Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2016 - 2017, 1 March 2017

Ref No: SQ17-000151

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Application to Redefine the Definition of Nicotine in Schedule 7 of the Poisons Schedule

Type of Question: Written Question on Notice

Senator: Smith, Dean

Question:

Input into the decision
It is understood that the TGA and/or the ACMS commissioned consultancy advice on the application, and may have engaged directly with some interested parties or experts.
1) Did the TGA, ACMS or any associated entity consult with the Department of Health in the consideration of the application?
2) Did the Department give any guidance, direction or suggestions in relation to this application?
3) In respect of consultancy advice:
a) What organization was contracted and who were the key personnel on the project?
b) Was it by select or open tender?
c) What were the terms of the tender brief?
d) How many other tenderers were considered?
e) What was the contract price of research and producing the report?
f) What weight was given to the report in reaching the Interim Decision?
g) Will the report be made public?
4) Besides the contracted advice, what organisations and/or individuals met with the advisory committee or the TGA as part of the consultation process (ie, meetings and discussions as opposed to written submission)?
5) Did any such people or organisations include:
a) Tobacco harm reduction advocates
b) Professional and advocacy associations (eg the AMA, the Cancer Council?
c) Providers of other nicotine products (eg tobacco companies and manufacturers of nicotine gum and patches)?
d) If so, can a list of direct consultees be provided?

Answer:

1) and 2)
The Therapeutic Goods Administration (TGA) is a part of the Department of Health. Internal consultations on this matter occur on a regular basis. The Advisory Committee on Medicines Scheduling (ACMS) did not consult with the Department, but it should be noted that there is

a Commonwealth representative on the committee. The delegate makes their decision in accordance with subsection 52E(1) of the *Therapeutic Goods Act 1989*.

3) The delegate can seek advice from anyone. The delegate is not required to go through a procurement process to seek specialist advice and in this instance advice was sought from a third party as well as the ACMS. The third party advice is not published. Details relating to the final decision, including the delegates reasons, can be found on the TGA website at https://www.tga.gov.au/book-page/21-nicotine-0

4) Nil.

5) All members of the public were invited to comment on the proposed scheduling changes during the two public consultation periods. These submissions have been, or will be published as per the legislative process.