Professor John McMillan AO
C/O Narcotic Drugs Act Review Secretariat
Health Products Regulation Group
Australian Government Department of Health
PO Box 100 Woden ACT 2606

1 April 2019

Dear Professor McMillan,

I am writing in response to your request for comments from interested parties on the terms of reference for the Review of the *Narcotic Drugs Act 1967* (the Act).

OVERVIEW OF TILRAY:

Tilray is a global leader in medical cannabis research, cultivation, processing and distribution. We aspire to lead, legitimise and define the future of our industry by building the world's most trusted cannabis company. A proud pioneer, we are the first GMP-certified medical cannabis producer to supply cannabis flower and extract products to tens of thousands of patients, physicians, pharmacies, hospitals, governments and researchers on five continents.

Tilray's experience is unmatched worldwide. Our team of professionals on the ground in 7 countries serves thousands of patients around the globe. Our flagship cultivation facility is among the most advanced in the world. As laws regarding medical cannabis evolve in different jurisdictions, we are actively seeking to expand our operations.

Tilray is the first GMP-certified medical cannabis producer to supply cannabis flower and extracts. All our products are produced with meticulous care to ensure the highest quality, consistency and purity for our patients.

We are committed to scientific research that leads to an improved quality of life for patients in a time frame that matters. We partner with leading hospitals and universities to advance the clinical applications of cannabinoids.

Tilray takes tremendous pride in our customer service, patient outreach, and physician interaction. We recognise the importance of tracking potential adverse events as well as therapeutic benefits to ensure the safety of our patients.

TILRAY AUSTRALIA & NEW ZEALAND:

Tilray was the first company to legally export medical cannabis from North America to Australia and New Zealand. Today, Tilray is one of the leading providers of medical cannabis in Australia and New Zealand for commercial, compassionate access and research purposes.

BEST PRACTICE REGULATION:

The Australian Council of Australian Governments (COAG) has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. establishing a case for action before addressing a problem;
2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
3. adopting the option that generates the greatest net benefit for the community;
4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:

    a) the benefits of the restrictions to the community as a whole outweigh the costs, and

    b) the objectives of the regulation can only be achieved by restricting competition;
5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
6. ensuring that regulation remains relevant and effective over time; and

7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and government action should be effective and proportional to the issue being addressed.[1]

The Act was passed in 1967. Endnote 3 of the Act indicates that the Act has been extensively amended since 1967. Notwithstanding, the Act does not articulate any clear policy objectives and fails to meet the best practice regulatory principles adopted by COAG.

Manufacturers, suppliers, and medical professionals (including doctors and pharmacists) currently must meet multiple sets of Australian, State and Territory standards, depending on the products or services that they deliver. This creates barriers to market entry and an unnecessary regulatory burden. It also produces excessive complexity and does not meet the needs of patients who are entitled to a quality framework that they can understand and use.

INTERACTION OF THE ACT WITH OTHER COMMONWEALTH, STATE AND TERRITORY LEGISLATION:

Page 6 of the Discussion Paper indicates that one of the major issues raised in public forums includes whether the Act interacts suitably with other Commonwealth, State and Territory legislation relating to the regulation of cannabis products and narcotic drugs. It is submitted that there is poor interaction between the Act and other Commonwealth laws and State and Territory laws, including the *Therapeutic Goods Act 1989* (Authorised Prescriber and Special Access Schemes).

In 2018 an online system was introduced to enable the lodgement of SAS applications and notifications. The TGA worked in collaboration with the State and Territory Health Departments to streamline the application processes pertaining to the prescription of and subsequent access to unapproved medicinal cannabis products in Australia.

The SAS online system includes functionality that now allows prescribers in certain (not all) States and Territories to submit an application to both the Commonwealth and the relevant State/Territory Health Department simultaneously. Prior to the introduction of this system, prescribers of unapproved medicinal cannabis products were required to complete and separately submit paper forms to the TGA and relevant State Health Department.

The TGA and relevant State and Territory Health Departments should be commended for this approach. Notwithstanding, it is submitted that dual application processes constitute an unnecessary level of red-tape which significantly impedes the independence of medical practitioners to exercise a clinical decision to prescribe medicinal cannabis under appropriate circumstances.

This red-tape is contrary to the principle that doctors are the gateway to the Australian health care system which should focus on the health of the whole person combining physical, psychological and social aspects of care.

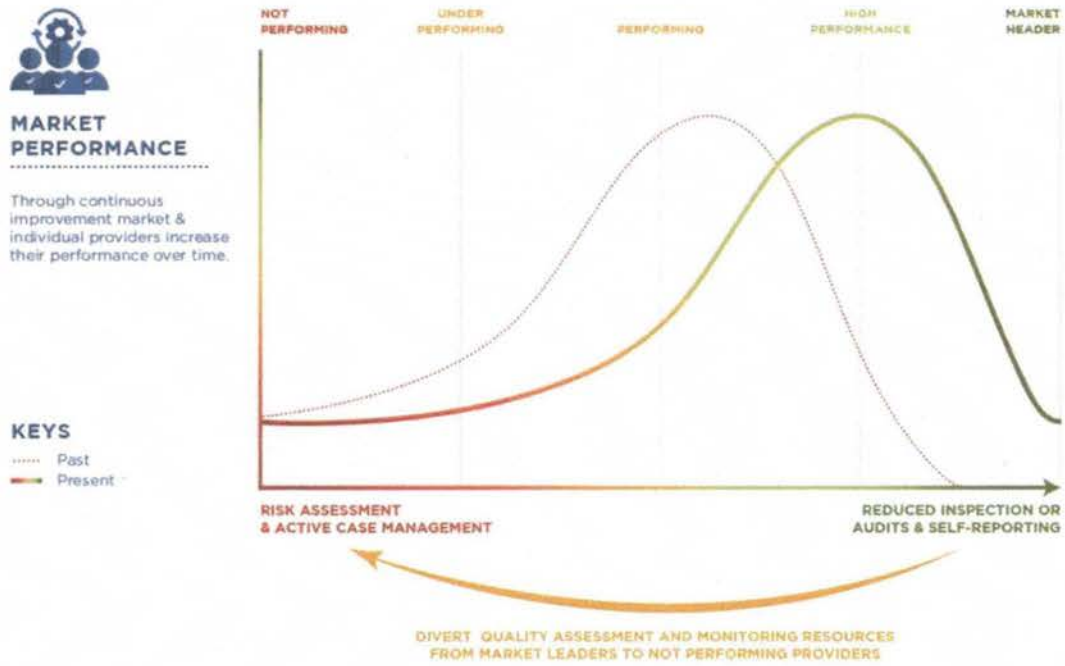
REGULATORY ROAD MAP:

In general, regulatory interventions are considered along a continuum from prescriptive command and control based regulation at the one end, towards self-regulation at the other. Traditional command-and-control based regulation does not acknowledge or reward high performance. Consequently, operators with high performance are often treated the same way as operators who are not performing.

It is recommended that the Australian Government, in consultation with the States and Territories (through COAG), develop a roadmap outlining an incremental approach to regulatory reform which is reflected in the regulatory approach/continuum below. The speed of this regulatory reform will depend upon the maturity and sophistication of the medical cannabis market and the extent to which it meets relevant standards.

REGULATORY APPROACH/CONTINUUM

Consideration should therefore be given to risk-based approaches that are less onerous for low risk operators, while focusing education, and compliance activity on high risk operators. Under this approach, organisations that show a consistent record of compliance and continuous improvement need less assurance by government. As outlined below, a risk based approach would enable these services to have less oversight and quality assessment, freeing up government resources to focus on the underperforming market segments who are struggling to meet expected standards of care and services.



CBD PRODUCTS:

CBD is a substance found in cannabis that has potential therapeutic value, with little or no psychoactive properties.

It is noted that CBD is no longer a class B1 controlled drug under the New Zealand *Misuse of Drugs Act 1975*. It is a prescription medicine under the New Zealand *Medicines Act 1981*.

Approval by the New Zealand Ministry of Health is not required to prescribe, supply or administer products for medical purposes if they meet the definition of a CBD product.

It is anticipated that the World Health Organisation will recommend that CBD be removed from the *Single Convention on Narcotic Drugs 1961*.

It is recommended that Australia follow New Zealand's lead and enable medical practitioners to prescribe products for medical purposes (without TGA or State or Territory approval) if they meet the definition of a CBD product.

Thank you for the opportunity to respond to the Discussion Paper.

Yours sincerely,

[redacted]

Ryan Fletcher
Government Relations Director

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[1] *Best Practice Regulation: A guide for ministerial councils and national standard setting bodies* (October 2007) @ 4.