

**PARLIAMENT**  
OF THE  
**REPUBLIC OF SOUTH AFRICA**

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**ANNOUNCEMENTS,  
TABLINGS AND  
COMMITTEE REPORTS**

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WEDNESDAY, 19 FEBRUARY 2014

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## ANNOUNCEMENTS

### National Assembly and National Council of Provinces

#### The Speaker and the Chairperson

#### 1. Classification of Bills by Joint Tagging Mechanism (JTM)

(1) The JTM in terms of Joint Rule 160(6) classified the following Bill as a section 76 Bill:

- (a) **Financial Management of Parliament Amendment Bill** [B 1 – 2014] (National Assembly – sec 76).

### National Assembly

#### The Speaker

#### 1. Committee bill certified as an urgent matter

On 11 February 2014, Adv J H de Lange, on behalf of the Portfolio Committee on Water and Environmental Affairs and in consultation with the Speaker, certified the National Water Amendment Bill, 2014 as an urgent matter in terms of Rule 241(5) and consequently the rules pertaining to prior notice of the introduction of a bill and the publication of the draft bill or an explanatory memorandum in the *Gazette* do not apply to the National Water Amendment Bill, 2014.

#### 2. Introduction of Bills

(1) **Dr M G Oriani-Ambrosini**

- (a) **Medical Innovation Bill** [PMB 1 – 2014] (National Assembly – proposed sec 75) (see below) [Bill and prior notice of its introduction published in *Government Gazette* No. 37349 of 18 February 2014.]

Introduction and referral to the **Portfolio Committee on Health** of the National Assembly, as well as referral to the Joint Tagging Mechanism (JTM) for classification in terms of Joint Rule 160.

In terms of Joint Rule 154 written views on the classification of the Bill may be submitted to the JTM. The Bill may only be classified after the expiry of at least three parliamentary working days since introduction.

REPUBLIC OF SOUTH AFRICA

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# MEDICAL INNOVATION BILL

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*(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.**
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**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 being 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

(2) **The Portfolio Committee on Water and Environmental Affairs**

- (a) **National Water Amendment Bill** [B 3 – 2014] (National Assembly – proposed sec 75) [Bill classified as urgent matter in terms of Assembly Rule 241(5)); prior notice of introduction published on website of Parliament.]

Bill initiated by the **Portfolio Committee on Water and Environmental Affairs** of the National Assembly, and referred to the Joint Tagging Mechanism (JTM) for classification in terms of Joint Rule 160.

In terms of Joint Rule 154 written views on the classification of the Bill may be submitted to the JTM. The Bill may only be classified after the expiry of at least three parliamentary working days since introduction.

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## TABLINGS

### National Assembly and National Council of Provinces

#### 1. The Minister of Police

- (a) Erratum notice to the Report and Financial Statements of Vote 25 – Department of Police for 2012-2013.

#### 2. The Minister of Transport

- (a) Report of the Railway Safety Regulator on the South African Railway State of Safety for 2012-13.
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## COMMITTEE REPORTS

### National Assembly

#### **1. Report of the Portfolio Committee on Rural Development and Land Reform on the Restitution of Land Rights Amendment Bill [B 35 – 2013] (National Assembly– section 76), dated 05 February 2014**

The Portfolio Committee on Rural Development and Land Reform, having considered the ***Restitution of Land Rights Amendment Bill*** (National Assembly – section 76, referred to it and classified by the Joint Tagging Mechanism as a section 76 bill), reports the Bill with amendments [B35A-2013].

The Bill was amended as follows:

#### **CLAUSE 1**

1. On page 2, from line 5, to omit "31 December [1998] 2018" and to substitute "[**31 December 1998**] 30 June 2019".

#### **NEW CLAUSE**

1. That the following be a new Clause:

#### **Amendment of section 6 of Act 22 of 1994, as amended by section 3 of Act 78 of 1996 and section 5 of Act 63 of 1997**

2. Section 6 of the principal Act is hereby amended—
  - (a) by the deletion in subsection (1) of the full stop at the end of paragraph (f) and the insertion of the expression "; and" at the end of that paragraph;
  - (b) by the insertion in subsection (1) after paragraph (f) of the following paragraph:

"(g) ensure that priority is given to claims lodged no later than 31 December 1998 and which were not finalised at the date of the commencement of the Restitution of Land Rights Amendment Act, 2014."; and

- (c) by the insertion after subsection (1) of the following subsection:

"(1A) (a) The Commission shall establish and keep a Register which shall be known as the National Land Restitution Register.

(b) The Commissioner shall enter into the Register the details of all land restitution claims from the date of the commencement of the Restitution of Land Rights Amendment Act, 2014.

(c) The Commission shall keep the Register up to date and the Register shall be open to the public subject to the Promotion of Access to Information Act, 2000 (Act No 2 of 2000).".

## CLAUSE 2

Clause rejected.

## NEW CLAUSE

1. That the following be a new Clause:

**Amendment of section 11 of Act 22 of 1994, as amended by section 5 of Act 78 of 1996, section 7 of Act 63 of 1997 and section 4 of Act 18 of 1999**

3. Section 11 of the principal Act is hereby amended by the substitution in subsection (1) for the words following paragraph (c) of the following words:

“he or she shall cause notice of the claim to be published in the *Gazette* and in the media circulating nationally and in the relevant province, and shall take steps to make it known in the district in which the land in question is situated.”.

**CLAUSE 3**

1. On page 2, in line 19, to omit "31 December [1998] 2018" and to substitute "[31 December 1998] 30 June 2019".

**CLAUSE 6**

1. On page 4, in line 7, to omit "2013" and to substitute "2014".

**CLAUSE 10**

1. On page 4, in line 23, to omit "31 December [1998] 2018" and to substitute "[31 December 1998] 30 June 2019".

**CLAUSE 11**

1. On page 4, in line 31, to omit "31 December [1998] 2018" and to substitute "[31 December 1998] 30 June 2019".

**CLAUSE 12**

1. On page 4, in line 38, to omit "31 December [1998] 2018" and to substitute "[31 December 1998] 30 June 2019".
2. On page 5, in line 5, to omit "State or]" and to substitute "State] or".

**CLAUSE 13**

1. On page 5, in line 7, to omit "2013" and to insert "2014".

Report to be considered.

**2. Report of the Portfolio Committee on Economic Development on the redrafted Infrastructure Development Bill [B 49B—2013] (National Assembly – sec 76), dated 18 February 2014:**

The *Infrastructure Development Bill* [B 49—2013] (National Assembly proposed sec 75) was referred to the Portfolio Committee on Economic Development ('the Committee') for consideration and report on 4 November 2013, and subsequently classified by the Joint Tagging Mechanism as a section 76 Bill.

A number of key issues were addressed by the Committee during its deliberations on the Bill, following the Economic Development Department's response to comments received from the public:

- 1) Clarifying the intention of the Bill without changing the objects thereof, as broadly outlined in clause 2 in the Bill.
- 2) Addressing arguments presented regarding the constitutional powers of the three spheres of Government as assigned by the Constitution of the Republic of South Africa, 1996 ('the Constitution'), so as to avoid possible encroachment of provincial or local government powers.
- 3) Recognising that the Bill does not compromise the importance of sustainability and environmental justice considerations, as reflected in existing legislation such as the National Environmental Management Act, 1998 (NEMA), without unnecessary duplication.
- 4) Ensuring that the Bill allows for reasonable timeframes and consultation, with due regard to the existence of circumstances that may require justifiable extensions.
- 5) Clarifying the structures and composition of the Presidential Infrastructure Coordinating Commission (PICC), noting the need to distinguish the leading structure of the PICC from the set of structures that constitute the PICC as a whole. Thus, the term 'Council' was recommended to distinguish the overall body ('the Commission') from the decision-making structure without changing the existing composition, functions and mandates of either.
- 6) Reviewing the developmental impact criteria to include reference to women's empowerment and persons with disabilities.
- 7) Expanding the scope of the Bill with regard to the role of the private sector by the introduction of an amendment to clarify that the private infrastructure projects may only be included in a strategic integrated project (SIP) with the consent of the owner. The definition of public infrastructure covered by the Bill was further amended to ensure that it includes Private Public Partnerships (PPPs) and Concessions.

- 8) Reformulating clause 5 to strengthen the procedures for expropriation for purposes of implementing a strategic integrated project, in compliance with the Constitution and relevant legislation.
- 9) Recognising, with regard to the provision relating to designation and implementation of strategic integrated projects, that the Bill:
  - a.) provides for the Commission to designate a SIP through the Commission's Council, on which all three spheres of government are represented;
  - b.) provides the Commission, through a designated Minister, with authority to request relevant authorities to call for tenders for projects in order to ensure coordination; and
  - c.) coordinates and aligns infrastructure development.
- 10) Supporting the addition of Schedule 3 to the Bill, listing 18 SIPs of the National Infrastructure Plan, as the Committee understood the Bill to also give legal effect to already existing structures and practices, thereby requiring facilitation of continuity in the structures of SIP implementation.

The Committee further supported the intention of the Bill that every organ of state must ensure that its future planning or implementation of infrastructure or its future spatial planning and land use is not in conflict with any SIP designated by the PICC.

During deliberations objections were however also noted. The Committee accordingly further reports, in accordance with National Assembly Rule 251(e)(i) and (ii), that the Democratic Alliance (DA) recorded objections, amongst others, on the following matters:

- 1) the title of the Bill, as the DA indicated that since the Bill is meant to ensure effective coordination of infrastructure projects, it should be titled "The Strategic Infrastructure Coordinating Bill";
- 2) clause 8 of the Bill, on the basis that it encroached on the powers and functioning of Provincial Authorities and Municipalities and would interfere with spatial planning; and
- 3) Schedule 2 of the Bill, indicating that the timeframes were irrational.

Subsequent to the above, the Democratic Alliance abstained from voting on the Bill.

The Committee sought legal and procedural advice and took note that specific amendments were introduced to address concerns relating to:

- 1) The powers and functions of all three spheres of government, with a new provision that requires powers in the Act to be exercised in a manner that is consistent with the Constitution and, in particular, with the functional competencies of the different spheres of government; and
- 2) The timeframes for public consultation in Schedule 2, to provide that an executive authority may extend the period on good grounds.

The Committee also appreciates the input made by the public during the processing of the Bill.

The Committee accordingly presents a redraft of the Bill [B 49B—2013] for consideration by the National Assembly.

**Vote:**

Report adopted unanimously by 10 votes.

No dissenting votes.

No abstentions.

Report to be considered.