

ISRAEL

AYR - Amar Reiter Jeanne Shochatovitch & co

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Israel?
 - a. The use of cannabis in Israel is prohibited since cannabis defined as a "dangerous drug" in accordance with the Israeli Dangerous Drugs Ordinance [New Version] 1973 (and not registered as a remedy).
 - b. Notwithstanding the above, in August 2011, the first governmental resolution (number 3609) was adopted with respect to the foundation of a governmental agency under the supervision of the Israeli Ministry of Health by the name of the Israeli Medical Cannabis Agency (IMCA or YAKAR). The main objective of the IMCA is on one hand to provide patients with continuous and appropriate supply of cannabis for medical purposes and, on the other hand, licensing occupations in the cannabis field.
 - c. Further to the governmental resolution mentioned above, a Government resolution (1587) resolved in 2016 sets the guidelines for the regulation of any activity regarding the cannabis plant, including growing, exporting, distributing, possessing, transporting, laboratory testing, dispensing or research of the cannabis plant or its products. Such activities are mandated to comply with the provisions of any law, including obtaining the adequate licences according to the Dangerous Drugs Ordinance from the YAKAR.
 - d. In addition, it is important to note that there is a new bill submitted to the Israeli legislature, the Knesset Israel, for the purpose of regulating private consumption of cannabis for recreational purposes. It is unclear at this stage whether the bill shall be adopted. Furthermore, although cannabis is not legalised, the non-official policy of the Israeli police is to not submit charges against private consumption of cannabis.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Israel?
 - a. The regulatory challenges in allowing the medical use of cannabis are, among others, related to the establishment of the new agency. Agency duties such as approving licences and supervision and research of cannabis require continual governmental support.
 - b. In addition, the regulatory challenges are focused on ensuring the quality of the cannabis products for potential patients and the security required for all the custody chain of cannabis.
3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Israel?

As stated above, the consumption of cannabis in Israel for recreational purposes is currently prohibited.

1. Medicinal Use

There are two ways in which a licence to possess and use medical cannabis can be obtained for patients meeting the criteria specified in Procedure 106 - licences for cannabis use, as follows:

- 1.1. Through a doctor authorised by the IMCA to issue a licence at the time of the visit.
- 1.2. Online application by a specialising doctor.

2. Occupation in the cannabis field

3. In order for individuals or corporate bodies to be occupied in the Israeli cannabis field, they must obtain the appropriate licence from the IMCA. There are seven different licences, as follows:

4. Production Licence – regulates the cultivation and replication stage of cannabis. The procedure is based on the general requirements for appropriate cultivation (GAP) for plants and World Health Organization guidelines and international standards for growing fruits and vegetables, as well as the “Best Known Practices” standards used by leading countries worldwide. Cannabis will only be grown on cannabis farms, in suitable growth homes which will hold a valid licence under the Dangerous Drugs Ordinance. Any growing licence holder will be allowed to exclude cannabis from the farm area only to a licenced manufacturing plant.
 - 4.1. Licence to manufacture cannabis products – Cannabis products are only manufactured in cannabis product manufacturing plants that hold a valid licence under the Dangerous Drugs Ordinance. Cannabis plants shall be processed into products in cannabis product manufacturing plants only and to be used in accordance with appropriate professional standards.
 - 4.2. Commercial house Licence (Storage) – Cannabis products shall be shipped to cannabis commercial houses with valid licences under the Dangerous Drugs Ordinance. The commercial houses shall operate in accordance with appropriate professional standards (the existing GDP for a drugstore, tailored to cannabis products) and from there the products shall be distributed to the pharmacies.
 - 4.3. Pharmacy licence to issue cannabis products – Cannabis products shall be issued at pharmacies applying to do so and meeting the required conditions. In such pharmacies, cannabis products shall be issued to patients holding a licence to use cannabis and in accordance with the licence conditions. The dispensing and administration of cannabis products shall be carried out in accordance with the instructions of the Israeli Ministry of Health.
 - 4.4. Cannabis service Laboratory – Cannabis products shall be examined, developed and researched at laboratories that hold a valid licence under the Dangerous Drugs Ordinance.

- 4.5. Cannabis extermination licence - Cannabis including cannabis products shall only be exterminated by a licensed exterminator.
- 4.6. Cannabis transportation licence - Cannabis products shall be transported only by transporters with valid licences under the Dangerous Drugs Ordinance.

5. Cannabis importation

In order for individuals or corporate bodies to import cannabis, they must obtain the following conditions/licences:

- 5.1. Receiving of commercial house licence (storage) from IMCA.
- 5.2. Receiving approval of the Ministry of Agriculture & Rural Development to import a dangerous drug.
- 5.3. Receiving the approval of the Ministry of Health Drug Import Department with respect to importation licence and dangerous drugs importation licence.
- 5.4. Importing the cannabis.
- 5.5. Releasing the cannabis from the Israeli customs in accordance with the Dangerous Drugs Ordinance.

4. Which body is responsible for legislative controls relating to CBD?

Although a bill to exclude CBD from the Dangerous Drugs Ordinance has been submitted in the year 2019, it has yet to be adopted; hence CBD is not legalised and the use and/or occupation in the field of CBD requires the same licences and approvals as hereinabove mentioned for cannabis.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Israel?

Not relevant - please see answer above.

6. What are the testing specifications in India for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Not relevant - please see answer above.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Not relevant - please see answer above.

Contacts in the firm

Advocate Yoav Caspi

Head of corporate and commercial department

Email: YoavC@ayr.co.il