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Medicinal cannabis in South Africa: Licensing, quality control and access to market

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Medicinal cannabis in South Africa: Licensing, quality control and access to market

While much has been discussed in the media regarding the lawful commercialisation of cannabis for recreational use, as vaguely alluded to in the latest draft of the Cannabis for Private Purposes Bill, South Africa's role as a global player in the medicinal cannabis market shouldn't be underestimated.

Aside from having a comparatively lower cost of agricultural production due to advantageous environmental conditions and the cost of labour, South Africa has a track record of agricultural process innovation, medical innovation and stringent quality control requirements for medical cannabis licensing, making it an ideal destination to cater to the global medical cannabis market.

Local production has been primarily geared towards raw cannabis flower and extracts for export to foreign markets as bulk active pharmaceutical ingredients. Demand is set to increase as pharmaceutical product development pipelines approach commercialisation globally.

This article aims to highlight the latest developments in the medical cannabis space, the currently applicable regulatory landscape governing it, and domestic access to medical cannabis.

LATEST DEVELOPMENTS

In the latest draft for public comment of the Country Investment Strategy (CIS), issued by the Presidency on 27 May 2022, cannabis is recognised as a legally and globally traded agricultural commodity. However, the CIS indicates that the state still regards the commercial cultivation of cannabis for recreational use as a highly uncertain value proposition, both locally and internationally, requiring extensive legal and institutional evolution.

Considering South Africa's agricultural competitiveness profile, the CIS concludes that cannabis grown and processed for medicinal use is the most viable competitive sales channel to pursue at an industrial scale and that capabilities developed for medicinal production can be rapidly deployed to service recreational demand from either local or international markets.

Given the above, the CIS proposes that the state enable the finalisation of a common cannabis regulatory framework geared towards industrialisation for export, with a focus on the medicinal value chain. Accordingly, what is being prioritised is the development of a supportive legal framework which both streamlines export-scale production and opens up domestic market access through clear, sensible regulation of medicinal cannabis coupled with investment mobilisation and enabling activity by the state.

CURRENT REGULATORY FRAMEWORK

Regardless of these latest developments, commercial medical cannabis is already legally possible within the current regulatory framework. However, it is not without its pitfalls, costs and shortcomings – hence the need for a more supportive and streamlined legal framework.

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The South African Health Products Regulatory Authority (SAHPRA) is the state body that regulates the medical cannabis market. SAHPRA issues licenses in terms of section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965 (Medicines Act) which enables the cultivation, manufacture, extraction, testing, import, export and distribution of medicinal cannabis and ensures the required oversight of SAHPRA in regulating these activities.

However, licenses for these activities are only issued after applicants have constructed fully compliant cultivation, processing, extraction, or testing facilities and are audited by SAHPRA in accordance with strict quality control and security protocols. The above and other compliance criteria (such as pre-negotiated off-take agreements or letters of intent) provided for by SAHPRA necessarily entail significant capital expenditure, which is unfortunately required before a section 22C license may be granted.

With regard to the quality control aspect of medical cannabis manufacturing, South Africa is a member of the internationally renowned, Pharmaceutical Inspection Co-operation Scheme (PIC/S), which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use and as required by relevant international marketing authorisations or product specifications.

SAHPRA audits are conducted according to the requirements of the South African Guide to Good Manufacturing Practice (GMP), which refers to:

- PIC/S Guide to GMP for Medicinal Products – Part I for pharmaceutical products
- PIC/S Guide to GMP Medicinal Products – Part II for manufacturing of Active Pharmaceutical Ingredients

Notably, a section 22C license does not automatically entitle the holder to global GMP status and a further application, which can be done through SAHPRA, is required.

As a result of this high standard of quality control, medical cannabis produced in South Africa under licensed conditions is among the highest quality in the world, thereby creating a compelling value proposition in international markets.

COST OF PRODUCTION

However, when it comes to cost of production, the strict adherence to GMP standards at the cultivation stage does entail an increased cost. Internationally, there is evidence of cannabis being cultivated in accordance with good agricultural practice and/or good agricultural

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collection practice standards, then processed in GMP facilities for sale as a GMP-certified product on the medicinal markets. By treating the cultivation stage as an agricultural activity in accordance with agricultural standards and the post-harvest processing stage as manufacturing in accordance with medical standards, significant cost savings may be realised, resulting in a more competitive price point in the global marketplace.

There is also an argument to be made that in order to include small-, medium- and large-scale open-field, rural cultivators in the cultivation side of the medical cannabis value chain, more needs to be done to ensure that strict adherence to standards like GMP does not continue to form a barrier to entry. This is especially apparent in single-molecule extract production lines which do not require cannabis to be cultivated solely in controlled, indoor or greenhouse environments.

ACCESS TO MARKET

Internationally, more than 60 countries have legalized medical cannabis in some form or another, whether that be in the production or use of medical cannabis, or the import of pharmaceutical cannabinoid medications. Germany has adopted a free-market approach for GMP-certified medicinal cannabis products, even allowing public healthcare reimbursement for these products. The UK has also adopted a free-market approach to medical cannabis, however reimbursement is restricted to private healthcare providers only. France is also seemingly set to legalize medicinal cannabis after the completion of a two-year trial programme concluding in 2023. These and other developments globally point to an increasing demand in the nearby future for quality-certified medical cannabis.

Domestically, the Medicines Act enables patients to access unregistered, medical cannabis products for therapeutic purposes through the provisions of section 21 of the Medicines Act. In order for patients to access these unregistered medicines, a registered medical practitioner or authorised prescriber needs to apply to the SAHPRA on the patient's behalf, to allow for the purchase and use of unregistered medicine as a treatment regime. This process has been significantly streamlined and can be completed through online submissions by the registered medical practitioner.

Once the section 21 application is complete, patients can access medical cannabis products through a variety of online and, more recently, physical pharmacies that are authorised to acquire and distribute medical cannabis products.

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However, the section 21 procedure highlighted above may be considered a stop-gap measure until registered cannabis medicines become more prevalent locally and are available for prescription by pharmacies across the country.

Accordingly, more work is required to establish and bolster domestic demand and consumption of medical cannabis, which provides for domestic revenue, scaled operations and a necessary hedge against demand shocks experienced by local, export-oriented medical cannabis businesses. This would include the finalisation and domestic registration of medical cannabis products.

Navigating the complex regulatory and commercial environment applicable to medical cannabis in South Africa can be challenging. To avoid onerous financial and other non-compliance implications it is always recommended to consult with qualified legal experts throughout decision-making, business development, investment, and transactional processes.

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BBBEE STATUS: LEVEL ONE CONTRIBUTOR
Our BBBEE verification is one of several components of our transformation strategy and we continue to seek ways of improving it in a meaningful manner.

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