Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia (MCIA)

Submission to the TGA: Potential reforms to medicinal cannabis manufacturing, labelling and packaging requirements

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1.0 About Medicinal Cannabis Industry Australia (MCIA)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to the TGA regarding the Interim Decision on Amendments to the Poisons Standard (Medicines/Chemicals).

MCIA is the peak industry organisation for Australia's medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation, importation, manufacturing and interaction with patients, the medical profession, and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

Medicinal cannabis has an important role to play in improving health outcomes. MCIA supports a holistic healthcare approach built around patients and their regular medical practitioner determining if medicinal cannabis is an appropriate medicine for their current medical condition. MCIA believes that patients should have easy and affordable access to a quality controlled, true to label, compliant product that is demonstrating the potential to positively contribute to a broad range of conditions.

2.0 Introduction

MCIA welcomes this consultation by TGA in relation to potential reforms to unlicensed medicinal cannabis manufacturing, labelling, and packaging requirements.

While MCIA recognises the role that imported medicinal cannabis products play in enabling timely patient access, particularly at this early stage of the Australian industry's development, MCIA also strongly supports a regulatory framework that provides patients with assurance in relation to the safety and quality of medicinal cannabis products, and delivers a level playing field for Australian products.

MCIA appreciates that a reliable supply of a wide range of well-priced TGA-compliant imported forms of medicinal cannabis products will remain an important component of our industry in the formative years of the industry, especially while locally manufactured product availability is being established. However, for Australian patients to have access to a reliable supply of Australian produced and quality products in the medium to long term, it is essential that there is a level playing field and that there is an efficient regulatory pathway for Australian manufacturers. This requires both strengthening requirements for imported medicinal cannabis products and improving and streamlining the existing legislation and operations of the Office of Drug Control ODC). To enable a domestic supply, there is an urgent need to ensure that licence holders have an efficient and timely pathway through the ODC, which is not hindered by unnecessary regulatory process or restrictions, to enable licence holders to obtain the relevant permits and other regulatory approvals required to support operations and facilitate the supply of Australian product to the market.

MCIA believes a strength of the Australian approach is 'Australian quality' product underpinned by GMP standards and relevant Therapeutic Goods Orders (TGO). The values of Australian quality, namely plant derived, regulated and true to label, will deliver confidence to patients and the healthcare sector.

Thus, we welcome this consultation around strengthening requirements for imported medicinal cannabis products, and other related issues, and the implementation of potential changes. The aim is to enable a sustainable level playing field for both locally manufactured and imported medicinal cannabis products and provide patients with confidence that they have access to appropriate (Australian equivalent) quality product. This will also support the Australian industry global opportunity as a supplier of quality medicinal cannabis products.

3.0 Responses to consultation questions

Part 1: Requiring equivalent GMP for imported and domestic medicinal cannabis

Q1. ***Would you support changes to the current requirements for imported medicinal cannabis products to ensure there is parity with the domestic requirements for GMP?***

MCIA supports parity across imported and domestic products, however, recognises that this requires definition and that it is important that changes to achieve this are implemented in a manner that does not

- adversely impact patient access
- impose additional burden on our young local industry
- disadvantage Australian manufacturers vis a vis imported products
- lead to misalignment with international regulatory requirements
- impact outcomes for patients through commoditisation of API products

Thus, to achieve this, the changes to requirements and compliance approaches need to be undertaken in a manner that is relevant to unlicensed products and does not cause undue delays or access to quality products and include sufficient transition timelines and milestones.

When considering parity between imported and domestic products, quality and safety equivalence should be taken into consideration as priority, but also competitive equivalence. While prioritising patient access to unlicensed products provided via SAS/AP schemes, it is also important that regulation does not impede development of a local value-adding and manufacturing sector due to imported products having lower hurdles than those that domestic manufacturers are required to meet.

Recognising that TGO93 provides appropriate regulatory controls to enable unlicensed medicinal cannabis products, and the ingredients used in the manufacture of those products, to meet minimum quality requirements, there is opportunity to improve the equivalence of application across domestic and overseas manufacturers. This is not to imply that there are not importers operating appropriately with imported products meeting quality and safety requirements. Rather, it is about ensuring that this occurs across all imports within an appropriate competitive framework.

Further, MCIA notes that the consultation document utilises terminology such as ‘acceptable’ and ‘appropriate’ in the options proposed. MCIA believes that this terminology should be defined to provide clarity to all parties.

Q2. ***Do you see any potential issues if GMP compliance for imported medicinal cannabis is assessed by reviewing evidence submitted to the TGA?***

The requirement for pre-evaluation of GMP compliance by the supplier before permitting medicinal cannabis products to be imported could result in time delays and thus, to avoid any adverse impact on patients, the transition timeline would need to allow for this potential. There may also be implications for specific companies depending on their inventories and supply chains.

Amending TGO 93, in the first instance, to increase oversight and controls in respect of imported products will be beneficial in that it would bring a consistent approach to the quality attributes of all medicinal cannabis products, and ingredients used in the manufacture of medicinal cannabis products. In the longer term, this should be transitioned to require imported products to meet GMP equivalence, to provide a level playing field for domestic and imported products.

However, it is recognised that an appropriate transition timeline with agreed milestones would be required for both these steps (refer Q3).

Q3. ***Do you favour any of the potential amendment options or are there any other ways to assure appropriate GMP for imported medicinal cannabis?***

MCIA supports an approach that would see the TGO 93 amended, in the first instance, to strengthen certain provisions in terms of both the Australian sponsor responsibilities and TGA's ability to enforce compliance with this, and with a longer transition amending TGO 93 to require GMP equivalence.

Thus, MCIA supports an option that incorporates aspects of Option 1 as a first step and moving to Option 3 over a longer transition. This phased approach will ensure that patients are not disadvantaged by undue disruption to supply, while prioritising the requirement for imported products to meet Australian safety and quality standards. In the longer term, MCIA supports strengthening GMP or GMP equivalence requirements in TGO93 as the preferred approach together with significant timelines allowed for transition.

MCIA recognises that there are challenges for both the industry and the regulator in implementing these changes and we would be happy to work with TGA to develop an appropriate approach and transition.

If the status quo option is maintained, MCIA believes that the requirements in relation to stability data and the methodologies supporting the data and testing need to be strengthened and clarified in guidance documents and forms. Likewise, requirements in respect of the conformity of starting materials (particularly cannabis plant dried flower) used in the manufacture of final products follows the minimum testing requirements found in Schedule 1 of TGO 93 must be evidenced by a certificate of analysis. In both examples, and in respect of all criteria set out under TGO 93, we propose that the local distributor (Sponsor, and on occasion also the importer) should be responsible for making necessary enquiries and obtain the necessary documentation to assure themselves that the imported product satisfies all requirements of TGO 93 and to make this information available on request by the TGA.

MCIA believes that the data underpinning the Declarations of Conformity with TGO93 are critical and that there should be greater responsibility on the Australian sponsor/importers to ensure the validity of the claims (of potency, purity, and stability) through obtaining of necessary supporting documentation (such as Certificates of Analysis), and that TGA should have a mechanism to be able to confirm this on request and actively undertake this task. MCIA strongly supports that the Australian sponsor should take technical responsibility for products imported. While noting that a number of importers are operating appropriately with imported products meeting quality and safety requirements, TGA should take action where any product is found to be non-compliant with safety or quality requirements.

This could be achieved through sponsor/importer being required to hold/have access to stability data rather than rely on a declaration alone, or the current documentation could be modified to provide for a second signature that obligates the Australian sponsor/importer to have sighted data and methodology. The advantage of this latter approach is that it would enable TGA to have a line of sight to the manufacturer and thus, the ability to request data and methodology.

As noted above, the transition timeline will be important to ensure that patient access is maintained. MCIA supports a transition period of up to 3 years, but would be happy to discuss/work with TGA to develop appropriate timelines and milestones for the transition period. MCIA also supports TGA updating its guidance materials to clarify requirements of TGO93 and the transition timeline.

Part 2: Removing exemptions for compounding medicinal cannabis products

Q4. ***Would you support excluding medicinal cannabis products from the extemporaneous compounding exemption in item 6 of Schedule 5 to the Therapeutic Goods Regulations, noting the difficulties with verifying compliance with the quality standard (TGO 93)?***

Q5. ***Alternatively, would you support the continuation of extemporaneous compounding undertaken by pharmacists and medical practitioners, provided those persons held GMP licences, consistent with the lawful supply arrangements under the Narcotic Drugs Act?***

MCIA recognises the role for single use compounding, however, is concerned about reports of batch or bulk manufacturing activities by some compounding pharmacies. MCIA is concerned that compounding pharmacists may be producing large batches of medicinal cannabis products and selling them at a later date, which has the potential for adverse impacts for patients if there are issues with stability or other aspects of medicinal cannabis products. The main concern for MCIA is public safety.

As such MCIA supports Option 1, but also strongly supports increased compliance monitoring and enforcement of activities by compounding pharmacies to ensure that they are operating within the Guidelines. Supply of compounding products should require SAS approval for single production for each individual patient.

Batch production and branding of compounding medicines should not be allowed, and there needs to be stronger monitoring, education and enforcement of this.

Part 3: Representation of active ingredients, amendments to labelling requirements and reporting of heavy metal results

Clarifying that the label for medicinal cannabis products must also specify the plant species

Q6. ***Would the requirement to specify the plant species and the plant part from which the product is manufactured provide greater clarity to the sector? Please suggest how this could be achieved and potential impact of any changes?***

MCIA does not support this proposal as we do not believe that it will provide any greater clarity to either healthcare professionals or patients given the lack of consistency in products.

Given the diversity in products and cannabinoids, there is no basis for mandating use of the plant species or plant part. However, it is appropriate to allow individual companies the option to use these terms in association with their specific products and composition.

MCIA recognises that the approach to labelling medicinal cannabis products is still being debated globally. There may be value in monitoring this and harmonising with key markets in the future.

Labelling requirements for unapproved medicinal cannabis products

Q7. ***Would the proposed labelling requirements for medicinal cannabis products help to provide clarity?***

Q8. ***What would be the impact of these proposed changes on you?***

Q9. ***What would be an appropriate transition period for implementation of these changes to labelling requirements?***

MCIA supports standardisation of labelling requirements in relation to active ingredient and stated content and believes that this would improve clarity and have benefits for pharmacies and patients, following the same principles as TGO 91 and 92. The key driver for labelling requirement should be the relevant information required for a healthcare professional in the prescribing of medicinal cannabis. This includes:

- Active ingredient - cannabinoid content and concentration should be the prominent information displayed on the product label, and there would be benefit in the active ingredient quantity being expressed in a standard form e.g. per millilitre of liquid, or per dosage unit, rather than the total amount in the container
- Stated content - consistency between labelled content and stated content would also provide clarity to the sector

However, we see challenges with the proposed method i.e., basis of stated content and dried plant material in the consultation paper due to the difficulties in determining and measuring active ingredient under the proposed model. Dry weight equivalence is not useful and requires a lot of specifics around %moisture etc. The addition of a dry weight equivalence would introduce confusion to both prescribers and patients and the inclusion of such additional information is questionable in respect of assisting a medical practitioner and/or patient understand the therapeutic attributes of the product.

Mass of actives per dose and/or unit volume is a much simpler way to express this information.

MCIA suggests that as part of standardisation that THC & CBD levels should be listed, but minor cannabinoids, terpenes and other components may be listed so long as they are accompanied by datum expressed in the same manner as THC/CBD.

Once an agreed approach is established, there should be a transition to this as there will flow on cost impacts and time delays associated with switching to the new labelling approach. MCIA supports up to 3 years as an appropriate transition, including a consultation period.

Minor amendment to the reporting of heavy metal results under specified tests

Q10. ***What would be the impact of this proposed change on you?***

Q11. ***What would be an appropriate transition period for implementation of this change to heavy metal results reporting?***

MCIA does not support this change as it would lead to inconsistency between Australian and globally practices, where 'ppm' is commonly used as it reflects the EP test methods and scientific units used to report these tests. Further, this is likely to cause issue with imported products where the overseas testing laboratories will continue to apply 'ppm'.

In the event there was a change, MCIA supports up to 3 years as an appropriate transition, including a consultation period.

Additional guidance for TGO 93

Q12. ***Are there any further areas that would benefit from additional clarity being provided?***

MCIA believes there would be benefit to the sector from greater clarity around TGA testing methodologies and laboratories. As such, test methods for key criteria such as active ingredient content should be specified in TGO 93. This will assist to prevent discrepancies between TGA internal laboratory audit testing and testing by industry parties. It should also be clarified if TGO 93 specified tests are to be performed on the input plant material, on all input materials including minor excipients, or on finished products, with appropriate limits for specified tests.

Part 4: Requiring child-resistant closures for medicinal cannabis products

Q13. ***Are the safety-concerns sufficient to require mandating of child resistant closures on all medicinal cannabis products, including when supplied through unapproved pathways?***

MCIA is supportive of the proposal for child resistant closures, subject to the requirements/standards being equivalent to other medicines/pharmaceutical products. This requirement is consistent with international standards and other medicines in Australia.

MCIA also strongly supports that this requirement also apply to products of extemporaneous compounding undertaken by pharmacists and medical practitioners.

Q14. ***Of the options proposed, which do you favour and why?***

MCIA supports Option 1 i.e., inclusion of the requirement for child-resistant closures in TGO93. However, when amending TGO93 consideration should be given to ensuring uniformity of requirements with other medicines and implementation at all levels across Australia.

Q15. ***What would be the impact of requiring child resistant closures on all medicinal cannabis products (both domestically manufactured and imported) on you?***

Q16. ***What would be an appropriate transition period for implementation of such a change to your business?***

A transition of up to 3 years is suggested.