

MEDICINES CONTROL COUNCIL



Press release

Medicines Control Council clarifies access to Cannabis for the treatment of medical conditions

From: The Chairperson of the Medicines Control Council

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Release

In the light of recent media reports, the Medicines Control Council wishes to clarify the current framework for access to cannabis for medicinal purposes in South Africa.

South Africa is a signatory to various international conventions and remains committed to ensuring that illicit drug-related activities in respect of cannabis are prohibited by law. Cannabis is classified as a Schedule 7 substance in South Africa, making it subject to special restrictions and controls. The official position of the government, as expressed by the Department of Health, is thus to regulate the use of cannabis in order to prevent its illicit use and its potentially harmful effects. As a controlled substance, it is illegal to cultivate, analyse, research, possess, use, sell or supply cannabis without the necessary authorization from the Department of Health as per the legislative requirements.

Measures to access cannabis for medicinal use

In recent years, a small but growing body of evidence has emerged suggesting that cannabis may have medicinal value for some patients in conditions where other treatments have failed. The Medicines Control Council is South Africa's drug regulatory authority which is governed by the Medicines and Related Substances Act, 1965 (Act 101 of 1965). Under this Act, medical practitioners can apply to the Council for permission to access and prescribe unregistered medicines - including cannabis - for their patients in certain exceptional circumstances. Medicinal cannabis products may thus be made available to specific patients under medical supervision. Only registered medical practitioners may apply for authorisation to prescribe a controlled medicine for a specific patient. Authorisation from Council is dependent on the submission of an appropriate dosage regimen and acceptable justification for the proposed and intended use. The necessary procedures for approval of the importation of suitable cannabis products for medicinal use by patients with defined medical conditions are already in place.

Cultivation of cannabis for medicinal use

The Medicines Control Council (MCC) has identified the need for a regulatory framework to effectively control the cultivation, production and manufacturing of cannabis products for medicinal use in South Africa. Licensed domestic cultivation of medicinal cannabis will be aimed at ensuring the supply of a standardized, quality assured product for medical, scientific and clinical research purposes, and the implementation of control measures necessary to prevent misuse and to ensure patient safety. Cannabis grown / cultivated for medicinal purposes, as well as any resulting products prepared from the plant material, will remain subject to stringent security and quality control measures. The legislative framework to allow for domestic cultivation of medicinal cannabis is currently under development by the Department of Health in consultation with the Medicines Control Council.

The Medicines Control Council recognises that cannabis is not a panacea and that continued efforts are needed to generate more data on efficacy as well as balancing the evidence of efficacy with potential risks of side effects resulting from use for medicinal purposes. Access to medicinal cannabis is aimed at being responsive to the wishes of patients and their carers in respect of conditions for which alternative, effective treatments are not available.

Notes:

1. *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.*
2. *Cannabis is also referred to as marijuana, and locally as dagga.*

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