TASMANIAN ALKALOIDS PTY. LTD.
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2 April 2019

Professor John McMillan AO
Review of the Narcotic Drugs Act 1967
Health Products Regulation Group
Australian Government Department of Health

Dear Professor McMillan AO

Consultation Submission: Review of the Narcotic Drugs Act 1967

Tasmanian Alkaloids (TasAlk) is one of the world's largest producers of alkaloid raw materials established in Tasmania for over 40 years. It employs over 180 Tasmanians consisting of scientists, engineers, technicians, marketers and administrators. The team can also include over 500 farmers throughout Tasmania. It's flexible and modern manufacturing facility is fully compliant with Good Manufacturing Practice (GMP) and can easily adapt to the production of new products including Medicinal Cannabis.

Following the amendment of the Narcotic Drug (ND) Act in February 2016 TasAlk made the decision to enter the medicinal cannabis industry and have had experience in applying for and receiving approvals for licences and permits under the Act. This has involved applications, site inspections, requests for additional information including numerous meetings in person and by telephone.

The amendment of the ND Act has allowed TasAlk to progress to a position of being able to offer medicinal cannabis products both within Australia and overseas as the demand increases. TasAlk have considered both the terms of reference (key themes and specific issues), their combined experience of working within the poppy industry for over 40 years and the emerging medicinal cannabis industry.

The review undertaken by TasAlk centred on recommendations to increase efficiencies and reduce the regulatory burden while still preserving the effectiveness of the Act. This has been presented as key recommendations, the critical area for Tasmanian Alkaloids however is the availability of large scale biomass from low Tetrahydrocannabinol (THC) crops grown on a broadacre basis.

Tasmanian Alkaloids has extensive experience in contracting growers to provide large scale biomass currently within the poppy industry. This model could be used effectively for the hemp industry, with access to the leaves and flowering heads (licensed manufacturers only) after the seed or other parts of the plant are utilised for the hemp food industry.

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Summary of Recommendations

In this submission, TasAlk have addressed both key themes and specific issues from the Review of the Narcotic Drugs Act 1967 Discussion Paper. To ensure ease of cross referencing the individual themes and issues will be reproduced in italics and use the same sub headings as the discussion paper.

Key Recommendations

1. Instigate a pre-screening system for the submission of application forms for licences and permits to increase the effectiveness of the application process.

2. Instigate a risk based assessment system to allow classification and acceptance of minor changes to licences and/or permits which are classified as not material in nature to reduce the regulatory burden to a level proportionate to the risk.

3. Implement a system with a single 'Medicinal Cannabis' licence with authority granted as required within the licence to remove duplication of processes and information submitted for individual licences.

4. Remove the requirement to record number of plants including the identification of individual plants by strain name and source and replace with the amount of active ingredient contained in the plant to allow transparency of reporting across all licence holders.

5. Allow the cultivation of certified cannabis seed varieties (with not more than 1% of THC contained in the plant) to be grown under an Industrial Hemp Licence but allow access to the leaves and flowering heads to entities holding a medicinal cannabis manufacturing licence.

6. Allow an avenue for licensed manufacturers to apply for approval to hold Schedule 9 materials where there is clear evidence of a link to medical research and potential commercial opportunity.

7. Apply a risk based approach to information required in support of an application or variation submission, if it is not critical to the approval of the application then a period of 10 business days should be allowed without incurring the 30 days reset before any further review.

8. Once an entity has shown adherence to monthly reporting for a trial period, allow an option to move to quarterly reporting.

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Key Themes

Key Theme 4

Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis?

a. Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits?

There is an appropriate level of regulatory burden placed on those applying for or holding licences and permits, the permit application process needs to be addressed to allow it to be proportionate.

The existing licence application and approval system would benefit from a pre-screening process. The pre-screen would ideally incorporate specific questions that could be completed on-line that would trigger an approval process to allow the applicant to progress to the next level. This system would allow the Office of Drug Control (ODC) to set minimum requirements before applicants could access the application process.

In regards to permit application and variations this should be more proportionate. The permit variation process needs to be based on a risk assessment model. As an example, if an entity is issued a Medicinal Cannabis permit there is a requirement to list specific strains by name, source, THC/CBD % & quantity of plants. If, during the time taken to issue a permit any of these criteria change then a variation is required which can take 6 to 9 months. Commercially, these time frames are not feasible when the changes are not material to the permit. A risk based approach would allow non-material changes to be approved as a permit attachment to allow commercial operations to proceed without any regulatory concerns. If the risk assessment classified the change as not materially affecting the decision to originally grant the licence and/or permit, then written notification of the variation would be deemed sufficient.

Recommendation 1

Instigate a pre-screening system for the submission of application forms for licences and permits to increase the effectiveness of the application process.

Recommendation 2

Instigate a risk based assessment system to allow classification and acceptance of minor changes to licences and/or permits which are classified as not material in nature to reduce the regulatory burden to a level proportionate to the risk.

b. As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?

Under the current system with three licences there is excessive duplication if an existing business on a single site needs to submit the same information three times.

The system should be changed to issue a single generic 'Medicinal Cannabis' licence with authority for research, production & manufacturing as required. This would allow the generic information to be submitted once and allow for additional information required for each specific authority.

The individual permits could still be retained, allowing the amounts of cannabis to be managed and transparency between research, production and manufacturing as they would be linked to a single licence.

The information required in permits and licences related to cannabis plant identification and quantity needs to be simplified to create efficiencies. The individual identification of plants is a good system for small areas with minimal number of plants but as the industry matures, an alternative system will be required.

The ND Act establishes a suitable framework to prevent diversion through licensing, inspections and the permit system. The use of individual plant identification within permits is cumbersome and does not add any further level of control. If an assay of THC or CBD is known, plant weights are recorded (wet & dry) and then extraction of active ingredient is known then this is sufficient for control. The information required should focus on the active ingredient in the plant based on recorded weights, assay and yield.

Recommendation 3

Implement a system with a single 'Medicinal Cannabis' licence with authority granted as required within the licence to remove duplication of processes and information submitted for individual licences.

Recommendation 4

Remove the requirement to record number of plants, including the identification of individual plants by strain name and replace with the amount of active ingredient contained in the plant to allow transparency of reporting across all licence holders.

Key Theme 5

Has an appropriate compliance and enforcement regime been implemented, both in the Narcotic Drugs Act 1967 and administratively?

a. Are risks being appropriately managed?

b. Is there excessive risk aversion?

Excessive risk aversion applies in that the fundamental issue with cannabis is that the diversion concern should be directed at the management and control of THC as the active ingredient and not CBD.

Cannabis (including seeds, extracts, resin and the plant) and THC (a psychoactive cannabinoid) are listed in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which is scheduled to the current Poisons Standard.

Schedule 8 informs State and Territory drugs and poison legislation that restricts the manufacture and availability of cannabis and THC to reduce abuse, misuse and physical or psychological dependence. CBD, a non-psychoactive cannabidoil, is listed in Schedule 4 of the SUSMP as a prescription only medicine.

The different Scheduling of both CBD and THC are inconsistent with the risk management under the ND Act. Medicinal cannabis or an Industrial Hemp crop containing predominantly CBD with low levels of THC currently has the same implied security & compliance requirements under the Act.

The Industrial Hemp Act 2015 (Tas.) defines Industrial Hemp as any plant of the genus Cannabis that has been grown from certified hemp seed; and has a concentration of THC in the leaves and flowering heads of not more than 1%.

Certified Cannabis seed varieties with not more than 1% of THC should be able to be grown as Industrial Hemp varieties on a broadacre basis with the same licensing requirements as Industrial Hemp is, but left for States to licence as per Industrial Hemp.

It is not the intention of TasAlk to vary the Scheduling of CBD or THC but to allow cultivation on a broad acre basis and allow harvesting of Industrial Hemp leaves and flowering heads. This allows cultivation of Industrial Hemp for food products to continue but would allow the leaves and flowering heads to be made available to licensed manufacturers under the ND Act. This still allows protection for leaves/flowering heads as farmers could continue to grow the crop for food related hemp products but also allow them to contract separately to licensed medicinal cannabis manufacturers for the remainder of the crop.

Recommendation 5

Allow the cultivation of certified cannabis seed varieties (with not more than 1% of THC contained in the plant) to be grown under an Industrial Hemp Licence but allow access to the leaves and flowering heads to entities holding a medicinal cannabis manufacturing licence.

Key Theme 6

Does the Act interact suitably with other Commonwealth, State and Territory laws relating to the regulation of cannabis products and narcotic drugs?

a. Are the intersection points clear?

b. Is there evidence of duplication?

In relation to Narcotic Drugs, TasAlk recommend that a mechanism be created to allow manufacturing licence holders, under the Narcotic Drugs Act 1967, to be able to research and manufacture drugs (or intermediates) that are specified on the Poisons Standard (SUSMP) as Schedule 9 substances.

Where TGA approved medical research in Australia or an overseas INCB signatory country e.g. NIH in the USA has the need for a Schedule 9 drug which can be manufactured in Australia by existing licence holder, the licence holder is currently unable to make a “bid” for the manufacturing element, due to manufacturing licence holders not being public institutions at a State level and thus not being able to hold the material is the first place.

This would potentially enable the assessment of new business opportunities, which Australian manufacturing licence holders are unable to participate in. The interaction would also need to be linked with the Therapeutic Goods Act 1989.

Recommendation 6

Allow an avenue for licensed manufacturers to apply for approval to hold Schedule 9 materials where there is clear evidence of a link to medical research and potential commercial opportunity.

Specific Issues

Issue 9

The Narcotic Drugs Act 1967 does not specify the period for which a licence or permit can be in force.

c. Nor is there a procedure for renewal of an existing licence or permit.

d. Should this be changed?

In general, the emphasis of any changes to licence or permit periods, or the need for a renewal procedure for permits and licences, should be on efficiency and reducing the regulatory burden (and cost) while preserving the effectiveness of the information used to approve the licence or permit.

Applying long term licences e.g. 5 years, with updates for business changes made that could materially impact the licence conditions (onus on licence holders updating the ODC), would minimise the regulatory burden. There should not be a need to submit an additional application to renew a licence unless there are substantial changes or personnel identified as either authorised or fit and proper person have changed.

Issue 12

An applicant can be required under s 14J of the Narcotic Drugs Act 1967 to provide additional information in support of an application. Is this information gathering mechanism being appropriately managed by the Office of Drug Control? Is the information that applicants are required to provide excessive?

The information collection under s14J is relevant to the application process and forms part of any regulatory scheme. The information gathering should be subject to a risk assessment process however as an application can be held up for 30 days once a request is made under s14J. If the request for additional information is not assessed to be critical to the approval of the application, then it should proceed if information is returned by the applicant within a set period.

Issue 13

A licence or permit may be varied either on the application of the licence holder or at the initiative of the Office of Drug Control. Has this power been appropriately managed?

In regards to licence or permit variations this should be more proportionate. The permit variation process needs to be based on a risk assessment model. As an example, if an entity is issued a Medicinal Cannabis permit there is a requirement to list specific strains by name, source, THC/CBD % & quantity of plants. If, during the time taken to issue a permit any of these criteria change then a variation is required which can take a further 6 to 9 months for approval.

Commercially, these time frames are not feasible when the changes are not material to the permit. A risk based approach would allow non-material changes to be approved as a permit attachment to allow commercial operations to proceed without any regulatory concerns. If the risk assessment classified the change as not materially affecting the decision to originally grant the licence and/or permit, then written notification of the variation would be deemed sufficient and could be granted within 10 business days.

Recommendation 7

Apply a risk based approach to information required in support of an application or variation submission, if it is not critical to the approval of the application then a period of 10 business days should be allowed without incurring the 30 days reset before any further review.

Issue 14

The Narcotic Drugs Act 1967 lists the standard conditions that apply to all licences, and other conditions that may be imposed on licences and permits.

e. Does the Act provide an appropriate list of relevant conditions?

f. Has the Office of Drug Control appropriately managed these provisions of the Act?

The conditions on reporting would benefit from a change to quarterly reporting as a month in a commercial business is often too short and creates overlapping information. An example of quarterly reporting used by other Government agencies could be followed, e.g. Business Activity Statement (BAS) reporting.

Recommendation 8

Once an entity has shown adherence to monthly reporting for a trial period, allow an option to move to quarterly reporting.

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Conclusion

Tasmanian Alkaloids appreciate the opportunity to take part in this review and have provided key recommendations that we believe would increase the efficiency of the Act whilst still maintaining public health and safety.

As part of this submission TasAlk management welcome further discussion on any points raised and extend an invitation for representatives to visit the site. This would give TasAlk the opportunity to present an overview of the submission, the poppy crop from broad acre to customer supply chain and the medicinal cannabis systems already in place.

Kind Regards

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