1 April 2014

Senator Ian Macdonald
Chair
Senate Legal and Constitutional Affairs Legislation Committee

Dear Senator,

Re Regulator of Medicinal Cannabis Bill 2014

At the conclusion of our discussion on Monday 30 March you requested a response once I had had the opportunity to review the detail of the Bill and to discuss it with the Chairman of the Group in the Victorian Law Reform Commission (VLRC) developing a proposal for Medicinal Cannabis for Victoria, at the request of the Victorian Government. I met with Dr Ian Freckelton QC on this matter yesterday.

As I made clear in my presentation on 30 March, both Victoria and NSW are committed to introducing medicinal cannabis programs as policy they took to recent elections. Both are engaged in detailed planning. NSW has already called for expressions of interest to develop a cannabis preparation for use in infantile epilepsy. ACT also has a Bill under review. In 2014 the Prime Minister stated that he favoured proceeding with medicinal cannabis. A health Committee in COAG, in October 2014, considered proceeding with planning.

My view, and that of the Victorian group, is that implementation will require cooperation with the Commonwealth to safeguard compliance with Commonwealth legislation, as set out in Section 4 of the Issues Paper on Medicinal Cannabis of the VLRC, recently released. (I am assured that this was forwarded to your Secretariat). The critical Act for this purpose is the Therapeutic Goods Act 1989, with reference to s3, which leaves authority to the Secretary of Health to vary requirements under certain circumstances and to approve departure from normal processes through the TGA. It can provide exemption from entry to the Register for Therapeutic Substances for particular purposes in ss19B and 19D of the Act. Whilst these provisions have, by convention and rules, related to use of a therapeutic agent for specific individuals, it would be possible to broaden these powers if Health and its Minister were to be satisfied that regulation at by a State Government would ensure that cannabis derived products would be available only to stipulated categories of people with certain diseases and that the Sates concerned would undertake all the necessary legal responsibility for monitoring quality of production in respect of security, and quality of the medicinal product.

To have individual States, going their own way with differing patterns would be regrettable, but might occur if the Commonwealth had no commitment to assist. The commitment to consultation was evident at COAG in October 2014.

In my view, negotiation of this kind is totally outside the experience and capacity of the TGA, which is geared to approval or otherwise of traditional therapeutic goods with incorporated entities meeting the costs, to be recovered through future earnings. It has not been involved with matters such as herbal remedies (eg. those associated with various traditional Chinese medicines coming into the country) or with the specific legislative requirements in respect of narcotic and psychotropic substances. These latter issues touch on the Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act and Part 9.1 of the Criminal Code. These are all matters with which Commonwealth Health is familiar. The document from VLRC sets out a path through all of these issues and plans discussions with the Health Department in the near future.

The major issues are legal, largely within the powers of the Commonwealth Health Department. Health also has carriage of planning relating to drugs in international consultations, including the 2016 UN Assembly debate on the illicit drug Conventions. If State Governments are willing to take full responsibility of oversight of secure production and use of the cannabis products, and being responsible for the costs and processes required in regulation of production and use, there is a question as to whether a complex and costly new Commonwealth statutory body, in parallel with the TGA is appropriate. As proposed it would be taking responsibility for production and distribution and management of medicinal cannabis programs across Australia.

The question of use of the Commonwealth powers through Health could be handled through a new Office for Medicinal Cannabis within the Department drawing on existing staff and expertise. Ongoing consultation with the relevant States will be essential as knowledge and practice in the field continues to evolve. It would be important to ensure co-ordination between States, but the requirement of compliance to access the necessary legal pathway would be a powerful incentive to cooperation. COAG facilitated consultation in 2014, but establishment of a standing committee bringing appropriate professional expertise to advise both States and Commonwealth might better be placed in the Australian Health Ministers Advisory Council (AHMAC) as an on-going path for consultation. This would not entail any Commonwealth budgetary allocation to implement.

The introduction of medicinal cannabis depends on developing safe products, which are not unduly costly, to relieve suffering, in comparison with the few costly international commercial pharmaceutical versions (Nabiximols and new synthetic replacement products). These would have to compete in the market with illicit drugs which are unsafe, but far cheaper. It is feasible for Australia to produce relatively cheap but safe products and success in one or two States can be shared with others as practice evolves. A simple and flexible process is favoured as the scene evolves internationally, ensuring that sick Australians have appropriate access to this development.

David Penington