MINISTERIAL INFORMATION REQUEST

MB19-004754
Date Sent to MO: 31/10/19

MINISTER: Greg Hunt

Issue: Options for streamlined prescribing of medicinal cannabis

You recently met with s22 [redacted], s22 [redacted] and s22 [redacted]. Following that meeting, you requested a brief on the pros and cons of moving medicinal cannabis from a special access scheme model to a prescription model.

Response:

Background

- Most medicinal cannabis products are 'unapproved' goods, consequently access is predominantly through the Special Access Scheme (SAS) and Authorised Prescriber (AP) schemes.
  - Currently only one medicinal cannabis product is registered on the Australian Register of Therapeutic Goods (ARTG). This product, Sativex (nabiximols), is indicated for some patients with multiple sclerosis.
  - As of 30 September 2019, over 12,000 patients are estimated to have accessed medicinal cannabis through the SAS and AP pathways. There are 56 medical practitioners with AP approvals for medicinal cannabis products.
  - In many instances, additional state or territory jurisdictional authorisation is required in order to prescribe medicinal cannabis products.
- From correspondence and complaints received daily from patients and members of the public, the biggest barrier for patients appears to be the reluctance of regular GP and specialists to prescribe unapproved medicinal cannabis products.
  - Cannabidiol (CBD) and tetrahydrocannabinol (THC) are included in Schedule 4 and Schedule 8 of the Poisons Standard respectively and require a prescription from a medical practitioner.
  - At present, scientific evidence for the use of CBD and THC is limited, and does not support medicinal cannabis as a standalone treatment.
- Current Government policy is to treat medicinal cannabis no differently to other medicines, that is, for it to be regulated under the therapeutic goods framework which requires relevant consideration of safety, quality and effectiveness.
- The intent of the Government when setting up the scheme in 2016 was to provide patient access to Australian-grown and manufactured medicinal cannabis outside the registered medicines route while recognising that provision of quality product provided through doctor's prescription was integral to the scheme. This process was to maintain the same high safety standards for medicinal cannabis products that applies to any other experimental or emerging medicine.

- Reducing regulatory requirements for medicinal cannabis by allowing its supply without it being registered on the ARTG, through the SAS/AP or the personal importation schemes would be inconsistent with the regulation of other therapeutic goods.
- Currently, any therapeutic good requires the use of these pathways to ensure legal supply for an unapproved therapeutic goods. Any change to increase medicinal cannabis access would require changes to the *Therapeutic Goods Act (1989)* and have implications for other unapproved therapeutic goods.
- This is an important consideration, as the majority of medicinal cannabis products have less evidence available for their quality, safety and efficacy than is available for many other products provided through the SAS.
- Unlike the majority of therapeutic products accessed under the SAS, medicinal cannabis products have not been approved by comparable international regulators as medicinal cannabis sits outside the medicine regulatory framework in other jurisdictions. The quality of these products is also highly variable, and consequently safety and quality are unpredictable.
- There are few medicinal cannabis products approved by regulators internationally with only one available in Australia:
    - Sativex (nabiximols) is approved for use in multiple sclerosis in multiple jurisdictions including the US, Australia, the UK and the EU.
- Unlike other products approved under SAS the product is often prescribed by GPs.
- Unapproved medicines have not been assessed by the TGA for safety, quality or efficacy. The medical practitioner takes medico-legal liability for any adverse events.

Options to allow streamlined prescribing of medicinal cannabis

The TGA has proposed four options below to allow streamlined prescribing of medicinal cannabis. Each option is not exclusive to medicinal cannabis alone on the basis that there is no evidence to support treating medicine cannabis as a separate case:

- Amend section 19 of the *Therapeutic Goods Act 1989* to remove the requirement to require approval from an appropriate ethics committee to supply the specified medicines for authorised prescriber status.
- Allow specified medicinal cannabis products for specified indications to be accessed via the SAS Category C notification pathway.
- Amend Section 19 of the *Therapeutic Goods Act 1989* to allow access to unapproved therapeutic products under SAS by notification and does not require approval (similar to Category A) from the TGA.
- Reduction in barriers to ARTG registration for medicinal cannabis products.

Option 1: Amend section 19 of the *Therapeutic Goods Act 1989* to remove the requirement to require approval from an appropriate ethics committee to become an Authorised Prescriber, for all unapproved goods.

Currently the legislation provides that a specific medical practitioner may be authorised to supply a medicine to a specified class or classes of patient where the prescriber holds approval from an appropriate ethics committee. This was to address the concern of the extent of the reliance on medical practitioners and institutions in the supply of unapproved goods. Under this option, this requirement would not be needed.

- Pros:
  - Removes the asymmetry between SAS B approvals (which do not require ethics committee approval) and AP approvals, removing the incentive for medical practitioners to prefer to seek case by case SAS B approval.
  - Reduces administrative burden for prescribers because the AP approval is not transactional (e.g. it would be in place for a specified period). Any Australian registered prescriber may apply to use any specified unapproved good in a specified class of patients.
  - Reduces TGA administrative burden in processing SAS B applications.
  - Allows continued oversight of applications for unapproved products by the TGA.

- Cons:
  - Some administrative burden on prescribers to apply for authorised prescriber status remains.
  - Time needed to make legislative change, will reduce any immediate benefits to prescribers.
  - State and territory requirements would still apply. Doctors would still need to apply to state/territory health departments in many instances in order to prescribe medicinal cannabis products.
  - Reduction in the control over the supply of unapproved therapeutic goods (and inconsistent with the reasons for the ethics committee requirement introduced in 2000).
  - Increased administration time required for the TGA to approve may impact on approval times for patients.

Option 2: Allow specified medicinal cannabis products for specified indications to be accessed via the SAS Category C notification pathway

- Pros:
  - Improves and streamlines access to unapproved medicinal cannabis products for patients.
  - Reduced TGA administrative burden in processing SAS B applications

- Cons:
    - There is limited history of use or registration of most medicinal cannabis products by comparable regulators and only in very specific indications (Multiple sclerosis, nausea, vomiting and seizures in specific conditions). This approach would treat medicinal cannabis differently from other medicines and is likely to be controversial with sponsors of other unapproved medicines.
    - 63% of SAS B applications over the last 12 months were for chronic pain. This means that, under this option, the issues in access to medicinal cannabis for a large proportion of the population would not be altered. The only products that could be listed in SAS C for their specific overseas approved indications would be Epiliodex, Nabilone and Dronabinol.
    - State and territory requirements would still apply so doctors would still need to apply to state/territory health departments in many instances in order to prescribe medicinal cannabis products.
    - Medicinal cannabis products are required to comply with the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 (TGO93) which is product specific. Entries to the Category C instrument would therefore need to be product specific or specify compliance with TGO93 is required.

Option 3: Amend Section 19 of the *Therapeutic Goods Act 1989* to allow access to unapproved therapeutic products under SAS by notification and does not require approval (similar to Category A) from the TGA.

Currently health practitioners seeking access to unapproved goods for patients who are not seriously ill (supplied under SAS category A) or for therapeutic goods without an established history of use (supplied under SAS category C) must apply to the TGA for approval under section 19(1)(a). It would be difficult to justify a lower regulatory requirement for medicinal cannabis products than other therapeutic goods, so the move to a notification scheme would be for all unapproved therapeutic products including medicinal cannabis under any changes to the SAS requirements.

There is precedent in New Zealand for the provision of unapproved goods through a notification only scheme (for goods additional to those in our SAS C).

- Pros:
    - Therapeutic products could be prescribed or used without having to wait for TGA approval.
    - Removes administrative barriers placed on medical practitioners in accessing medicines and devices they have determined are appropriate for their patients as all other treatment options on the ARTG are inappropriate or have been used without effect.
    - Reduces TGA administrative burden in processing SASB and AP applications. This will allow the TGA to focus on a compliance approach to the use of unapproved good, to identify deviations from safe prescribing practices and regulatory requirements.

- Cons:
  - Significant change to the current system shifting the entire risk of supply of unapproved goods to the medical practitioner with no pre-supply check / balance by the TGA and may exacerbate the reluctance to prescribe medicinal cannabis.
  - Significant consultation with health professionals, consumers and industry will be required and a RIS may be needed.
  - Time needed to make legislative change will reduce any immediate benefits to prescribers.
  - State and territory requirements would still apply so doctors would still need to apply to state/territory health departments in many instances in order to prescribe medicinal cannabis products.
  - Removing the need for a SAS approval pathway for all unapproved therapeutic products may remove incentive for sponsors to register medicines on the ARTG. This risk could be mitigated by a robust and well-resourced compliance scheme.
  - Reduction in the control over the supply of unapproved therapeutic goods, which may result in use of unsafe of ineffective products.

Option 4: Reduction in barriers to ARTG registration for medicinal cannabis products.

An amendment to regulation 45 would be required to reduce or waive application fees for medicinal cannabis products and additional specialised support for small medicinal cannabis enterprises seeking to register their medicines through the ARTG, for example providing information on literature-based submissions.

- Pros:
  - Removes administration barriers placed on prescribers in accessing medication deemed appropriate for their patients.
  - Products are assessed by TGA for safety, quality, efficacy. May provide greater confidence for prescribers to provide access to medicinal cannabis.
  - Reduces TGA administrative burden in processing SASB applications.

- Cons:
  - Departure from cost recover approvals by the TGA.
  - Reputational risk and may cause controversy with other therapeutic goods sponsors including the sponsor of Sativex.
  - Might cause significant issues with equitable access to TGA assistance for medicine approvals in Australia.

Minister	**Greg Hunt**
PDR Number	**MB19-004754**
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Adviser/DLO Comments:

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