THE BARBADOS ASSOCIATION OF MEDICAL PRACTITIONERS

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Mr. Pedro Eastmond
Clerk of Parliament
Parliament
Parliament Building
Bridgetown
Barbados.

Dear Sir,

Following my oral presentation to the Joint Select Committee of the Medical Cannabis Industry Bill, 2019 on Tuesday, 10th September 2019, I was asked to return for further discussion on the proposed Bill.

I attach an expanded version of the prior written submission and advise you of my preparedness to return.

I await your response.

Sincerely,

P. Abdon DaSilva.
President

Comments on proposed Act:

Interpretation

2.(1) In this Act,

"medicinal cannabis" means

(a) cannabis that is grown and sold pursuant to this Act; etc.

Is this to be interpreted as separate and distinct from the tried and tested (synthetic) preparations approved for current clinical use?
It would appear that the Act speaks to medicinal cannabis as an entity requiring a product license or authorization (to be recommended by a physician) versus a synthetic drug requiring drug approval by a regulatory authority (to be prescribed).

Doctors generally prescribe drugs that have been rigorously tested, their clinical results reported in published articles, and information about indications for their use, the mechanisms by which they achieve results, and their expected side effects are available in package inserts or in readily available publications for reference.
None of these resources for information about the efficacy, dosing, or regulations that come from the Federal Drug Administration (FDA) and/or other regulatory body are available for medicinal cannabis.

Pharmaceutical regulation has excellent quality control and enable precise dosing, and whereas it is customary for all approved drugs to be assigned a Drug Identification Number (DIN), no current cannabis- based drug enjoys that status. To date, the only such approved drug has been voluntarily recalled by its manufacturer.

What is the cannabinoid profile of the medicinal products being offered (THC, CBD, THC+CBD?) Might this medicinal product interact with other prescribed drugs?
If a prescription is not offered, might the patient seek or use a non-medicinal product lacking safety and quality assurance? This is likely given the increasing trend toward the use of "natural" herbal preparations.

"Minister" means the Minister responsible for Agriculture and Food Security;

Is it to be assumed that the Minister of Agriculture and Food Security now has the responsibility for health- related matters? Shouldn't this be the charge/role of the Minister of Health and Wellness?

"recommendation" means a written recommendation dispensing cannabis for medical purposes;

Under the international drug control treaties, the use of cannabis is limited to scientific and medical purposes (United Nations Office on Drugs and Crime- UNODC, 2013). The treaties impose requirements on signatory countries that permit the medical use of cannabis and other drugs that are under international control (INCB, 2017). The treaties require tighter regulation of cannabis than medicines that are not under international control.

The treaties also require that the medical use of cannabis and cannabinoids be supervised by medical practitioners and that these drugs be dispensed by prescription.

There is also the requirement for reporting to the International Narcotics Control Board (INCB) on the quantities of cannabis that are used for medical purposes and on the number of patients who are treated using cannabis-based medicines.
What are the proposed mechanisms and who will be responsible for this undertaking?
Is it being proposed that matters of patient confidentiality now fall under the aegis of the Ministry of Agriculture and Food Security?

Where does the prescription of currently approved synthetic preparations fit into the scheme of things? Is this to be overseen/governed by the Barbados Drug Service/ Ministry of Health and Wellness? If so, why is there the need for a separation/duplication of authority?

"young person" means a person who is a patient and who is under the age or 21years;

Does this preclude the use of synthetic cannabis in children who have a rare form of epilepsy or other conditions from which benefit may accrue?

Protection from personal liability: *Should extend to those recommending and administering the product. Additionally, users should be required to sign a document that states specifically that they understand that consumption may lead to harm that is not currently known.*

Functions of the Authority:

4.(1) The Authority

(e) where required, assist with the provision of analytical services:

Heterogeneity in the types of product tested, including differences in pharmacokinetics and the balance of THC and CBD content, makes it difficult to establish optimal therapeutic formulations and dosing regimens.
The National regulatory authority should only approve/license the use of a medicinal product when there is good evidence that it has been manufactured to a required level of quality and there is evidence from clinical trials that it is safe and effective when used to treat patients with specified medical disorders.

Evidence of quality is ensured by a specific chemical or biological evaluation and requires the use of standards of good manufacture.

To whom will the Authority be providing analytical assistance in face of the fact that no facility exists currently (locally or regionally) for adequate drug analysis?

Evidence of safety and efficacy requires preclinical pharmacological and toxicological research as well as clinical trials. It is confirmed usually by randomized controlled clinical trials that compare the effects of the medicinal product with those of a placebo, or an active treatment, in patients with the specified medical condition.
High-quality research also helps guide practitioners in evidence-based decision making when prescribing and managing patients using drugs.

After a medicine has been licensed by national authorities, its safety is monitored through the national pharmacovigilance system.

How will the necessary pharmacovigilance schemes and data collection for reporting to the INCB be organized?

If cannabis is made available for medical use, how will the government address the possible reluctance of physicians to prescribe cannabis for ethical or medicolegal reasons and uncertainty about clinical indications and dosing?

Left unaddressed, there is the potential for the creation of tension within the patient-doctor relationship when the patient desires medicinal marijuana but the physician will not recommend it, either for reasons having to do with its therapeutic potential, lack of control over the dosage patients receive, or overall objections to its use.

Use of Medical Cannabis:

25. (3) A person who consumes medicinal cannabis without being authorized to use medicinal cannabis by a prescription or recommendation from a medical practitioner is guilty of an offence and is liable on conviction on indictment to a fine of $100 000 or to imprisonment for a term of 10 years or to both.

At the national level, the medical use of cannabis should involve monitoring the behaviour of prescribers, dispensers, providers and patients alike to ensure that cannabis-based medicines are appropriately prescribed and that they are not diverted to non-medical use or abused by patients.

This is an attempt to eliminate bogus prescriptions and/or rogue prescribers.

This is distinct from 40(1) d.

When considering the outcomes of regulatory changes to allow access to cannabis and cannabinoids for medical use, in addition to considering health risks and benefits for patients, it is important to take into account the potential broader social and public health impacts.

In particular, studies into cannabis poisonings among young children and emergency room contacts raise concerns about the potential for increases in accidental poisonings.
There is need for the prohibition of cannabis-containing products that could be attractive to minors (candy and/or beverages), and a requirement for childproof packaging of other edible products.

There should be the requirement for all cannabis and cannabis-containing product labels to include evidence based informed health warnings, contraindications and harm reduction messages.

Health risks include acute cannabis intoxication in adults, respiratory disorders (including deaths from vaping), and the potential for increased use among young adults.

Other evidence points to the increase in fatal motor vehicle accidents in jurisdictions where cannabis use has been permitted.

Cannabis smoking by middle-aged adults probably increases the risks of myocardial infarction.

The impact of medicinal cannabis use in the workplace requires careful consideration.

CBD products are widely available in health food shops and on the internet and are not scheduled or regulated as medicines as with other herbal remedies. The declared contents of non-medicinal CBD preparations are variable, often inaccurate, and these products sometimes exceed the legal limit of THC.

As healthcare providers, our goal is to help patients, to treat their illnesses, to improve their quality of life and to alleviate suffering – all within the bounds of scientific evidence.

The Barbados Association of Medical Practitioners remains committed to this ideal and encourages research on medicinal cannabis use in an effort to promote public health and public safety.

It is our duty to be an impartial body with regard to the medicinal use of marijuana and we urge our government and legal system to take a similar approach, using science and reason as the basis of policymaking.

Finally, there is need for the development of a comprehensive strategy for communication of the details of the regulations prior to implementation, so that the public and other stakeholders clearly and unambiguously understand what is permitted to facilitate informed decisions.