Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2016 - 2017, 1 March 2017

Ref No: SQ17-000149

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:

Substance of the Decision

In respect to the delegates' Interim Decision on the application, what steps were taken to ensure:

- The Interim Decision satisfactorily met TGA assessment criteria for a risk: benefit analysis?
- The substantial potential public health benefits of vaping as seen from 10 years of research and overseas experience was fairly and fully taken into account?
- Overseas experience in which nicotine vaping is permissible – especially the United Kingdom and the European Union – that to date indicates little empirical evidence of the range of risks and uncertainties raised in the Interim Decision findings?

1) The Poisons Standard specifically exempts nicotine when 'tobacco prepared and packed for smoking'. How can exempting nicotine in 'tobacco prepared and packed for smoking' while banning its use in low concentrations in a far safer delivery system for helping smokers to reduce the harm from smoking?
2) Given this, is there any intention to review the current Poisons Schedule exemptions for tobacco prepared and packed for smoking, given the logical inconsistency of this position with the delegates' findings in the Interim Decision?

Answer:

The delegate makes scheduling decisions in line with the criteria under subsection 52E(1) of the *Therapeutic Goods Act 1989* (TGA Act), including the risks and benefits of the substance, the purposes for which a substance is to be used, toxicity, the potential for abuse and any other matters the delegate considers necessary to protect public health.

For the interim and final decisions on nicotine, the scheduling delegate considered scientific information, such as publically available journal and research articles, and the extensive public submissions received during the consultation process, as well as the advice received from the expert members at a joint meeting of the Chemicals and Medicines Scheduling Advisory Committees (ACCS and ACMS). Further details, and reasons, in relation to the final decision can be found on the Therapeutic Goods Administration (TGA) website at https://www.tga.gov.au/book-page/21-nicotine-0

1) In this instance the application to the scheduling delegate in relation to nicotine in e-cigarettes was on the basis of tobacco harm reduction. The scheduling application proposed that e-cigarettes can assist with the cessation of smoking (a therapeutic aid), and the application was considered on this basis in line with subsection 52E(1) of the TG Act.

2) There are currently no plans to review the wording in the Poisons Standard as it relates to nicotine ‘in tobacco prepared and packed for smoking’. No application has been made to the TGA to review this.