MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

11 March 2015

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

Dear Committee Secretary

Re: Regulator of Medicinal Cannabis Bill 2014

Medicines Australia is the peak association representing the research-based pharmaceutical industry in Australia. Our members are responsible for the discovery, research, development and manufacture of new medicines, vaccines and health services for the Australian community. This sector plays a fundamental role in the health and well-being of Australians, as well as making a significant contribution to the national economy.

Provisions for the regulation of medicinal cannabis products are already established under the *Therapeutic Goods Act 1989* (the *Act*). The *Act* is administered by the national regulatory agency, the Therapeutic Goods Administration (TGA). For that matter, medicinal cannabis-based products have already been registered on the Australian Register of Therapeutic Goods (ARTG) under existing legislation. As stated in the Explanatory Memorandum to the Regulator of *Medicinal Cannabis Bill 2014*, the *Narcotic Drugs Act 1967* provides for a mechanism for authorising the cultivation and production of drugs (including cannabis).

The flourishing Tasmanian poppy industry supplies up to 50% of medicinal opioids to the world market, is decades old and is a good example of how the existing *Narcotic Drugs Act* operates in practice. There is a strong and collaborative history of Government and industry working together to manage the risks associated with these types of products and to ensure that we continue to meet the world's supply needs. Australia also has a strong working relationship with the International Narcotics Control Board (INCB) to appropriately manage quotas and exports and ensure there is not an over-proliferation.

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As such, Medicines Australia does not see a need for, and therefore does not support, the introduction of the *Regulator of Medicinal Cannabis Bill 2014* to establish a Regulator of Medicinal Cannabis and a system of regulating medicinal cannabis that is entirely separate from the TGA. This will introduce an additional level of regulation that is unnecessary; existing provisions for regulating medicinal cannabis products are effective and have been used.

Furthermore, in the context of the government's deregulation agenda, which aims to reduce unnecessary red tape, the introduction of an additional level of regulation and the establishment of a separate regulator where one already exists is counterintuitive to this agenda. Pharmaceutical manufacturers of prescription medicines are subject to a strict regulatory regime to ensure medicines made available to the Australian public are safe, effective and of a high quality. This is entirely appropriate. Introducing regulations and administrative processes that duplicate existing processes will impose unnecessary regulatory burden on the pharmaceutical industry.

In fact, the foremost barrier that Medicines Australia members have experienced in attempting to supply medicinal cannabis products in Australia have arisen from state and territory poisons legislation. In particular, differences in permit, prescription and risk-management plan requirements. These issues would not be overcome by the introduction of the *Regulator of Medicinal Cannabis Bill 2014* without appropriate changes to state and territory legislation.

Medicines Australia, therefore, recommends that the focus should be placed on harmonising state and territory legislation, rather than introducing a new level of national regulation, where appropriate and functional regulation already exists.

Please do not hesitate to contact me if I can be of any further assistance.

Yours sincerely

Tim James
CEO

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