that our members are losing half of their potential revenue. This is restrictive and has an upward pressure on the cost that the consumer pays. As the objective is to allow free access to affordable CBD de-scheduling is necessary. In this scenario market forces will determine the cost.

How the proposed changes will affect the economy and public opinion

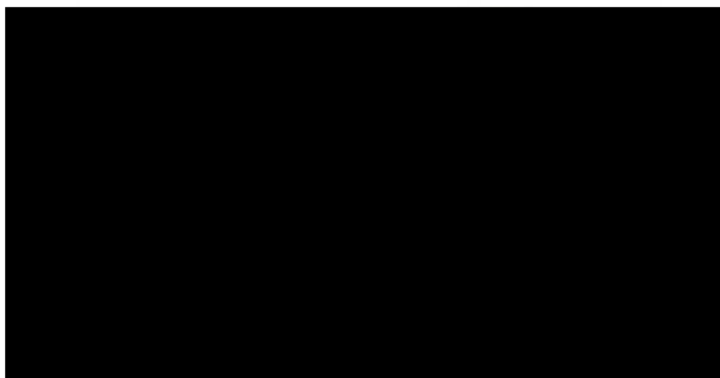
De-scheduling CBD will be a stimulus to the Australian economy as it will give the maximum return to the rural communities where the industrial hemp is cultivated and processed. There will be a flow through involving processing, packaging, transport, marketing, and sales. There will also be a stimulus that benefits the building industry where facilities are built from the ground up, or where existing facilities are remodelled or repurposed.

The economy will also benefit from a healthier population, especially in the area of mental health and well-being. This is important now and will grow in importance due the Covid 19 pandemic and the aftermath.

The government has many schemes in place to respond to the current pandemic and the effects on the Australian people and the economy. Many of these actions have required significant investment and ongoing complex management and administration processes. De-scheduling CBD will have positive outcomes for the Australian people and the Australian economy. This will be felt in rural areas where cultivation takes place and new employment will be generated. This will require no direct investment from the government but will be perceived as a proactive and positive action by the public.

Many studies have identified health workers as amongst the most at-risk people during the current pandemic. They are also a group that is affected when a pandemic subsides, and restrictions are lifted. Again, this would make the de-scheduling of CBD be seen in a very positive light by the Australian public.

Yours faithfully,



President NSW Industrial Hemp Association

www.ihansw.org.au



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