

**Submission
No 359**

**INQUIRY INTO IMPACT OF THE REGULATORY
FRAMEWORK FOR CANNABIS IN NEW SOUTH WALES**

Organisation: TRACEE
Date Received: 28 November 2024

TRACEE submission: Inquiry into the impact of the regulatory framework for cannabis in New South Wales.

Focus of this submission

This submission focuses on the following Terms of Reference:

1. That Portfolio Committee No. 1 - Premier and Finance inquire into and report on the impact of the regulatory framework for cannabis in New South Wales, including:

(f) alternative approaches to the regulatory framework for cannabis in other jurisdictions

Acknowledgement

We would like to thank the Committee for accepting this submission and allowing us to share some of our knowledge and insights.

Company background

TRACEE are technical advisors to governments on highly regulated industries, with a focus on ensuring transparency and public value in regulatory frameworks.

The team have expertise in public policy, technology design and development for regulated frameworks, regulatory compliance and major project and program development for the public and private sectors.

We have worked in jurisdictions including Australia, New Zealand, United States, Europe and the United Kingdom.

The crucial role of the regulatory framework

In order for the State to generate revenue that at a minimum covers the cost of legislative regulation, and at best to raise revenue, the industry itself must be efficient and profitable. Therefore it is critical that the most efficient regulation is achieved that protects the public interest while delivering a thriving industry.

A well-designed regulatory framework is essential for the cannabis industry, encompassing laws, policies, and guidelines that regulate the cultivation, processing, distribution, patient management, prescriptions and sale of cannabis products. This framework provides a structured approach, ensuring:

- Consistency in regulatory practices;

- Transparency across the supply chain; and
- Accountability for industry stakeholders.

However, transparency across the supply chain is only effective if robust protocols are in place. To develop a comprehensive framework, it's essential to consider the following key factors:

1. **Framework Objectives:** What are the primary objectives of the framework, and how are they measured?
2. **Stakeholder Roles:** What role does each stakeholder play in the supply chain, and what are their responsibilities?
3. **Framework Impacts:** What are the potential impacts of the framework on the industry, consumers, and the broader community?

A well-designed regulatory framework is crucial for ensuring safe legal cannabis products are available, and illicit activity is minimised. To achieve this, the framework must incorporate the expertise and perspectives of all stakeholders, including:

- Government agencies;
- Medical professionals;
- Researchers;
- Industry operators;
- Law enforcement;
- Advocacy groups; and
- Patients/ Consumers.

The global experience with cannabis regulation has yielded valuable lessons. Countries and jurisdictions that have pioneered in this regulatory space have encountered common challenges and made mistakes. Australia and NSW can benefit from these lessons.

Focus on the priorities that benefit Australia

The United States (US) provides a prime example of the complex and rapidly evolving landscape of cannabis regulation. As the industry expands, governments are struggling to keep pace. Globally, a similar framework is being replicated, but it's often falling short in meeting two critical government priorities:

- Ensuring public health and safety; and
- Preventing illicit activity and promoting a legitimate industry.

When the economic opportunity is substantial, as it is with cannabis, it's crucial that the framework is robust and adaptable to manage high growth and the inevitable iterations that follow. A well-designed framework must be able to balance competing priorities, address emerging challenges, and promote a safe, responsible, and thriving industry.

Governments worldwide are navigating the complex process of regulating cannabis. To assess the effectiveness of these efforts, we'll delve into three crucial aspects:

1. **Governance:** Examining the policy frameworks, laws, and enforcement mechanisms in place.
2. **Technology and Transparency:** Investigating how governments leverage technology to facilitate transparency, compliance, and public engagement.
3. **Capacity Building:** Analysing the investments made in education, training, and infrastructure to support a well-functioning regulatory ecosystem.

By examining these three key areas, we can identify areas of strength and weakness to inform data-driven improvements to the regulatory framework.

1. Governance

Regulatory frameworks for cannabis vary globally, with different models offering unique benefits and challenges. This section examines approaches from various jurisdictions, including the US states of New Mexico and California. By exploring these models, we can identify opportunities for NSW to develop an effective and efficient regulatory framework for the cannabis industry.

Australian Context

Australia's medical cannabis industry is jointly regulated by the Office of Drug Control (ODC) and the Therapeutic Goods Administration (TGA). While this dual-regulatory approach aims to ensure rigorous standards, it can create confusion among licensed operators.

The ODC issues permits for cultivation/production and manufacturing, whereas the TGA regulates manufacturing and production standards for cannabis products, adhering to the EU's Good Manufacturing Practice (GMP) guidance.

In practice, this dual-regulatory model can lead to confusion where it may not be clear which agency is responsible for what. We have anecdotal evidence of situations where a licensed manufacturer operator received a licence from the TGA when that license was not required as they already had the required permissions from the ODC.

Approaches from other jurisdictions

Some US states, such as New Mexico, have implemented a dual-agency model when transitioning from medicinal to recreational cannabis. The key difference lies in the division of responsibilities: for New Mexico, the Department of Health focuses on regulating medical patient management (such as coordinating and issuing Medical Cards which provides for zero tax sales), while the Cannabis Control Division (CCD) oversees the regulation of both the medical and recreational cannabis markets including licensing, compliance and enforcement (NM CCD 2024).

A single agency model provides the benefit of centralised visibility and oversight as well as authority. This single regulator model is used most often, including in Canada, Germany and in US states including California, New York and Colorado.

California's Department of Cannabis Control (DCC) law enforcement division has an interesting collaborative model where it operates within a Unified Cannabis Enforcement Taskforce (CA DCC 2024a) which includes federal agencies such as the Federal Bureau of Investigation (FBI), other state agencies such as the Department of Fish & Wildlife, and local Councils. The DCC takes the lead on enforcement for all large-scale indoor operations, and where there are organised crime networks involved, but other enforcement activities including smaller operations and outdoor grows are delegated to local government for enforcement.

The law enforcement approach in California highlights how essential collaboration is to the success of any regulated framework, and for resources and intelligence to be accessed in a centralised way. Technology is critical to enabling this collaboration.

Opportunities for NSW and Australia

For NSW, a regulatory framework can build on the existing shared responsibility models we have in place with Health, Workplace Health & Safety and Road Use. These functions all have harmonised legislation at the federal level and have a responsible state agency. Federal laws are enacted through state-based agencies with their own legislation and regulations.

The easiest and quickest path to harmonisation is for a leading State like NSW to develop best practice and share it with its Federal and other State and Territory colleagues.

What is critical in this delegated model is there is a consistent way of working nationwide that provides certainty and mobility for both operators and consumers, yet allows for the specificity of more local needs. Shared responsibility, particularly with regard to ensuring public health and safety and preventing illicit activity, can further be enacted using a Chain of Responsibility approach similar to the way that heavy vehicles are regulated in Australia.

However, regardless of whether NSW and Australia choose to move forward with the existing dual regulatory model, or move to a single agency model, we would recommend that there is a singular technology platform that agencies work within to manage the cannabis supply chain from licensing through compliance and enforcement. This platform should connect all relevant government agencies and stakeholders, licensed operators and patients/ consumers with secure role-based access to ensure there is transparency and accountability across the supply chain.

2. Technology and Transparency

The convergence of technology and transparency is vital in the cannabis industry. This section examines the limitations of current systems, particularly the US approach to track-and-trace platforms.

These platforms exemplify a framework that neglects stakeholder considerations, perpetuating anti-competitive practices and siloed operations. This opacity hinders regulators' ability to detect illicit activity and ensure safe product manufacture and distribution. We will discuss opportunities for improvement in the Australian context

With transparency, we can support stakeholders, regulators, and licensed operators to ultimately drive industry growth and development.

Approaches from other jurisdictions

Ineffectiveness of track-and-trace

In the United States, the concept of traceability has become central to the way the cannabis industry is regulated. Initially implemented in Colorado as the first state to legalise recreational cannabis in 2012, the notion of traceability has permeated throughout US states and is typically implemented through a state-mandated track-and-trace software.

However, traceability is not equal to transparency, and the focus on traceability has resulted in some unintended consequences that impact on the ability for the industry to grow, and for regulators to be effective. It is also questionable whether traceability has made any real impact on ensuring safe products are in the market, or that illicit activity is being curbed or prevented.

These software platforms rely on licensed operators reporting on their operational activities in real time (or close to it) in an attempt to detect illicit activity when there are smarter ways to identify and prevent illicit activity.

In addition, many US states have mandated the use of printed or RFID tags to track inventory at the individual plant or package level. However, both track-and-trace and individual tagging have proven to be ineffective and unnecessary, and only report activity retrospectively. The primary purpose of these tags appears to be generating revenue for software companies that provide the state-based tracking systems.

Most US states pass the cost of tags on to licensees, creating a significant financial burden that's hard to budget for due to variable production. This has led to a system where costs spiral out of control, sometimes forcing operators out of business. In the US state of Missouri, a state track-and-trace provider was taken to court and lost its case (MJBiz 2021) as it was passing these tag costs onto licensees. The court ruled that the cost of the tags should have been disclosed in the contract with the state (by not disclosing this cost, the provider was able to keep their contract value low and hence, competitive). Fortunately, Australia's medicinal cannabis industry has not taken this approach with mandating tags.

California is a rare exception in the US, covering the cost of RFID tags to the tune of around US\$23 million annually, plus an extra US\$8 million in track-and-trace software charges (Higher Origins 2023). Despite this significant investment by the taxpayer, California has failed to realise the purported benefits of these tags, which were supposed to help identify counterfeit products.

The legal market in California continuously exceeds US\$4 billion in sales per year, and the illicit market is thriving, generating over twice the revenue of the legal market (LA Times 2019).

Recent product recalls in California were triggered by an investigation into labs allegedly falsifying test results (MJBiz 2024). Recalls have sometimes been issued over three months from the dates the products were distributed to consumers, which have further highlighted the ineffectiveness of these tags. Notifying consumers of these recalls is challenging, with recalls being posted on the DCC's website and social media. Currently, there is no way to notify patients or consumers directly and could mean that contaminated products, such as vape cartridges or edibles, may have been consumed by patients months before a recall is issued.

Some US states, such as Minnesota, continue to develop regulations mandating the use of these RFID tags, despite evidence they don't prevent illicit activity. Instead, these tags contribute to electronic and plastic waste, and place an unnecessary cost burden on operators. Earlier this year, TRACEE provided feedback on these regulations including alternative approaches.

Anti-Competitive Practices

Another track-and-trace provider in the US also has a company that sells ERP software to cannabis operators (which in our opinion, presents serious probity issues). Their advantage for years was to not charge for tags/ IDs and win the state's track-an-trace contract. They would then not release their API to enable third parties to integrate (except for point of sale), enter the market early with their own ERP system, and advise operators as the state's mandated track-and-trace, that they were also required to use their company's ERP system (for example in New Mexico, the Cannabis Control Division has a warning on their website about this practice (NM CCD 2023), and the New York Office of Cannabis Management had to issue a similar warning)(NM OCM 2023).

In an attempt to deal with recent industry push back of monetising the digital IDs generated by their system (which has been implemented in states including New York)(NY OCM 2023a), this same provider is now looking to push their costs from industry to other technology companies. Knowing that state contracts will eventually force them to open their API as they have for New York, they have set up an 'API Concierge program' (Biotrack 2023) that will charge technology companies between US\$81,000 to \$114,000 per year to integrate.

In a market where technology companies are often charging less than US\$1,000 per month for their own ERP software just to stay competitive, it is highly unlikely any companies will be able to pay this annual fee. The outcome will be an API that competitors can't afford to integrate with, therefore removing choice for licensed operators, and offer their own ERP as the only solution which will capture the market.

Integrated regulatory framework platform

In order to deliver on transparency, a regulatory framework needs to be delivered with an integrated platform to provide visibility end-to-end. NSW's success with digitising government services from multiple agencies on Service NSW is a good example of how an integrated system connects industry and consumers with government services and announcements in an easy-to-use platform.

The recent launch of the ODC's Health Business Services Portal (ODC 2024) is a welcome development. It will be useful to assess how this online process improves permit application processing times, data on applicant trends, and manages applicant expectations.

A significant improvement in both customer experience and administration can be achieved through an online application process. This allows all stakeholders to track the status and timeline of applications. For example, California's online application process has an average processing time of 221 days (CA DCC 2024c) which is quite short for the US. But despite being online, it doesn't necessarily mean there is visibility. Notably, the California Department of Cannabis Control is currently conducting a market study due to its two online application portals – one for cultivators and one for all other licence types – not integrating or sharing information (CA DCC 2024d). This highlights the importance of an integrated online platform.

Transformation shouldn't stop at licensing. To drive change and maximise efficiency, online portals should integrate all necessary information and approvals from various agencies, including local councils and utilities. This transparency layer, where all relevant parties can collaborate on the same platform, is crucial for implementing a regulatory framework and informing future policy.

Implementing smart technologies and digital-first processes can significantly reduce the regulatory and administrative burden on regulators and the cannabis industry, reducing operational costs. With innovative solutions, we can pinpoint vulnerabilities in the supply chain and start to detect and prevent illicit activity by identifying irregular patterns and alerting regulators. We have recently been working with California on algorithms to better detect illegal activity. Taking a data-driven approach enables proactive regulation.

Providing Patients/ Consumers with Information

Most regulatory frameworks, including in Australia, fall short in providing consumers and patients with essential information about cannabis products. Labels and packaging often lack critical details, such as the strain of cannabis, the product's origin including the manufacturer or grower, and details about production, harvesting, and packaging. We have seen labels in Australia that only display the patient's name, the pharmacy sticker and the THC percentage of the cannabis.

This lack of transparency is unacceptable and is not consistent with Australian's expectations, or delivering a regulatory framework that prioritises public health and safety. To ensure patients and consumers can make informed decisions, cannabis product labels should, at a minimum, include:

- Product name and strain/cultivar
- Manufacturer/producer name and country of origin
- Manufacture/harvest date
- Package date
- Use by/Best before date
- Expiry date
- Primary cannabinoids (e.g. THC, CBD, CBG) and terpene profiles with proportions
- Correct dosage, application, and storage instructions
- A QR code or similar mechanism providing access to lab results, safety information, side effects, distribution locations, and a channel for feedback and complaints

By providing this essential information, consumers and patients can make informed decisions that prioritise their health and safety. Similarly, medical patients should have easy access to their current prescription and their history, as well as any doctor's letters they may need for travel or to demonstrate their condition. All of this information would be included in the integrated platform via a secure interface.

3. Capacity Building

To establish a successful capacity building framework, we must define its key components. Capacity building will be crucial across the entire supply chain, from licensed operators to government regulatory teams.

As we develop local capacity, we can leverage data and research from other jurisdictions. This will enable us to identify areas of focus, avoid unnecessary hurdles, and prepare for challenges. The US experience in rolling out state markets offers valuable insights.

We've identified multiple areas for capacity building, affecting both government and licensed operators. Transparency is crucial, but it can be difficult to achieve without the right methodologies. A systems approach to automation, education, and ongoing training is essential.

To align with the two main priorities for government, we recommend:

1. **Ongoing capability testing:** Licensed operators should undergo yearly renewal testing to mitigate issues around unsafe handling and miscommunication about legislation changes.
2. **Automated systems and ongoing training:** Governments regulating the industry need automated systems for repetitive processes, as well as ongoing training and education on the global cannabis industry.

In Australia, as in most international jurisdictions, licensed operators must demonstrate they are "fit and proper persons." This assessment primarily focuses on the applicant's history of criminal convictions. However, this requirement may not adequately address the complexities of the cannabis industry.

We break down in more detail some of the key findings we are seeing in the US and how we can avoid them. Regardless of whether a licensing system is open market or restricted, a well-designed regulatory framework should acknowledge the need for a prolonged period of capacity building within the legal cannabis industry.

Approaches from other jurisdictions

Experience in the US has demonstrated that after 10 years of legalising recreational cannabis, there is much to be done to support industry and regulators.

Experience from the US has shown that many new entrants to the cannabis industry, particularly after recreational legalisation, lack prior experience in the industry and often in running a business. Alternatively, if they do have experience, it is often as illicit operators or homegrowers, requiring significant adjustments in operational management to comply with legal market regulations.

New York's recreational cannabis program rollout serves as a cautionary tale. Despite projections of over \$3 billion in revenue (NYC Comptroller 2018) in its first year, the program fell short due to several factors. In May 2024, the New York State Governor Kathy Hochul ordered the Office of General Services (OGS) to conduct an urgent 30-day review of the Office of Cannabis Management (OCM)(NY Governor 2024). The report's key findings were significant (NY OGS 2024):

Specifically, the task force found the OCM had:

- 1. Limited depth in administration;*
- 2. Failed to centralise licensing operations;*
- 3. Created complex and obscure licensing requirements;*
- 4. Provided sparse customer service;*
- 5. A lack of data and key performance indicators (KPI);*
- 6. And utilised multiple disparate IT systems.*

These findings resulted in an overhaul of the OCM and a change in leadership. The struggles of the OCM were in estimating the type and intensity of resourcing needed to regulate and not having visibility over progress against key requirements.

In particular, the OCM was struggling with processing the queue of licensing applications, and had become so overwhelmed, the queue had been abandoned without informing applicants. These actions led to deep distrust in the industry of regulators, and as change started to take shape, the OCM began the long process of rebuilding its reputation within the industry.

Licensing Approaches

Feedback from industry is that the licensing process for Australian cannabis operators is notoriously complex, time-consuming, and costly. The process often takes 18 months or more (despite a target timeframe of 9 months)(ODC 2024a), during which time potential licensees must hold a property and prepare extensive documentation. While having rigour in the process is important, the costs associated with this process, including the need for specialised consultants, can total millions of dollars.

The impact is that the current framework not only causes frustration and confusion but also restricts access for individuals and organisations lacking significant wealth or experience in raising capital. This limitation hinders the potential for economic impact of a legal cannabis industry.

In the US, most states that have legalised cannabis have implemented a social equity program. The intent of social equity programs are to provide social justice to disadvantaged groups, but especially Black and Brown communities that have been disproportionately affected by the prohibition of cannabis. Usually the program is effected through specialist licence types, grant funding or similar. Unfortunately, there have been no US states that have implemented their programs well, and have struggled to gain traction on key participation and leadership metrics (Ordoñez 2024).

However, a positive of the current Australian system is the relative simplicity of the licence structure with only three licence types (cultivator/ producer, manufacturer, importer), unlike other jurisdictions with overly complex and/ or somewhat restrictive licence structures related to factors such as canopy size, lighting type, method of production (e.g. indoor, outdoor) etc.

For example, California has 13 different types of licences for cultivation alone as shown in Figure 1 below.

License Type Volume	
MANUFACTURER - TYPE N	101
MANUFACTURER - TYPE P	26
MANUFACTURER - TYPE S	16
MEDIUM INDOOR	163
MEDIUM MIXED-LIGHT TIER 1	66
MEDIUM MIXED-LIGHT TIER 2	41
MEDIUM OUTDOOR	614
MICROBUSINESS	373
NURSERY	295
PROCESSOR	141
RETAILER - NON-STOREFRONT	356
RETAILER STOREFRONT	1,220
SMALL INDOOR	355
SMALL MIXED-LIGHT TIER 1	609
SMALL MIXED-LIGHT TIER 2	288
SMALL OUTDOOR	1,438
SPECIALTY COTTAGE INDOOR	33
SPECIALTY COTTAGE MIXED-LIGHT TIER 1	50
SPECIALTY COTTAGE MIXED-LIGHT TIER 2	15
SPECIALTY COTTAGE OUTDOOR	53
SPECIALTY INDOOR	307
SPECIALTY MIXED-LIGHT TIER 1	101
SPECIALTY MIXED-LIGHT TIER 2	35
SPECIALTY OUTDOOR	249
TESTING LABORATORY	28

Figure 1 - California licence type snapshot (<https://cannabis.ca.gov/resources/data-dashboard/license-report/>)

Some jurisdictions, like Pennsylvania and Florida, have opted for a limited licensing model, with high costs that favour large corporations. In contrast, states like New Mexico, Oklahoma, and Michigan have adopted an "open market" approach with no limit on licences and a low barrier to entry.

While the latter approach has enabled smaller operators to participate, it has also led to market saturation, causing many small businesses to fail (Forbes 2024). For example, in New Mexico there are over 22 dispensaries per 100,000 population (ABF 2022) (the state has a population just over 2 million people) and Oklahoma has 36 dispensaries per 100,000 population (Pew Research 2024).

Investing tax revenues

Some US states divert a proportion of tax revenues collected to fund government programs or to provide grants for industry enablement.

For example, Nevada has a tax excise program (Nevada Independent 2022) that reinvests tax revenue from cannabis to build new schools and support school programs. In 2022, US\$147 million was invested into school districts to support programs and new buildings.

California reinvests tax revenues from cannabis into grant programs to support research and industry capacity (CA DCC 2024e).

Education and Proficiency in the Cannabis Industry

A critical component of capacity building in the cannabis industry are education and proficiency. Currently, there is a lack of tailored education for new industry entrants, which can hinder their ability to succeed in the industry.

To address this, a recognition of prior learning (RPL) approach could be implemented, similar to that used in universities. This would allow individuals with prior experience in business and/ or cannabis operations to demonstrate their skills and knowledge, facilitating their transition to commercial operators. A similar approach is used in training chefs, where on-the-job training is combined with testing and qualification.

In addition to initial education and training, there is a need for continuing education and proficiency testing in the cannabis industry. This is particularly important given the sensitive nature of the work and the constantly evolving regulatory landscape. To address this, a requirement for licensees to demonstrate their proficiency in industry knowledge, laws and regulations should be integrated into the online platform that supports regulatory activity (including licensing and renewals, as well as verification activities). This would ensure that licensees remain up-to-date with the latest developments and requirements.

Licensing structures that support broad participation

A licensing structure needs to have the flexibility to scale with change as regulations and market conditions adapt. This is particularly true as an industry transitions from medicinal to recreational. Licensing should take into account key differentiators of an operation that impact yield and location (e.g. inner city vs rural; outdoor vs vertical indoor grow), and the commercial size of an operation, for example, it would be unreasonable to require the same regulatory approach for a small business as a multinational operator.

Licence types to support more equitable participation are small, vertically integrated “microbusiness” types that support access for people from disadvantaged backgrounds as part of a social equity program. These licenses are available in California, New York, Missouri, New Mexico amongst others.

A similar model could be used in NSW and Australia to support social justice outcomes for Aboriginal communities, as well as encourage participation from people previously convicted of minor cannabis offences and other targeted groups.

Investing in NSW Government programs

The hypothecation of revenue for targeted government programs can prove extremely effective, particularly when the program funds long-term impact. A famous example is that funds raised

from the Congestion Charge in London were dedicated to improving public transport (Arup 2023).

NSW could use any funds raised from cannabis taxes or levies to assist with the delivery of critical infrastructure (including civil and social) to support the implementation of the NSW Government's housing agenda.

While hypothecation has significant benefits at the commencement of a change program to ensure that the promised interventions and outcomes can be achieved. However, given the inherent inefficiency of hypothecation in the long term it should be grandfathered, with a review at 5 years from commencement to determine ongoing necessity of hypothecation in part or full.

Personal Cannabis Use and Regulation

A regulatory framework for cannabis can include home growing with reasonable limits, such as:

- A maximum number of mature plants per person; or
- A maximum number of mature plants per household (whichever is greater)

To allow for the various living arrangements in Australia, growing methods, including indoors or outdoors, should not be restricted. Additionally, unimpeded access to seed and tissue cultures through licensed suppliers with the chain of custody verified supports public health outcomes and legitimacy of its source. As with other medicines or products such as alcohol, cannabis products should be stored out of reach of children and minors.

Consideration should be given for how the recent banning of vaporisers affects medicinal cannabis users in NSW and Australia (TGA 2024) and allowing common consumption methods. Current TGA guidance (TGA 2017) states, “[cannabis flower] for medicinal purposes should be vaporised but not smoked”. Finally, existing laws in Australia regarding designated smoking areas should be extended to include cannabis use.

Next steps for NSW: Shaping a transparent and effective regulatory framework

In conclusion, this Parliamentary Inquiry presents a pivotal opportunity for NSW to reassess its regulatory framework for cannabis and explore alternative approaches from around the world. Our submission has leveraged our expertise in advising regulated industries, including cannabis, with a particular focus on the US market.

We firmly believe that NSW can establish a regulatory framework that prioritizes transparency, collaboration, and the well-being of all stakeholders. By harnessing an inclusive approach to technology and capacity building, NSW can ensure the dual priorities of public health and safety, and preventing illicit activity, are met.

While our submission has addressed key issues and opportunities related to governance, technology, transparency, and capacity building, there is still much to explore. We look forward to continuing to support the NSW Parliament in developing a comprehensive and effective regulatory framework for the cannabis industry in NSW.

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