DELTA TETRA CONSULTANCY
SPECIALISED PROFESSIONAL MEDICAL CANNABIS MANAGEMENT

Delta Tetra Group Pty Ltd
Ph: 0422064904
Email: Timoates@deltatetra.com.au
Web: www.deltatetra.com.au

Date: 28 / 03 / 2019

# Review of the Narcotic Drugs Act 1967

**Scope:**

Delta Tetra Consultancy and its core management team have been actively engaging with the Australian medical cannabis industry and its associated regulatory nuances since the conception of the sector.
Having played a key role as principle representative for a number of active cannabis companies and individuals, Delta Tetra has been privy to a wide range of exposures with regard to engaging with the current regulatory framework and associated regulatory bodies.

Delta Tetra finds itself in a position to offer unique pieces of feedback around the Narcotics Drugs Act and the Medical Cannabis framework that has been placed within it.
Moreover, we have direct and ongoing operational experience in terms of consistent engagement with the Regulatory bodies such as the ODC & TGA.
These sets of experiences allow Delta Tetra to offer an informed and refined viewpoint regarding the effectiveness and efficiency of the current sector and its associated regulations.

**Does the Narcotic Drugs Act 1967 establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes?**

- While the NDA 1967 has, in theory, created a federal framework for the safe production and supply of medical cannabis products, in reality this has yet to come to fruition.
- Slow and cumbersome regulatory requirements have enforced stagnation on an aspirational and vibrant sector.
- The current framework was developed with minimal involvement from industry experts, thus creating a regulatory system that has been forced to 'learn on the go'.
- The framework's chief and principle concern is 'Risk of Diversion' – this overzealous approach has created an inflated sense of risk.

**Does the Narcotic Drugs Act 1967 establish a suitable framework for ensuring the availability of cannabis products for research purposes?**

- The framework has encouraged clinical trials on internationally imported products.
- Hypocrisy between imported products and Australian manufactured product standards, allows for concerns in moving forward with research initiatives.
- The framework has resulted in a strong clinical trial culture within Australia, with clinical data a pre-requisite to product development.
- However, the unwillingness to accept international trial data to support product development has resulted in an inordinate amount of data recreation, seemingly arbitrarily.

**Does the Narcotic Drugs Act 1967 establish a suitable framework for preventing the diversion of controlled narcotics to illegal uses?**

- Seemingly, the NDA 1967 was drafted with the exclusive concern for Risk of Diversion in mind.
- From an operational stand point, the broad-stroke terminology utilised within the NDA 1967 creates an ultimately endless barrage of roadblocks through 14J processes.
- Allowing the regulations to be open to interpretation creates a 'one up' culture within the ODC and the nascent industry.
  Each company presents a new and potentially improved solution to a security concern, the ODC then accepts this solution as the 'new standard' and requests that all other applicants in the queue meet this newly imposed standard.
  One company improves on that solution and becomes the 'new new standard' and so on and so forth.
  This will invariably create a never-ending feedback loop for the industry as it attempts to play catch up with an ever-shifting regulatory goal post.
- From a security perspective the framework presents, clearly, the importance of securing your cannabis site against all and any risk factors.

**Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis? Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits? As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?**

- The ODC has left the burden of context and application to the nascent industry. This has allowed for the effective manipulation of the system through poorly compiled applications and poor revision processes.
  This has created a 'slip stream' for early applicants, applicants whom had they submitted the same application now would receive lengthily 14J requests. However, as the submitted while the ODC was still learning they have had licenses approved that may not meet requirements.
- The disparity between the ODC issued 'Guidelines' and the regulations as stipulated in the NDA 1967 must be resolved. The observation of what must be legally addressed in an application vs the observation of what is expected as per the ODC guidelines is significantly varied.
- Delineations between the License phase and the Permit phase have not been adequately observed. It was expected that the License phase would cover a range of details relating to the applicant and the associated business activities and the Permit phase would then provide operational, mechanical, engineering & build-out stages of the application process – clarity around this would benefit industry stakeholders and regulatory bodies.
  This has not been the case; Permit level information is routinely requested throughout Licensing phase – creating ambiguity with regard to what level of information is actually required.
- License processing should be contained to a single case manager, familiar with the applicant and the relevant details of the case.
  In reality, every interaction is with a different individual. Each 14J is handled by a separate and potentially new assessor, this is creating a double-handling culture within the ODC. Our clients are routinely having to re-supply information and documentation that has been previously submitted. This creates confusion in both camps.
- For those applying for a suite of licenses (Cultivation & Manufacturing) there is the double up of dealing with both the MCS & DCS.
  The two departments operate independently of one another, as such there are separate 14J systems relevant to the Cultivation

License (MCS) and the Manufacturing License (DCS).
The lack of transparency and contact between the two departments results in two 14J processes that have no relation or cohesion with one another – often these two departments will be months apart from one another in terms of the processing times.
This leads to significant changes in information being supplied to one arm without the other knowing

- Time frames.
  The time frames currently being supplied to industry are incorrect.

**Has an appropriate compliance and enforcement regime been implemented, both in the Narcotic Drugs Act 1967 and administratively? Are risks being appropriately managed? Is there excessive risk aversion?**

- Given the scheduling of THC and CBD, it could be sensibly argued that the Risk of Diversion considerations are justified. However, in reality, there is an excessive focus on risk aversion.
- It would be fair to consider that the broad-stroke nature of the regulations itself creates a risk.
  Early approved licenses were approved at a much lower standard due to the ODC's knowledge base and standards being effectively lower.
  We have seen a stark difference in the 14J's of 2018/2019 compared to 2016/2017.
  Licenses that were approved early in the process would gain far greater scrutiny than that of what they actually received prior to approval. This has, as mentioned previously, created a slip-stream for numerous first movers. As well as an industry with dual-standards.
- By utilising a non-cannabis industry specific regulatory body to approve and enforce all applications and regulations, time-frames are significantly blown out due to the ODC being up to date with cannabis specific nuances as well as a rigorously enforced focus on the security of product. The combination of these two things creates a system overly concerned with risk that it stagnates the whole process.
  There needs to be some faith placed in industry that assumes industry wants to be the most efficient, effective and secure version of itself.
- The ODC should be looking to play a more collaborative position with applicants. If applicants had a dedicated case manager, there would be nuanced understanding of the applicant at their aspirations from the regulators. Vice versa, the applicant would understand the regulators focus and be able to find a

solution that appeases the assessor. As things stand, both sides are consistently attempting to infer from one another. The 14J's are purposefully vague as to stimulate a transparent response from the applicant, which in turn encourages the applicant to over-share for fear of not addressing the concern of the assessor.
This then provides more information for the assessor to review and question, causing the issue to compound. In our experience, this can be put down to inefficient and inconsistent communications, as well as lack of transparency in the assessing process.

In summary, Delta Tetra Consultancy has had an hands-on set of experiences with the regulations and associated departments.
Our feedback is rooted in our experience and is of course objective and is offered with the view to help allow for an informed review process.

I would also like to note, we have great admiration for the work the ODC has and continues to do.
We understand the complexities and challenges of this industry better than many. I hope the recipient of this feedback is understanding of the spirit in which this feedback has been offered.

We would like to extend the offer to support the ODC throughout this review process should it be required.
If your office would benefit from further context around some of the points stipulated above, please don't hesitate to contact us to do so.

Warm Regards
Tim Oates
CEO
Delta Tetra Consultancy