Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2016 - 2017, 19 October 2016

Ref No: SQ16-000654

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Medicinal Cannabis

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

Please can you outline the timeframe for patients getting access to medicinal cannabis?
a) What is the next step in companies getting licenced to cultivate or manufacture the product?
b) How much product do you anticipate will be required to meet the need of patients?
c) Will there be a cap on licences?
d) What products will be licenced?

Answer:

Patients are already able to access medicinal cannabis products, the majority of which are unregistered medicines, through importation; however, there is not a large supply of domestic products available.

Access will continue to be largely through the Special Access Scheme or Authorised Prescriber Scheme or clinical trials.

Access to medicinal cannabis products will be on prescription from an appropriately qualified medical practitioner approved by the state/territory to prescribe these products and who has the appropriate Therapeutic Goods Administration approvals.

a) The legislation that enables the legal cultivation of cannabis for medicinal purposes commenced on 30 October 2016 and companies have started applying for licences to cultivate medicinal cannabis through the Office of Drug Control's website. The Department of Health cannot comment on the number or type of applications for privacy and security reasons.

   The Department is aiming to process applications in 20 working days, not counting time taken by other Commonwealth agencies and state and territory agencies to respond to queries relating to applicant suitability to hold a medicinal cannabis licence; or the time taken for applicants to respond to questions from the Office to clarify matters in their applications.

Pending successful assessment of an application, the new licence holder will need to then both complete construction on their facilities (including putting approved security measures in place) and apply for a permit, which will set out the limits on the amount of cannabis to be cultivated and produced.

It is expected to be several months before cultivation will begin and several more months after that before product becomes available. However, Victoria is already growing cannabis under an authorisation under section 25A of the *Narcotic Drugs Act 2016* for supply to patients in early 2017 in accordance with its legislation.

b) Work undertaken by the University of Sydney Business School suggests that for 30 000 patients, Australia would need to produce around 8 tonnes of cannabis per annum. The exact number of patients likely to receive medicinal cannabis products depends on the doctors who are willing to prescribe it within their practice, so the exact amount needed is unknown at this time, with patient estimates varying widely from 20 000 to half a million, depending on the conditions that the medical profession might be willing to prescribe for.

c) There will be no cap on licences. However, applicants for manufacture licences will need to convince the Department that they have a well-defined supply chain; applicants for cultivation licences must demonstrate a relationship with a licensed manufacturer. The Department will not licence 'on speculation'.

Actual amounts cultivated and manufactured will be rigorously controlled through the permit system to ensure that Australia does not over-produce and accumulate product, which it is not permitted to do under the *Single Convention on Narcotic Drugs 1961.*

In effect, there will be as many licences issued as necessary to meet patient requirements.

d) The legislation does not licence 'products' – it provides for three licences:

- A medicinal cannabis licence for the cultivation of cannabis for medicinal purposes
- A cannabis research licence for the cultivation of cannabis for research purposes
- A manufacture licence for the manufacture of medicinal cannabis products.

Applicants for a manufacture licence will need to satisfy the Department around what they intend to manufacture and that there is a supply route for that product. In doing this, they will need to undertake appropriate market research and business planning, taking into account the legislation in the state or territory where they intend to supply the product, as well as Commonwealth legislation dealing with supply, the *Therapeutic Goods Act 1989*.