Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia (MCIA)

Submission to the House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into the Approval Processes for New Drugs and Novel Medical Technologies in Australia

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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 House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into the Approval Processes for New Drugs and Novel Medical Technologies in Australia.

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and 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

The House of Representatives Standing Committee on Health, Aged Care and Sport is undertaking an inquiry into the approval processes for new drugs and novel medical technologies in Australia, with a particular focus on those for the treatment of rare diseases and conditions where there is high and unmet clinical need.

The aim of this inquiry is to ensure that Australia continues to be well positioned to access new drugs and novel medical technologies in a timely manner and respond to emerging global trends.

The Government enabled the legalisation of medicinal cannabis in late 2016 and established a regulatory framework through the Therapeutic Goods Administration (TGA) and Office of Drug Control (ODC) so Australian patients could access this new medicine which has an important role to play in improving health outcomes. The medicinal cannabis industry in Australia is still at a formative stage and it is important that patients can have trust and confidence in the sector and its products.

3.0 MCIA comment on key terms of reference

The inquiry's terms of reference and MCIA's comments in relation to medicinal cannabis are discussed below.

Range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies.

Medicinal cannabis as a whole is a relatively new drug and therapy that is currently going through a rapid period of innovation globally. Australia has one of the more stringent regulatory frameworks globally and thus, innovation has lagged some other parts of the world.

Outside Australia there are advancements in using medicinal cannabis in vaporisers, suppositories, targeted release capsules, gels for topical uses, trans dermal patches and slow release technologies that could be beneficial therapies in Australia. MCIA believes that the industry would benefit from the ability to explore these innovative technologies and this should be encouraged domestically if Australia is to be well positioned to access these new drugs at a reasonable price and in a timely manner.

Whole plant medicinal cannabis is an evolving science as cannabis is more complex than single isolated compounds. The MCIA recognises that a legislative framework which permits the cultivation, manufacture and supply of medicinal cannabis is a relatively new development in Australia. As a result, there has been limited opportunity for research and development in respect of cannabinoid science.

The amendments to the *Narcotic Drugs Act 1967* have enabled the medicinal cannabis industry, but there remain a number of regulatory restrictions which impede research and development activities. Specifically, the listing of 'CANNABIS' as a schedule 9 substance under the SUSMP's, unless certain conditions are met resulting in a reduction to either schedule 8 or 4 listing (as the case may be) noting that these conditions do not generally apply for research activities is particularly challenging. This has impeded research and development activities where research organisations handle CBD/cannabis prior to it being in a form that enables products to fall under the schedule 8 or schedule 4 exemption. As a result, this has limited access to the compound by a number of researchers who would otherwise have been able to participate in the critical scientific review of this substance, and has limited ability of licensed companies to undertake the R&D required to characterise the raw material in order to develop a product/formulation for therapeutic use. While MCIA recognises and supports the need to manage/control cannabis being used for research purposes, the schedule 9 categorisation provides considerable difficulties for research organisations, who routinely handle sensitive materials, in terms of storage and movement of the material. MCIA believes that some flexibility around the scheduling for research purposes would accelerate critical investigation into medicinal cannabis.

Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions.

Medicinal cannabis is a relatively new drug that is still challenged in terms of research and development activity in Australia due to strict licence requirements, and the complexity and interaction of many active ingredients present in the botanical form of the product.

Medicinal cannabis in Australia is currently only available through the Special Access Scheme (SAS) or Authorised Prescriber Scheme , via clinical trial of through a compound pharmacist (each posing their own regulatory burdens). As at 31 December 2019, TGA had accepted over 130 conditions (as described by the applicant) for medicinal cannabis use. Despite this, there remain many barriers to access for patients (recently captured in the Senate Inquiry on Barriers to Patient Access for Medicinal Cannabis March 2020) and a substantial unmet demand for a range of conditions.

In the UK, Europe and the US, there is a more open approach to using medicinal cannabis as a treatment for orphan conditions, while in Australia there is little incentive. At present, the US FDA has approved medicinal cannabis for Drug Designation for the following conditions:

- Epidermolysis bullosa
- Complex Regional Pain Syndrome
- HIV-associated wasting syndrome
- Hepatocellular Carcinoma
- Huntington's disease

Other orphan diseases where medicinal cannabis has shown varying degrees of success where other medicines have not are:

- Tourette's syndrome
- Dravet syndrome
- Stiff person syndrome
- Achalasia
- Idiopathic intracranial hypertension

MCIA encourages increased Government funding and support into medicinal cannabis research.

Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies.

As indicated above, the regulatory framework is limiting the opportunity and incentive for research into medicinal cannabis and ability to undertake clinical trials. MCIA encourages the removal of unnecessary red tape and restrictive scheduling for research using medicinal cannabis, particularly cannabidiol (CBD) which has no psychoactive properties, as this will make Australia more attractive for clinical trials and other research.

Allowing easier access to medicinal cannabis and subsidising costs for research institutions is another measure that should be taken.

Again, as indicated above, allowing novel delivery methods outside the traditional oil, tablets and injections, such as vaporisers, trans dermal patches and slow release methods would have benefit for the local industry.

Removal of these barriers would incentivise companies to advance the research of medicinal cannabis in Australia, and leverage Australia's strong R&D capability.

Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

There may be opportunity to advance access to medicinal cannabis through enabling drugs that have been given approval overseas in jurisdictions equivalent to Australia to be fast-tracked for approval in Australia. For example, this could include:

- requiring smaller trial cohorts and shorter trial periods
- utilising comparative data from other trials rather than placebo (due to ethical considerations especially when dealing with children and infants with potentially fatal conditions)
- inclusion of large-scale observational studies as supporting evidence
- allowing the use of the TGA's SAS data as an observational instrument