**3. REPORT OF THE PORTFOLIO COMMITTEE ON HEALTH ON THE MEDICAL INNOVATION BILL [PMB1-2014], DATED 22 NOVEMEBER 2017**

The Portfolio Committee on Health (the Committee), having considered the Medical Innovation Bill [PMB1 - 2014] (National Assembly – section 75), referred to it and classified by the Joint Tagging Mechanism (JTM) as a section 75 Bill, reports as follows:

1. The Medical Innovation Bill [PMB1 - 2014], is a Private Member’s Bill that seeks to make provision for innovation in medical treatment and legalize the use of cannabinoids for medical purposes and beneficial commercial and industrial uses. The Bill however lapsed in accordance with National Assembly Rules at the end of the 4th Parliament, and was revived at the beginning of the 5th Parliament. Upon the passing of Dr Oriani-Ambrosini, MP, the Bill was then subsequently adopted and re-introduced by Hon. Narend Singh, MP. The Committee received its first briefing on the Bill from Hon. Singh, MP, on the 17 September 2014. On 11 March 2015, the Committee received input from the Medicines Control Council (Department of Health) following the introduction of the Bill. On 27 May and 12 August 2015, the Committee received briefings from clinician experts and medical researchers and the Central Drug Authority. Further inputs from the Department of Health were received on 23 November 2016, 13 September 2017 and 15 November 2017.

The Bill makes provision for the following:

* 1. Legalising the use of cannabinoids for medical purposes;
  2. Legalising commercial and industrial use of cannabis;
  3. Allowing for innovation in medical treatment – medical practitioners may depart from existing evidence-based treatments where patients are no longer deriving benefit;
  4. Preventing reckless, illogical and unreasonable departure from standard practice;
  5. Regulating the use of cannabis for medicinal and research purposes; and
  6. Regulating cannabis for commercial and industrial use.

1. The Committee acknowledges the fact that the Bill resulted in significant developments in the area of the use of cannibinoids and other innovative medicines for medical and research purposes and wish to report on the following achievements that were achieved as a direct result of the Bill:
   1. Legalising the use of cannabinoids for medical purposes: under the Medicines and Related Substances Act (Act 101 of 1965, as amended) a person desiring to sell an unregistered medicine subject to registration in terms of Section 14 of the Act, for purposes other clinical trial, shall apply for authorisation in terms of Section 21 of the Act to sell such medicine.
   2. Legalising commercial and industrial use of cannabis: a collaboration between the Department of Health, Department of Agriculture, Forestry and Fisheries [DAFF] and the South African Police Services will be established to explore the commercial suitability of growing hemp in South Africa. The Committee noted and expressed concern over hemp trials and research that have been ongoing since 1999 without a clear timeline. The Committee agree that such trials must be expedited and concluded by DAFF.
   3. With regard to innovation in medical treatment, the Medicines and Related Substances Act provides for a person desiring to initiate or conduct a clinical trial to apply for authorisation to conduct such a clinical trial.
   4. As a consequence of the introduction of the Bill and Committee deliberations, the Department of Health amended the scheduling status of registered cannabis products for medicinal use. The exemption from Schedule 7 of: cannabis specified in Schedule 6; processed hemp fibre (as specified); and processed products made from cannabis seeds (as specified). Cannabidiol has been rescheduled from Schedule 6 to Schedule 4 substance. These changes were approved by the Minister on the 24th October 2017 and were then gazetted on the 17th November 2017.
   5. The Department of Health has finalised the guidelines on the cultivation and manufacture of cannabis-related pharmaceutical products for medicinal and research purposes. The guidelines provide minimum operating procedures relating to the cultivation and manufacture of cannabis-related products, in order to regulate the availability of quality cannabis for medicinal purposes.
   6. On the 5th November 2017, the Department of Health (Medicines Control Council) published licence application forms on its website to cultivate, manufacture or import cannabis for medical and research purposes. Any interested party can now, subject to certain requirements, apply for a licence to cultivate, manufacture, export or import cannabis for medical and research purposes.

The Committee takes special note of the statement by Professor Banoo (representing the Department of Health and Medicines Control Council) during the briefing to the Committee, when he stated that “we are at the beginning of an evolving journey into medical innovation and innovative treatments”.

However, after extensive work and engagements on the Bill and as a direct result of the positive developments in the legal framework around the use of cannabinoids for medical and research purposes, the Committee adopted a motion that the Private Member’s Bill is not desirable, as the objectives of the Bill and its purpose have been addressed through the amendments to the legislative framework as outlined in paragraph 2.

Report to be considered