REPUBLIC OF SOUTH AFRICA

MEDICAL INNOVATION BILL

(As introduced in the National Assembly (proposed section 75 Bill))
(Bill and prior notice of its introduction published in Government Gazette No 37349 of 18 February 2014)
(The English text is the official text of the bill)

(Mario G. R. Oriani-Ambrosini, MP)

[PMB1 - 2014]

GENERAL EXPLANATORY NOTE:

[ ]	**Words in bold type in square brackets indicate omissions from existing enactments.**
_____	**Words underlined with a solid line indicate insertions in existing enactments.**

BILL

To make provision for innovation in medical treatment and to legalise the use of cannabinoids for medical purposes and beneficial commercial and industrial uses.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

Definitions

1. As used in the Act —

"cannabinoids" shall mean any part or chemical constituent of the plant known as cannabis, marijuana or dagga, any genetic modification thereof, and any extract thereof or product containing it or resulting from the processing thereof;
"condition" shall mean a medical condition which, if not cured, may cause the patient's death or severe impairment to his or her medical condition or quality of life;
"Constitution" shall mean the Constitution of the Republic of South Africa, 1996;
"medical practitioner" shall have the meaning set out in the Health Professions Act, No. 56 of 1974
"Minister" shall mean the Minister of Health;
"patient" shall mean an individual receiving treatment by a medical practitioner;
"pilot health centre" shall mean a private or a government-owned hospital or other health service provider identified and authorised by the Minister by means of a proclamation published in the *Gazette*;
"regulations" shall mean regulations made by the Minister in terms of this Act:
"Republic" shall mean the Republic of South Africa; and
"treatment" shall include, without limitation, actions prescribed by a medical practitioner aimed at curing, managing, ameliorating or treating a condition or inaction.

Purposes

2. The purposes of this Act are to—

(1) codify existing best practices as to decisions by medical practitioners to innovate in cases where evidence-based treatment or management is not optimal or appropriate because the available evidence is insufficient or uncertain;
(2) enhance certainty and clarity for medical practitioners and others regarding the criteria to be applied in determining whether to innovate in the cases referred to in subsection (1);
(3) encourage responsible innovation in medical treatment and management by supporting reasonable and logical clinical decisions;
(4) deter reckless, illogical and unreasonable departure from standard practice; and
(5) legalise and regulate the use of cannabinoids for medical purposes and for beneficial commercial and industrial uses.

Application

3. Save for section 8 which shall apply throughout the Republic, this Act shall apply only with respect to one or more pilot health services, provided that—

(1) within three months of the coming into force of this Act, the Minister shall identify and authorise at least one pilot health centre which shall have the capacity of treating a minimum of one hundred patients at any given time; and
(2) any pilot health centre shall operate in terms of, and subject to, regulations, if any.

Innovation in absence of evidence-based treatment

4. (1) Where a medical practitioner believes that it is not possible or appropriate to make an evidence-based decision in determining how to treat a patient's condition, because in the medical practitioner's opinion there is no research or other evidence available in relation to the condition or alternative treatments thereof, or the available research or other evidence is insufficient or uncertain, that medical practitioner may, subject to this Act, administer or prescribe a treatment other than a generally accepted or legally authorised ones.

(2) In determining whether to depart from what the medical practitioner referred to in subsection (1) believes to be the pre-existing range of acceptable treatments for the relevant condition, that medical practitioner shall consider—
(a) the reasons why the available research or other evidence is insufficient or unclear including, without limitation, whether such insufficiency can be referred to the nature of the condition or the limited number of patients subject thereto;

(b) the relative risks that are, or can reasonably be expected to be, associated with the treatment the medical practitioner proposes to apply and other treatments;

(c) the relative likely success rates of the treatment the medical practitioner proposes to apply compared to other treatments, and, in the medical practitioner's reasonable judgement, the relative likely consequences of applying, or failing to apply, the treatment the medical practitioner proposes to apply, and other treatments;

(d) opinions or requests made by, on behalf of, or in relation to, the patient;

(e) the informed consent of the patient or his guardian or other person legally entitled to provide such consent on behalf of such patient;

(f) any other matter that appears to that medical practitioner to be reasonably necessary to be considered in order to reach a clinical judgement; and

(g) what process or protocol should be adopted with a view to ensuring that the decision to innovate is made accountably, transparently and with full consideration of all relevant matters.

Liability of medical practitioner

5. Notwithstanding any other law but subject to the Constitution, it shall not in itself be negligent for a medical practitioner to depart from what that medical practitioner believes to be the pre-existing range of acceptable treatments for a condition, or is the pre-existing range of acceptable treatments for that condition, where that medical practitioner takes the decision to innovate in accordance with this Act.

Informed consent

6. Nothing in this Act shall permit a medical practitioner—

(1) to provide treatment without consent that is otherwise required by law; or

(2) to administer treatment for the purposes of research or for any purpose other than the best interests of the patient.

Cannabinoids

7. Notwithstanding any other law, but subject to the Constitution, no one shall be liable or guilty of any offence for growing, processing, distributing, using, prescribing, advertising or otherwise dealing with or promoting cannabinoids for purposes of—

(1) treatment; and

(2) commercial or industrial uses or products identified by the Minister of Trade and Industry in a proclamation of general application to be published in the *Gazette*.

Regulations

8. After consultation with the Medical and Dental Council contemplated in the Health Professions Act, No. 56 of 1974, the Minister may make any regulations aimed at implementing this Act and pursuing its purposes, provided that when making regulations with respect to section 7, the Minister shall act in consultation with the Minister of Trade and Industry.

Short title and commencement

9. This Act is called the Medical Innovation Act of 2014, and shall come into force on its publication in the *Gazette*.

MEMORANDUM ON OBJECTIVES OF MEDICAL INNOVATION BILL, 2014

1. BACKGROUND

Under current legislation, medical practitioners are being legally prevented from prescribing and administering effective and harmless treatments, including those involving the use of cannabis, with respect to several life-threatening diseases, including cancer, because such treatments have not been approved in terms of presently legally required double-blind *in vivo* clinical studies. However, such clinical studies are often economically unviable, as the treatment or the substances used for it, such as bicarbonate of sodium or cannabis, are in the public domain and not capable of been patented, thereby preventing any relevant party from recouping the costs of such studies from future profits. This results in unnecessary human suffering and death on a mass scale, with consequent immense social and economic costs.

2. OBJECTIVES OF THE BILL

The objectives of the Bill are to establish one or more research hospitals where medical innovation can take place, especially with regard to the treatment and cure of cancer, and to legalise the medical, commercial and industrial use of cannabis in accordance with emerging world standards. The Bill creates a special legal dispensation, which applies only in research pilot hospitals authorised by the Minister of Health where medical practitioners are granted greater professional discretion to administer innovative and alternative medical treatments on the basis of the patients' informed consent.

3. FINANCIAL IMPLICATIONS OF THE BILL

This Bill will reduce the cost of private and public health services without imposing additional costs on the State.

4. PROPOSED CLASSIFICATION

4.1 It is proposed that the bill be dealt with in accordance with the procedure established by section 75 of the Constitution since it contains no provisions to which the procedures set out in sections 74, 76 or 77 of the Constitution apply.

4.2 It is proposed that it is not necessary to refer this bill to the National House of Traditional Leaders in terms of section 18 (1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.

5. BODIES CONSULTED

Cancer Treatment Campaign
Cancer Society of South Africa
Minister of Health
Minister of Trade and Industry
Deputy Minister of Justice
MamaAfrica
Democratic Alliance
Congress of the People
Wallace Global Fund