AusCann

Committee Secretary
Senate Community Affairs References Committee
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600
AUSTRALIA

Via Online Submission Portal

Submission to the Senate enquiry - Current barriers to patient access to medicinal cannabis in Australia (the "Enquiry")

AusCann Group Holdings Ltd is an Australian publicly listed pharmaceutical company focussed on cannabinoid based medicines.

Context

AusCann is supportive of the Australian regulatory approach to manage medicinal cannabis as a therapeutic good. The company recognises the need to ensure that Australian patients receive access to high quality products, and the framework controlling medicines is both appropriate and well established. This approach also leverages a broader existing framework controlling, among other things, therapeutic claims, packaging and labelling, complaints, product recalls, and pharmacovigilance, which provide protection to the public.

It is in this context that AusCann makes the following submission to the Enquiry.

AusCann's submission is provided against specific Terms of Reference.

Submission under Terms of Reference

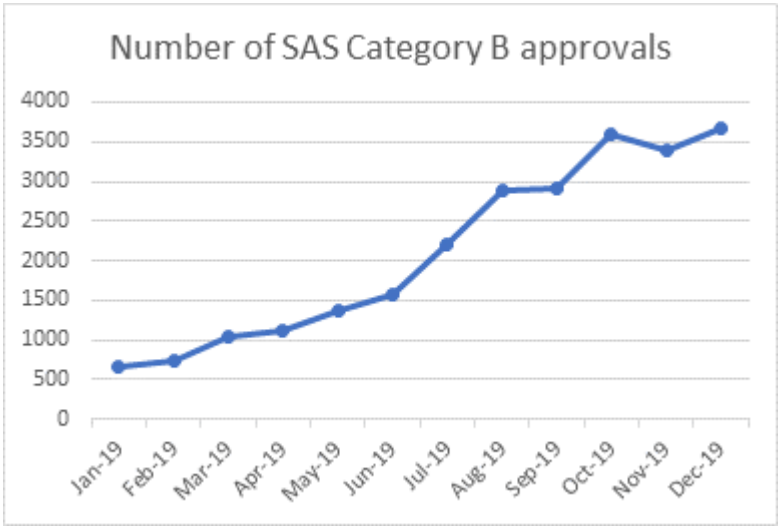
(a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber (AP) Scheme and clinical trials

We believe that the general framework provided under the Authorised Prescriber, Special Access Schemes and clinical trials was an excellent initial response strategy for enabling Australian patient access while maintaining a focus on public safety given the cannabinoid medicines are unregistered medicines. Substantial in-roads have been made in further enabling patient access under this framework, through:

a. Removal of many of the State/Territory based cannabis-specific approval processes, which were largely duplicative of TGA approvals, caused delays and lacked harmonisation – although improvement is still required in this area, and jurisdictions should be held accountable to meeting their commitments under the COAG meeting of Health Ministers (13 April 2018);
b. The online TGA application process for approval to prescribe;

c. The commitment by the TGA to fast turnaround of compliant applications.

We highlight however that the access provisions for unregistered medicines (Authorised Prescriber, Special Access Schemes) were established primarily for new chemical entities under the proprietary development of a pharmaceutical company. These schemes did not envisage the numbers of applications currently associated with medicinal cannabis, and we do not believe that the approach is sustainable. The number of SAS Cat B approvals associated with medicinal cannabis over the last 12 months[1], has increased significantly as represented on the graph below, from numbers published by the TGA.



Historically these pathways have been utilised by doctors within research and teaching hospitals, accessing experimental drugs. Doctor resource investment (including access to necessary bodies to endorse AP applications) and treatment responsiveness under these schemes is a different proposition when applied to medicinal cannabis.

Authorised Prescriber

Under the AP scheme authorisation is sought by a doctor on a 'by patient cohort, by product' basis. The doctor seeks authorisation having provided a clinical justification for a patient cohort which they have defined in their application, and for a specified product.

Prior to submission of an application to the TGA, endorsement must be received by either a Specialist College or a Human Research Ethics Committee (HREC). This adds to the overall timeline, where responsiveness of either of those bodies lies outside the control of the doctor and the TGA. Furthermore, a doctor who is unaffiliated with a hospital, or whose patients are outside of the hospital system, can only access a commercial HREC which is at a cost to the doctor. The associated timeline and/or cost to secure endorsement is a disincentive to doctors. Where doctors pursue this path, their ability to respond to patient needs is hampered by third party responsiveness.

A new application, and associated endorsement, is required if the doctor seeks to alter the cohort or the product.

[1] TGA, *Access to medicinal cannabis products* [online], 13 January 2020 [accessed 14 January 2020], https://www.tga.gov.au/access-medicinal-cannabis-products-1

The relevant parameters of a patient cohort initially identified by the doctor when applying for AP status may change over time, as the doctor assesses treatment effectiveness against patient commonalities. The doctor will need to submit a new application if they wish to extend the treatment to patients currently outside the cohort, who they believe have the characteristics that they have noted as being aligned with a beneficial response. The necessity of seeking endorsement, the associated cost (where a commercial HREC is involved) and timeline are disincentives to responsiveness in this area.

A new application is also required if the prescriber wishes to use a new product for one or more of the patients within the cohort. The products may be by the same manufacturer, for the same route of administration and have the same active (or ratio of actives), but the doctor may need to access a product with a different strength in order to practically enable a change in dose (lower or higher) for an individual patient. This personalisation of treatment requires the granting of a second AP authorisation, or for a SAS application to be submitted for each relevant patient.

The AP scheme enables a single authorisation for a cohort of patients, but it is offset by the involvement of a third party (adding time and cost) and the constraints around the patient and product which decrease flexibility/personalised treatment approaches.

SAS Category B

Under the SAS scheme authorisation is sought by a doctor on a 'by patient, by product' basis. The doctor seeks authorisation having provided a clinical justification for a patient and for a specified product.

As above a new application is required if the prescriber wishes to use a new product for the patient. The products may be by the same manufacturer, for the same route of administration and have the same active (or ratio of actives), but the doctor may need to access a product with a different strength in order to practically enable a change in dose (lower or higher) for that patient.

The AP and SAS frameworks provided a solid framework to introduce access to medicinal cannabis, particularly with the introduction of the online application system and the responsiveness of the TGA addressing initial timeline concerns. However, as highlighted above, the rapid increase in the number of applications make sustainability of this approach a concern. The framework needs to evolve to take into account the unique aspects of medicinal cannabis – most particularly, the number of patients and the number of products.

Key considerations for a framework moving forward

Medicinal cannabis must meet certain standards prior to supply in Australia – notably GMP manufacture and Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis). These standards must be demonstrated to the TGA prior to the product being listed on the online application portal. The TGA has the power to audit the supplier and/or test the products. This defines what products are available for prescription and sets a standard of those products.

A doctor submits a clinical justification to the TGA under the current processes. The onus of prescribing an unregistered medicine is on the doctor and, in the absence of feedback from the TGA (e.g. collation of national learning from other applications), this process is more aligned with a notification process than an authorisation process.

The framework should reflect the reality that, given products are constrained to those logged with the TGA and in the absence of value add in response to submission of clinical justifications, the doctor is notifying the TGA of intent to use a particular product, and logging their clinical justification. While it can be argued that the AP process involves peer assessment of the expertise and experience of the prescriber in the clinical area defined by the cohort, and of the clinical justification, it must be recognised that a doctor can submit multiple SAS Category B applications and achieve a patient treatment cohort in the absence of third-party review.

The option to either notify the TGA of intent to use a medicinal cannabis product or seek TGA review and authorisation would be of value – in much the same manner that a clinical trial is 'registered' with the TGA through either a CTN (notification) or CTX (authorisation), with the latter drawing upon a value-add processes of the TGA.

Key risk parameters can be identified, defined and monitored by the TGA. Based upon experience gained to date, particularly from the large number of SAS Category B applications, the parameters can be set to direct an application through an authorisation rather than a notification pathway.

A move to a framework based primarily on a notification process, with the responsibility of prescription firmly placed on the prescriber, and with a potential to seek authorisation/value-add from the TGA at the discretion of the prescriber (or on the basis of pre-identified risks), would decrease resource requirements of the TGA. It also enables flexibility of treatment options for the doctor, with the patient benefiting from a timely and individualised treatment approach.

(b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;

PBS is only available for registered therapeutic goods and currently medicinal cannabis does not meet the criteria for consideration.

A more suitable framework is necessary to address subsidies for this particular unregistered medicine, which is now benefiting so many patients.

(c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes

At the coal face of patient access, it is imperative that the State/Territory jurisdictions be held accountable to meeting their commitments under the COAG meeting of Health Ministers (13 April 2018) to remove remaining State-based replications of TGA approval processes and all medicinal cannabis specific processes.

The unregistered medicine aspect is under the remit of the TGA, and existing processes around prescription and narcotic drug management at the State level are well established.

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;

We are broadly supportive of the regulatory approach of Australia – ensuring that doctor involvement is guaranteed, which in turn prioritises patient care. In other jurisdictions patients are free to source medicinal cannabis without consistent monitoring by a health care professional, and the resultant assessment of the ongoing treatment plan based upon clinical review. We are very

supportive of the establishment of explicit quality standards pertinent to medicinal cannabis through the Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis).

(e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;
(f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;
(g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;

We recognise the implementation of the TGA online application process and associated support material to assist doctors with understanding the operation of the regulatory regime, and we were highly supportive of the commissioned reviews undertaken by the TGA to provide a series of guidance documents for the use of medicinal cannabis.

Robust, fact based educational programs for health care professionals, including doctors, nurses and pharmacists, covering the endocannabinoid system (ECS) and medicinal cannabis, will be valuable in supporting patient care and we note the approach of the NZ Ministry of Health in pursuing funding to support prescriber education.

Currently there is no government response to supporting relevant doctor training in Australia.

(h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;
(i) the current status of the domestic regulated medicinal cannabis industry;

There remains disparity in the regulatory expectations placed on imported products versus domestically produced products. This impacts the competitiveness of the domestic sector. It is critical that imported products are required to meet the same standards as domestically produced products to ensure a level playing field. Active monitoring of imported (and domestic) products is essential, coupled with appropriate action against a Sponsor supplying non-compliant products.

A strong domestic sector will decrease the impact of changing priorities of international manufacturers supplying Australia.

Pipeline management for uninterrupted and responsive supply to Australian patients is impacted significantly by multiple authorisations required across the manufacture/supply process and highly variable turnaround times by the regulators, even for repeat activity by a single applicant. This results in out-of-stock issues that may result in a patient being subject to changing medication, or interruptions in treatment with an effective medication due to stock issues.

(k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;
(l) the significant financial barriers to accessing medicinal cannabis treatment

The impost on wholesaling unregistered medicines essentially means that movement of medicinal cannabis is package by package, adding additional cost, and impacting timelines, particularly for supply to rural and remote areas.

We submit that the classification of medicinal cannabis as prescription only and, in the case of THC, controlled drugs, coupled to both the commercial reality that a pharmacy is unlikely to hold

excessive stock and that it must account for prescription medicines/controlled drugs stockholdings, provides the necessary controls against diversion. Noting that these same controls are in place for all other prescription/controlled drugs.

The ability to wholesale product would enable inclusion of medicinal cannabis products in broader consignments to individual pharmacies, significantly reducing logistics costs and increasing timeliness of access for patients. This would also smooth out supply projections of manufacturers, enabling better pipelines management. In addition, it supports competitive retail pricing, with direct cost benefit to the patient.

(m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that.

Addressing access barriers – particularly cost and responsiveness of treatment plan for individuals – is key to addressing numbers of Australian patients relying on unregulated supply of medicinal cannabis.

It is imperative that this be addressed as the risks to the individual are significant, including:

a) Lack of medical monitoring;
b) Untested quality of product, and potentially harmful quality shortfalls (e.g heavy metal contamination);
c) Inconsistency of treatment.

Due to the Advertising Code as it applies to unregistered medicines, the public is not aware of what products are available for prescription. A listing, accessible to the public from the TGA Access to medicinal cannabis page, which does not 'market' the products, and which controls the information available, may assist.

We appreciate the opportunity to comment on the substance of this enquiry.

Regards,