CANNABIS FOR MEDICINAL PURPOSES *Legislative, Regulatory and Clinical Implications*

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PURPOSE

Medicinal cannabis entails evolving dynamics, marked by considerations of therapeutic potential and safety concerns, ambivalent perceptions and scientific evidence, alongside accessibility issues tantamount to limited harmonisation across jurisdictions. Cannabis for medicinal purposes is largely regulated by provisions implemented on a State-by-State basis.

The Laws of Malta were amended in 2018, enabling the prescribing of cannabis-based products manufactured under Good Manufacturing Practice (GMP). The national legislative amendments present an opportunity to assess the implications of regulatory requirements for controlled, quality medicinal cannabis products and to examine local predispositions in prescribing and clinical use.

Figure 1: Sample of tamper-evident labels for serialisation of individual cannabis-based product packs sourced to Malta

METHODS

The Malta Medicines Authority (MMA) established a procedure to review applications from licensed wholesale dealers or manufacturers to source cannabis-based products. The review considers requirements including EU-GMP certification, manufacturing process, specifications, certificates of analysis, stability studies and labelling criteria. The Authority submits a recommendation to the Superintendence of Public Health (SPH) for the issuance of a notification of approval. Sourcing of approved products is subject to an import permit and each individual product pack is provided with a unique serialized tamper-evident label (Figure 1) for traceability through the controlled supply chain. A research and education contribution is pegged to the provision of labels, as commitment towards further scientific studies in the field.

The SPH considers applications by licensed medical practitioners to prescribe cannabis-based products on a named-patient basis taking account of the patient's condition, previous treatment, product(s) to be prescribed, dosage form and concentration of the active cannabinoids. Once endorsed, the respective patient may access the approved product(s) from licensed pharmacies.

RESULTS

A total of 17 applications for cannabis-based products intended for the local market were received by the MMA between July 2018 and October 2019; 10 for oral preparations and 7 for flowers, with varying concentrations of tetrahydrocannabinol (THC) and cannabidiol (CBD). A notification of approval was issued for 4 products in dried flower form, with concentrations of 22%THC/<1%CBD in 2 products, and 20%THC/<1%CBD and 6.3%THC/8%CBD in the 2 other products respectively. The route of administration is via inhalation using a vaporiser, or by means of a tea infusion. The 13 applications on hold are pending submission of relevant requirements including analytical data related to heavy metals, pesticides, aflatoxins, microbiology, assays and stability.

During the period under study, 4,905 unit products were sourced to Malta in pack sizes of 5g or 10g. In clinical practice, the number of prescribers amounted to 34 medical practitioners, attending to a total of 449 patients. Cannabis-based products were prescribed in wide-ranging medical conditions, including anxiety, insomnia, depression, fibromyalgia, pain, migraine, cancer, post-traumatic stress disorder and multiple sclerosis.

CONCLUSIONS

Limited harmonisation across regulations, with considerable divergences on the legal status of THC/CBD, quality standard measures and labelling requirements, amplifies the complexity in the implementation of national regulatory frameworks. Equivalent products may be categorized differently by competent authorities in the respective States, intensifying uncertainties related to availability and accessibility.

In Malta, the regulated medicinal cannabis market translated in a number of physicians considering cannabis-based products in diverse clinical presentations. It is anticipated that advanced research shall assist policy-makers in consolidating protocols, drive industry towards quality products pertinent for clinical studies, and stimulate medical communities to assess safety and efficacy evidence.

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