The Hon Greg Hunt MP
Minister for Health
Minister for Sport

Senator Nick Xenophon
PO Box 6100
Senate
Parliament House
Canberra ACT 2600

Dear Senator Xenophon,

I am writing to you to seek your support for the *Therapeutic Goods and other Legislation (Narcotic Drugs) Regulation 2016*. As you are aware, Senator Di Natale is seeking to disallow these regulations.

These regulations give effect to existing Government policy that was agreed by Parliament unanimously in February 2016 that medicinal cannabis products should only be available through pathways for unregistered medicine, those being the Special Access Scheme Category B and the Authorised Prescriber Scheme. This policy is imposed on Australian medicinal cannabis product manufacturers (through section 11K of the *Narcotic Drugs Amendment Act 2016*) and, by default, Australian licences cannabis cultivators.

When the TGA rescheduled cannabis to schedule 8 of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP or Poisons Standard), it was to facilitate access across the states and territories. It has the unintended and inappropriate effect of opening up the Special Access Scheme Category A notification process *to imported products only*.

Disallowance would put the new burgeoning Australian industry at a significant disadvantage to international suppliers.

It would also put Australian patients at undue risk. The Special Access Scheme Category A is used for terminal patients for which other treatments have failed. However, exclusively, the products currently used under that Scheme have already been assessed for safety, quality and efficacy and registered by overseas regulators. This means they have comprehensive information on dosing, adverse events, contraindication, drug interactions and many other matters that doctors require to ethically and responsibly prescribe these products.

This information isn't available for medicinal cannabis products, except for Sativex. As such, it is appropriate and in the interests of patient safety for there to be a formal clinical review of any decision to prescribe an unregistered medicinal cannabis product. This review is provided by medical officers at the TGA through the Special Access Scheme Category B approval process. This protects patients from poor prescribing decisions and doctors, who are under professional obligations to act in the best interests of their patients.

There has been criticism that the SAS Cat B approval process is too slow. However, this is based on single case studies, in patients that probably would not meet the requirements for

SAS Cat A and where the doctors were either unable to identify the particular product being prescribed or justify their prescribing decisions in a timely fashion.

I am advised the TGA is routinely approving SAS Cat B applications in an average of 2 working days, where the doctor is able to justify their prescribing decision.

I would note that the AMA, RACGP and the Australian New Zealand Society of Palliative Medicine all oppose the disallowance motion on safety and quality grounds. However, in recognition of the concerns you have, I make the following commitments:

- I, along with the Therapeutic Goods Administration (TGA) will work with State and Territory Ministers and Health Departments through COAG Health Council to further streamline the interface between State and Commonwealth Access Schemes to Medicinal Cannabis – to reduce any duplication of information requirements from applicants and any duplication in evaluation of information provided by applicants.
- To support medical practitioners across Australia the Therapeutic Goods Administration will work with expert clinicians, peak groups and academics to develop communication of guidance documents to support the prescribing of medicinal cannabis for particular conditions
- The TGA and the Office of Drug Control (ODC) will develop website educational materials and take part in professional education activities for medical practitioners and pharmacists so that they are aware of the administrative requirements for prescription of medicinal cannabis
- The TGA will provide a 1-800 enquiry phone line for healthcare professionals and members of the public
- In conjunction with the Consumer Health Forum and peak patient groups, the TGA will undertake a patient education program on medicinal cannabis and how products can be accessed
- The TGA and ODC will meet with relevant departments, interested industry and doctors' groups in all States.
- The Government will investigate early opportunities through potential regulatory change to enable export of medicinal cannabis products grown and manufactured by Australian companies.

I trust that this will go a long way to addressing any concerns you have about the medicinal cannabis framework the Government has put in place.

Yours sincerely

Greg Hunt