Medical Innovation Bill

Comment by the Department of Health

Briefing: Portfolio Committee on Health
23rd November 2016

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

20 YEARS OF FREEDOM

Medical Innovation Bill, 2014 (PMB1 2014)

GG Notice 37349, 18 February 2014: PMB1, 2014

Bill provides for:

- innovation in medical treatment
- legalising the use of cannabinoids for medical purposes
- legalising commercial and industrial use of cannabis

Medical Innovation Bill, 2014 (PMB1 2014)

Purpose:

- allow innovation in medical treatment – allow medical practitioners to depart from traditional treatment regimens when existing evidence-based treatments are no longer supportive of patients
- prevent reckless, illogical and unreasonable departure from standard practice
- legalise and regulate the use of cannabis for medicinal purposes
- legalise cannabis for commercial and industrial use

Medical Innovation Bill, 2014 (PMB1 2014)

Cannabis:

Treatment or **commercial and industrial** use:

- No person will be liable or guilty of any offence for:
  - growing, processing, distributing, using, prescribing, advertising, dealing with or promoting cannabis

International Developments: Saachi Bill, UK

Medical Innovation Bill (Saachi Bill), 2015

- The UK Bill provides for the same arguments as the proposed Bill in RSA
  - responsible innovation in medical treatment
  - allow medical doctors to depart from existing and acceptable medical treatments for a condition.
  - UK Bill **does not address** Cannabis specifically
- Status of Bill: UK Medical Innovation Bill has not progressed
- Concerns: patient safety and protection, risks reckless practice, protects quackery and could harm medical research

The Legal Status of Cannabis: INCB

- RSA is a signatory to the United Nations (UN) Single Convention on Narcotic Drugs, 1961
- UN: Cannabis is classified under Schedules I and IV of the 1961 making it subject to special restrictions.
- INCB requires member countries to establish:
  - regulatory procedures for licensing and registration
  - define control systems for hemp cultivation
  - define which cannabis varieties are authorised for cultivation
- INCB continues to oppose cannabis reform at the international level with reference to:
  - efforts to ease restrictions on cannabis use under international treaties.

The Legal Status of Cannabis: RSA

In RSA, cannabis is controlled in terms of :

- The Drugs and Drugs Trafficking Act, 140 of 1992; Sections 4(b) and Section 5(b), read with Part 3 of Schedule 2.
- The Medicines and Related Substances Act, 101 of 1965; Section 22A read with Schedule 7.
- The Criminal Procedure Act 51 of 1977; Section 40(1)(h)

The Medicines and Related Substances Act, 1965

- Section 22A (9)(a)(i) of the Medicines and Related Substances Act provides that **no person** may acquire, use, possess, manufacture or supply cannabis as the whole plant or any portion or product thereof, and includes synthetic derivatives.
- Section 22 provides for the Scheduling of all substances
  - Cannabis listed as a Schedule 7 substance
- Director-General may issue a permit authorising a medical practitioner, analyst, researcher or veterinarian to use cannabis:
  - on specific prescribed conditions
  - for the treatment or prevention of a medical condition in a particular patient
  - for the purposes of education, analysis or research.

Legal Framework for Scheduling and Control

- 'Scheduled substance': defined as “any medicine or substance prescribed by the Minister under Section 22A”.
- All medicines are subject to a scheduling process on the basis of the substances they contain (active pharmaceutical ingredients/ substance).
- Section 22A(2) – Schedules approved by the Minister, on the recommendation of the MCC.
- Section 37A – provides for amendments to the Schedules.
- Schedules are published in the Gazette or amended by subsequent notice in the Gazette.

Criteria for Scheduling

- Primary emphasis is on evidence of safety and requirements for professional intervention and/or supervision of use.
- Requirements for control, in international agreements, are considered where appropriate.
- Scheduling decisions involve the consideration of a number of factors, including:
  - evidence for the toxicity of the substance and the safety in use
  - the proposed indication for the substance
  - the need for medical diagnosis
  - the potential for dependence, abuse and misuse
  - the need for access to the substance.

Framework for Scheduling

- Schedule 0: Available through general sales outlets
- Schedule 1: Pharmacy OTC products
- Schedule 2: Pharmacist-prescription products
- Schedules 3-6: Prescription-only medicines; authorised prescribers
- **Schedule 7: Prohibited substances**
- Schedule 8: Limited use; special permits issued by DG

Schedule 7 (Banned substances)

- Substances not recognised for routine clinical use.
- Extremely high potential for abuse and dependence.
- Possession and use prohibited.
- Restricted to scientific and clinical research use only.
- Special permits issued by the DG on the recommendation of the MCC.

Inscription in Schedule 7: Banned substances

Cannabis (dagga)

- the whole plant or any portion or product thereof
  - May be separately specified in Schedule 6 (access through prescription)
- Synthetic cannabinoids

But Cannabis may be used as

- hemp fibre : may not contain more than 0,1 % THC or whole seeds
  - May not be in a form suitable for ingestion, smoking or inhaling purposes.
- processed product: may not contain more than 0,001 % THC or whole seeds

Cannabis for medicinal use

- Patients that are in position of both a prescription and permit from the DG can source the product in the following ways:
  1. Pharmaceutical cannabis products registered by the MCC
  2. unregulated illegal herbal cannabis, which may be grown or bought from the black market and generally has unknown concentrations of cannabinoids and potentially harmful contaminants.
  3. controlled and standardised herbal cannabis products obtained from licensed producers, which have standardised levels of cannabinoids and tested to be free of harmful contaminants.
- Current legislation does not allow for option 3 but future legislation (SAHPRA act) will allow this. [President to proclaim Act 72/2008 and Act 14/2015]

Cannabis for medicinal use: Section 21 Access

Access in terms of the Medicines and Related Substances Act, 1965: Section 21 with specified conditions:

- Patients suffering from a serious illness where a clinical need can be demonstrated and where evidence exists to support the request.
- Mechanism for continued access to medicines provided to patients following completion of a clinical trial.
- Clinical need exists for a medicine available in other countries, but not registered in South Africa.

Section 21 Access (cont.)

- Objective evidence to support the proposed use must be provided.
- The dosage, route of administration and duration of treatment must be provided.
- Appropriate monitoring of the patient during and after treatment must be in place in order to assess efficacy and adverse events.
- Reports on treatment outcomes must be provided.
- Treating physician must be a specialist in the field.
- Informed consent by the patient or legal representative is required.

Way forward: Future legislation: Supply

- The Department of Health, Director General will regulate the proposed growers of medicinal cannabis by issuing a permit to allow for the controlled cultivation of cannabis for medicinal use.
  - Cultivation, manufacture and supply of standardised, high quality medicinal cannabis products

Way forward: Future legislation: Patient

- Patient eligibility with the following conditions:
  - Severe muscle spasms or severe pain in patients with multiple sclerosis
  - Severe pain, nausea, vomiting or wasting arising from cancer, HIV/AIDS (including of the treatment thereof)
  - Severe seizures resulting from epileptic conditions where other treatment options have failed or have intolerable side effects
  - Severe chronic pain
  - Appropriate clinical oversight involving specialists, general practitioners, nurses and pharmacists
  - The need for ongoing research and clinical trials.

Way forward: Future legislation: Research

- The Department of Agriculture
  - to pronounce on the outcome of the cultivation trials at the 4 research facilities which are jointly overseen by the Department of Health and Department of Agriculture

- The Medical Research Council and other academic research centres
  - will be supported to conduct ongoing research on the clinical use of medicinal cannabis

Current Registered Products in RSA and other Countries

- Dronabinol is registered in some jurisdictions, including RSA, for nausea and loss of appetite in cancer and AIDS patients respectively.
- Nabilone is registered for nausea in other countries.
- Sativex is currently being reviewed for use in spasticity in multiple sclerosis and cancer pain).
- Ongoing R&D for use in glaucoma, pain management and some forms of childhood epilepsy.

Adverse effects of Cannabis Use

Short term use:

- Impaired short–term memory and attention.
- Impaired motor co-ordination and reaction times.
- Altered skilled activities.
- Anxiety and panic reactions.
- Acute psychosis, auditory and/or visual illusions, and pseudo-hallucinatory responses.
- Ataxia from selective impairment of reflexes.
- Dissociative states such as depersonalization and derealization.

Adverse effects of Cannabis Use (cont.)

Long term use:

- Addiction potential particularly in those who begin use in adolescence.
- Poor educational outcomes.
- Cognitive impairment.
- Respiratory and reproductive system effects.
- Increased risk of schizophrenia, depersonalization disorder, bipolar disorders, and major depression.
- Possible role as a gateway drug.

Framework for Medical Use and Research

Key elements of the framework:

- Licensing of growers to enable controlled cultivation for medical, scientific and research purposes.
- Availability of a standardised, quality-assured product for medical use indications.
- Clinical decision-making support for approval of medical use in terms of Section 22A(9)(ii) and Section 21 of the Medicines Act
- Review and approval of clinical trials and related scientific research in terms of Section 21.

Conclusions

- Mechanisms to enable controlled access to cannabis for medical use and clinical research already exist within the current legal framework of the Medicines Act.
- More work/research is needed on causality and strength of association of some adverse effects.
- More research is needed on age-related cognitive effects.
- More research is also needed on THC-related effects seen in higher potency strains from newer cultivation methods.
- A better understanding needs to be gained of the benefit/risk of cannabis for each indication considered.

Thank you

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