The Pharmacy Guild of Australia

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13 March 2015

Committee Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam

Regulation of Medicinal Cannabis Bill 2014

The Pharmacy Guild of Australia wishes to comment on *Regulator of Medicinal Cannabis Bill 2014* that is currently being considered by the Senate.

The Guild supports the medicinal use of cannabis preparations, following appropriate consideration by Australia's regulatory bodies as with other therapeutic goods.

However, the Guild does not support the creation of a new regulator for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis due to the following reasons:

- These powers and responsibilities should be delegated to the relevant regulatory area within the Therapeutic Goods Administration (TGA) and any required amendments to the law should be made to the *Therapeutic Goods Act 1989*.

- The TGA is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. Its key roles include classifying medicines based on their risk, implementing appropriate regulatory controls for manufacturing of medicines and the monitoring of medicines which includes a comprehensive adverse event reporting programme.[1] Therefore, the TGA is the most appropriate regulatory body to oversee the supply and export of medical cannabis as they possess the necessary experience and expertise in this area.

- The creation of a new regulator solely to regulate medicinal cannabis has the potential to fragment the regulation of medicines in Australia as well as lead to confusion and unnecessary duplication of regulatory processes.

- The explanatory memorandum notes that the Bill is designed to be a parallel system for the authorising the cultivation and production of cannabis for medicinal use and research with sponsors able to have their products authorised by the TGA. However, it is unclear what benefits this approach will bring as opposed to having a specific regulatory division for

[1] www.tga.gov.au/what-tga-regulates

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medicinal cannabis in the TGA. In addition, if the majority of companies elect to have their products registered through the TGA, then the proposed new regulator becomes redundant.

- If the cost of registering a cannabis product through the TGA is deemed to be a potential barrier to market entry, consideration should be given to reducing the application fees for these types of products. This approach will ultimately be a more efficient option than establishing a new separate regulator.

- The Advisory Committee on Medicine Scheduling (ACMS) has recently made a recommendation to create a new Schedule 4 entry for cannabidiol preparations containing not more than 2 per cent of other cannabinoids found in cannabis. This decision if adopted will likely lead to an increase in the number of products being registered for medicinal use.

- The TGA has prior experience registering products developed from cannabis such as Sativex® (nabiximols).

- The National Health and Medical Research Council (NHMRC) could also develop clinical guidelines to assist health professionals in determining the suitability of medicinal cannabis treatment for individual patients as well as ongoing management of symptoms and side effects.

Should you require any clarifications on the issues raised, please do not hesitate to contact Ms Khin Win May, National Manager – Policy and Regulation at the Guild National Secretariat

Yours sincerely

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Executive Director