

UPDATE ON THE REGULATORY FRAMEWORK

In January, the Authority for the Responsible Use of Cannabis (ARUC) launched a convention on the regulatory framework for non-profit associations interested in obtaining a licence to cultivate and distribute cannabis for non-medical purposes, as provided in the legislative reforms enacted in December 2021. The associations shall be known as Cannabis Harm Reduction Associations. The Authority's operations have since become fully fledged. Key actions during the last months include :

- Continuous stakeholder engagement and open dialogue with all parties involved.
- Publication of a Legal Notice and directives which stipulate how the associations shall function.
- Opening of application process as of the 28th of February.
- Building up the Authority's administrative capacity and its internal technical and scientific expertise by increasing its staff complement.
- Engagement with relevant international bodies to explain Malta's regulatory feedback.

PROFILE OF THE ASSOCIATIONS

- Seven prospective associations have submitted their application.
- Eleven have reserved their prospective names of the association. Several other associations are preparing their application and are in contact with the Authority regularly.
- The submissions consist of voluminous documents consistent with the level of knowledge and qualifications expected.

PRINCIPAL ASPECTS OF THE FRAMEWORK

- Associations must carry out entire operations from seed to distribution for the benefit of their members only.
- Associations shall be community-based, and the administrators shall be democratically elected from among members.
- Associations to operate on a not-for-profit basis. Salaries and other expenses are in line with market rates.



- No marketing is allowed, including through social media. Associations' sites shall not be identifiable.
- Only dried flowers may be distributed to members.
- Sites must be located 250m from schools and other sites serving youths.
- Only local residents may become members.
- Administrators must have resided in Malta for the last five years and be of good conduct.
- Licence fees shall remain as stipulated in the legal notice.
- Distribution to members may be done from approved sites only. Deliveries are not allowed.
- No other operations besides the cultivation and distribution of cannabis may take place at the associations' premises.
- Audited accounts and financial reports are to be submitted regularly. Rigorous procedures for the prevention of money laundering shall be in place.
- Cannabis with a THC content exceeding 18% may not be sold to individuals aged 18 – 21.

UPDATING OF THE DIRECTIVES

The Authority has continued with its stakeholder consultation process and obtained feedback about obstacles encountered in the preparation of the application submission. The Authority has fine-tuned the directives on operating practices to take into account the feedback received. These changes will facilitate the operations of the associations without compromising on the Authority's key tenet of promoting harm reduction amongst cannabis users through a grassroots approach of community-based non-profit associations.

Application Format

The current format of the application stipulates that all documents must be submitted with the application, thereby compelling prospective associations to secure prospective hold over the chosen properties before submitting the application. Feedback has shown that prospective associations are finding it difficult to secure prospective hold for the duration of the application process. The application format shall be amended to allow prospective associations to adopt a modular approach through the application process.



Transportation

The Authority had stipulated that transportation of cannabis between the cultivation and distribution sites shall be done through ADR-certified individuals. This certification, usually required for the transportation of dangerous goods, was chosen as no certification for the transportation of cannabis is currently available. The Authority shall be issuing its certification, which satisfies all the criteria required to ensure that cannabis is transported securely whilst facilitating operations. The following conditions shall apply:

- Certification may be requested through a prescribed form.
- The due diligence process applicable for individuals who apply to set up an association shall also apply to applicants for this certification.
- The transportation must be done by the individual who obtains the certification using the vehicle indicated in the application form.
- The vehicle must be enclosed (quad bikes and open hatch trucks will not be allowed).
- Cannabis must be transported between the cultivation and distribution sites of the association without any stops enroute or other undue delay.
- Cannabis must be stored in a temperature-controlled container locked inside a safe.
- Transportation shall not take place at night.

Waste

The Authority had stipulated that waste must be incinerated in an approved landfill to ensure that all waste material is duly accounted for, as unused parts of the cannabis plant are also deemed a restricted material in terms of the Dangerous Drugs Ordinance. The Authority has acknowledged the feedback received about the substantial costs and adverse environmental impact of the approved disposal procedure. As an alternative, associations will be allowed to compost the waste in a sealed container within the cultivation site. The compost must be used as nutrients for the associations' operations. To avail of this option, associations must demonstrate that they can document all stages of the waste composting procedure. The Authority will inspect the associations' operations regularly to ensure compliance.



Testing

The Authority has received feedback about the costs that will be incurred in implementing the testing regime. The regime is being maintained in its entirety, but the frequency and modality through which the testing shall take place have been fine-tuned to address the risk of each specific component of the testing criteria.

Testing for bacteria, yeast and mould, moisture content and analysis for foreign matter shall be done by the associations prior to the release of each batch. Testing to establish the phytocannabinoid profile shall be done periodically. Testing for harmful chemical and biological contaminants shall be done by the Authority.



