Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2015 - 16, 21 October 2015

Ref No: SQ15-000718

OUTCOME: Outcome 7 – Health system capacity and quality

Topic: Medicinal Cannabis

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

a) We have concerns about the issues associated with the TGA's role in fettering access to cannabis-derived medicines in Australia. We understand there is at least a way (which the TGA is well aware of) to provide immediate lawful access to medicines containing CBD, subject to the grant of licences and permits by the Drug Control Section (DCS) of the TGA. Is this accurate?

b) Given that CBD was placed in Schedule 4 in earlier this year and it is not prone to misuse or abuse, on what basis does the TGA justify withholding licence and permits for the import of CBD? If it is because CBD is captured under the listing for "cannabinoids" in the Customs (Prohibited Imports) Regulations 1956, shouldn't CBD have been excluded from that listing when it was determined that it should be placed in Schedule 4 and was not prone to misuse or abuse.

c) I understand that Professor John Skerritt (TGA National Manager), Ms Philippa Horner (TGA legal counsel) and Mr Darren Jones (Director, DCS), are well aware of the lawfulness of the proposed scheme but are still withholding a decision in this matter after 4 months. Is this right? Is it also the case that there are a number of websites that are obtaining illegal supplies of CBD, of questionable quality, and yet these websites seem to be able to operate in an unfettered way, whilst at the same time the TGA is obstructing companies who are taking the required steps to operate lawfully and provide a safe, high quality means of access to CBD products?

d) We understand the TGA is currently delaying making a decision in respect of a licence and permit application for an applicant who has submitted applications to import CBD raw material for use in clinical trials and for the extemporaneous compounding of patient-specific medicines, under an exemption scheme pursuant to the Therapeutic Goods Regulations 1990. Can the TGA explain the reasons for this delay?

e) We understand that there was a particular urgency in granting this application because CBD had to be imported in time to commence a clinical trial involving CBD by 11 September, otherwise the researcher would lose the funding that had been allocated for the trial. We understand that despite being advised of this, the TGA refused to grant

the licence and permit, and the researcher lost the funding and is now unable to conduct the trial. Can you please provide an explanation as to why this situation was allowed to occur?

f) Given the above circumstance, are these delays by the TGA in making a decision justified?

Answer:

a) In order to import medicines containing cannabidiol (CBD) a person must have both a licence and permit issued under regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*. Applications are processed by the Drugs Control Section (DCS) in the Department of Health. A licence cannot be granted unless, amongst other things, the applicant is a "fit and proper person" to be granted a licence to import drugs and that the premises on which the applicant proposes to keep the drugs are secure.

DCS has processed licences and permits under regulation 5 to import cannabidiol and cannabis products for medicinal use. Since 2006, there have been 20 permits issued.

b) The inclusion of a product in Schedule 4 of the Poisons Schedule does not determine whether or not it should or can be subject to controls under the *Customs (Prohibited Imports) Regulations 1956*. What is controlled under those Regulations is in part determined by Australia's international obligations. There are a number of Schedule 4 prescription medicines requiring permission to import under the Customs (Prohibited Imports) Regulations.

c) In order to come to a view about whether a licence can be granted under regulation 5, it may be necessary for the Department to gather information from other Commonwealth agencies such as the Australian Border Force, the Australian Crime Commission, state and territory health departments and police services. Where information is provided that could be relevant to the criteria the Secretary is obliged to consider under regulation 5, the applicant is given an opportunity to address those matters.

Depending on the nature of the drugs being imported it may be necessary for the applicant to demonstrate that they have appropriate state and territory licensing approvals.

The Department acts on reports of unlawful advertising of therapeutic goods and the supply of unlawful therapeutic goods.

d) The Department cannot comment on specific applications.

e) We are unaware of any researcher that has lost funding as a result of any alleged delay in processing an import licence application.

f) As noted above, the Department cannot comment on specific applications.