MEDICINES CONTROL COUNCIL CLARIFIES PROCESS TO OBTAIN A LICENCE TO GROW CANNABIS FOR THE USE AS A MEDICINE

This document has been prepared to clarify the current status on the process to apply for a licence to grow cannabis for the use as a medicine and for which claims of safety, quality and efficacy are being made.

Recent reports in the media that the Medicines Control Council (MCC) has authorized the use of cannabis for medicinal use has led to the belief that the MCC is issuing licences to prospective growers of cannabis to allow for cultivation and harvesting of the plant with the view to supply the product to patients for therapeutic use.

The MCC wishes to advise that this is not the case and that no licences or permits are being issued to authorize the manufacture, harvesting, growing or cultivation of cannabis for purposes of medicinal use. The MCC is working towards implementing a detailed regulatory framework to enable applications for licences and permits for the cultivation, production and manufacture of medicinal cannabis products.

The MCC confirms that cannabis remains a prohibited substance, making it illegal to cultivate, possess, use, sell or supply cannabis for medicinal or non-medical use without the necessary permit from the Director General of Health.

What is status of the MCC licence to grow Cannabis for medicinal use?

The MCC is a statutory body appointed by the Minister of Health in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, to oversee the quality, safety and efficacy of a medicine registered and available to the public. The Medicines Act allows for patients to access a registered medicine or, in exceptional cases, an unregistered medicine.

Cannabis sativa is a plant that contains at least 100 different pharmacological active substances of which tetrahydrocannabinol (THC) and cannabidiol (CBD) are but two, and which have shown to have the greatest pharmacological effects in man. However, THC has also shown psychoactive characteristics which affect negatively the risk benefit profile of the substance.

Cannabis is listed as a Schedule 7 substance in the Schedules to the Medicines Act making it illegal to have the plant in your possession.

To date the MCC has registered one medicine containing cannabinoids appearing in the plant and has listed the medicine as a Schedule 6 product, making it legal to possess the medicine provided that it has

been obtained with a prescription from a medical practitioner. In addition, the MCC has also issued authorizations for the use of an unregistered medicine containing cannabinoids.

As new legislation [The Medicines and Related Substances Amendment Act, 2015 (Act 14 of 2015)], still to be promulgated by the President, will make provision for the licensing of manufacturers of Scheduled substances, the MCC, in an endeavour to be proactive, has initiated a framework to allow for the preparation of guidelines for the growing of cannabis for medicinal use and thus the manufacture of a Schedule 7 substance to be processed into a medicine. These guidelines will soon go out for public comment.

Once the Amendment Act, Act 14 of 2015, has been promulgated to create the legal framework for growing cannabis for medicinal use, and the MCC guidelines in this regard are in place, the public will be able to apply for a growing permit. Currently this framework is not yet in place and no applications for the growing of cannabis for medicinal use can be considered by the MCC. As the MCC needs to consult the Department of Agriculture, Forestry and Fisheries (DAFF) on agriculture related requirements such as soil quality, geographical preference, seed quality and seed cultivars, it is envisaged that these guidelines and applications forms will be available later this year. It is advised that interested parties monitor the MCC website at www.mccza.com to download the latest documents in this regard.

DR J GOUWS

REGISTRAR OF MEDICINES

Notes:
The Medicines Control Council (MCC) is responsible for regulating all medicines and medical devices in South Africa by ensuring that they meet standards of efficacy, safety and quality. The MCC operates in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Regulations issued in terms of that Act, and associated guidelines.
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