

ISRAEL



Law and Practice

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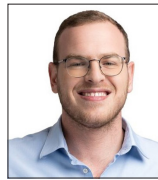
and trade marks; employment agreements; and general financing matters. Herzog Fox & Neeman's cannabis desk offers a range of strategic and legal services, both locally and internationally. The firm advises clients on all stages of the supply chain – from cultivation, manufacturing, marketing and distribution to sale. The office maintains direct contact with regulatory cannabis bodies in Israel and overseas, leading foreign firms servicing the cannabis industry, and research and pharma entities at the forefront of cannabis technology.

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1. Regulatory Framework

1.1 Primary Laws & Regulations

The State of Israel signed the 1961 Single Convention on Narcotic Drugs (“the Convention”) aimed at stepping up comprehensive measures and international co-operation against drug trafficking. In particular, the Convention establishes unique supervision and controls of cannabis, including the existence of a government agency responsible for regulating its use.

In addition to the Convention, local laws, an ordinance, government resolutions, and official procedures regulate Israel’s medical cannabis industry. The 1977 Penal Law sits at the heart of criminal law in Israel, and addresses the matter of drugs, including cannabis, although mainly within the context of convictions. The Dangerous Drugs Ordinance (New Version) enacted in 1973 (the “Ordinance”) and the Dangerous Drugs Regulations of 1979 (the “Regulations”), as amended from time to time, regulate the use of cannabis in the country. The Ordinance is divided into two additions, with the first further separated into two parts that distinguish between substances, the lawful possession of which requires a licence from the Director as defined in the Ordinance – “the Director General of the Ministry of Health or a person authorised by the Director” (“The Direc-

tor” or “IMCA”, respectively), and those that only require a prescription. Currently, cannabis is listed under the first part of the first addition, and therefore a licence from the IMCA is required for lawful possession.

In April 2022, the Knesset, or Israeli parliament, officially approved the Administrative Offences Regulations (Administrative Fine – Possession of Cannabis and its Use for Personal Consumption), 5772–2022 (“Administrative Offences Regulations”) that completely rescind the possession of up to 15 grammes of cannabis for personal use as a criminal offence, and stipulate that such possession will constitute an administrative offence only.

In 2011, as part of Government Resolution 3609, the government committed to a programme that included policy development, enforcement, and supply for cannabis patients and researchers in the field. The development of this programme has made the state of Israel one of the first countries in the world to allow a quality supply source for medical cannabis patients similar to that of other medicines. Following this Resolution, in 2011, the Israeli Medical Cannabis Agency at the Ministry of Health (IMCA) was established.

Additionally, in 2013, Government Resolution 1050 was approved to regulate the area of cannabis for medical use, creating a proper cannabis supply source according to predetermined and established standards, as committed to by Resolution 3609.

In 2016, Government Resolution 1587 introduced regulation for the field of cannabis for medical use and research. The IMCA published the procedures, instructions and standards for handling the high-grade medical cannabis required for medication. The aim was to position cannabis closer to medicine by applying as many similar standards as possible, ensuring that the products produced from the plant are of high quality, and also to make the process of obtaining a medical cannabis licence/prescription easier for patients.

In 2016, the IMCA published procedures (“IMCA Procedures”) for the medical cannabis industry that are still continuously updated to this day and include the following.

- Procedure 106 specifies the indications and medical conditions alongside the criteria for obtaining licences and/or prescriptions for the use of cannabis products.
- Procedure 107 specifies the guidelines for the operation, licensing, and manufacturing process applicable to cannabis and its derivatives for medical use (the “Road Map”).
- Procedure 108 specifies the guidelines for submitting applications for licensing research and approving new forms of administration in the field of cannabis.
- Procedure 109 outlines the guidelines for the approval process for applications to import cannabis as a dangerous drug for medical use and research.

- Procedure 110 specifies the approval process of applications for the export of cannabis as a dangerous drug.
- Procedure 151 (GAP-IMC) stipulates the proper growing conditions for medical cannabis.
- Procedure 152 (GMP-IMC) specifies the quality requirements in manufacturing cannabis products for medical use.
- Procedure 153 (GDP-IMC) stipulates the specifications needed for storage, distribution and delivery of medical cannabis products.
- Procedure 155 (GWDP-IMC) mandates the correct elimination process for cannabis intended for destruction.

In August 2023, the Ministry of Health published an “Enabling Reform Outline” (“the Reform”), in light of which, on 1 April 2024, the IMCA’s Regulations and Procedures were amended. In accordance with the Reform, it is now possible for doctors to prescribe cannabis for medical purposes within the framework of public medicine, according to the Regulation’s guidelines, as opposed to the previous licence model. Subject to Procedure 106, the prescriptions may be given to patients under certain indications set down by the IMCA. The Reform also eliminated cannabis as a “last resort treatment” for some indications, as detailed in **3.1 Access to Medical Cannabis**.

In addition, the Reform has made cannabis research simpler. The research approval process now includes a structured research licence for farms or factory owners and a standardised method of proving the safety and efficacy of new delivery systems. It also facilitates research on new products in various fields including cosmetics, nutritional supplements and animal products, etc.

Moreover, the Reform calls for several easements, as follows:

- significant alleviation of the export process;
- changes to product packaging; and
- the approval of new delivery systems due to the significant health risks associated with smoking, resulting in vast public interest in enabling new ways of cannabis consumption, etc.

Furthermore, some cannabinoids are expected to be exempt from the Ordinance (see **3.2 Non-Controlled Cannabinoids in Food**).

1.2 Regulatory Bodies

As the Convention required the establishment of the IMCA, it was set up in 2011 under the Ministry of Health, according to Government Resolution 3609. Subject to the Ordinance, the IMCA grants patients who meet the criteria licences or prescriptions to use medical cannabis. Procedure 106 laid down the indications, conditions, and situations in which a medical cannabis licence can be issued to a patient. As mentioned, according to the Ordinance, cannabis is defined as a dangerous drug, and prohibited for use without a licence or prescription.

The IMCA is the responsible regulatory entity for all regulation regarding the issuance of licences to operators in the field of medical cannabis, and thus constitutes a significant and almost exclusive regulatory body in the field. Any entity interested in engaging in the medical cannabis market that meets the threshold conditions specified by the IMCA will be able to engage in commercial cannabis activity, such as propagation, cultivation, manufacturing, transportation, warehousing, distribution, pharmacies, R&D, destruction, etc.

That said, there are several other regulatory bodies involved in the medical cannabis industry, as follows.

The Israeli Police

Once the initial application has been made for a licence to operate/use cannabis, the police are responsible for checking whether any information about the applicant could disqualify them from receiving a licence. If such information exists, the request will be denied. If no disqualifying information comes to light, it is possible to obtain an initial approval/licence, assuming the applicant satisfies all remaining conditions. In addition, the police examine and issue security approval for the location of a cannabis business every time a licence is renewed.

The Ministry of Agriculture

Applications for a cultivation licence require preliminary approval for the location of a cannabis farm from the Rural Planning and Development Division of the Ministry of Agriculture. In certain cases, approval from the Ministry of Agriculture will also be required in order to perform pesticide residue tests with respect to the agricultural produce of the farm.

The Israel Land Authority

The Land Authority restricts the use of agricultural land for commercial purposes (see **1.4 Challenges for Market Participants**).

The Planning Administration

To obtain a licence to operate facilities, one must meet the requirements of planning and building laws. Additionally, for some applications, a certificate proving that the applicant has lawful rights in legally constructed buildings may be required; or, in the case of building plans, a building permit must be attached.

1.3 Self-Regulatory Authorities

While in Israel regulation and supervision of the activities of patients and operators in the cannabis market is carried out exclusively by the government and the competent authorities, there are entities and associations that act for the benefit of patients and the public. The main associations are as follows.

- The Medical Cannabis Association, established by medical cannabis patients in 2016 with the aim of promoting their public activities and patient rights. The association promotes its goals, inter alia, by filing petitions to the High Court of Justice and providing voluntary accompaniment in the approval process for individual patients. In addition, the association advises and guides hundreds of cannabis patients annually through bureaucratic and legal channels.
- The medical cannabis lobby in the Knesset, which assists in the promotion of legislation and protection of patient rights, and carries out parliamentary, legal and media activities to raise awareness and promote solutions to issues within the cannabis field.

1.4 Challenges for Market Participants

Market participants face several notable challenges in Israel, the main one being frequent regulatory fluctuations arising from the fact that the cannabis market is still new and cultivating a body of knowledge via research. As such, regulations are constantly adapting to catch up with a rapidly developing industry, and local industry players that are developing new products must take this impaired reliability into account in making business decisions.

Also, it should be noted that, according to the Ordinance, cannabis, and that includes any part of the plant, is still defined as a dangerous drug.

This has resulted in the adoption of a slightly negative attitude towards the local market and the entrepreneurs who wish to operate within the related legal framework provided. However, the market's public image is steadily improving.

In addition, considering the political instability that the State of Israel has been experiencing, various arrangements and laws regarding some areas of the cannabis field remain unclear, increasing uncertainty and reducing confidence in the norms currently in force.

Finally, as of the time of this publication (May 2024), the Israeli market is limited in several areas compared to other markets around the world, due to the existing legal prohibition on the following products/components:

- cannabis oil for vaping and smoking; and
- cannabis or hemp in consumer products/goods such as food, supplements, and cosmetics.

Agricultural Settlement Law

In accordance with Section 8.12.1 of the Israel Land Council Resolution 2024, the use of agricultural land for commercial purposes is restricted such that cannabis companies operating on agricultural land owned by the government (which represents over 90% of land) are limited in their share capital. This introduces a built-in restriction on operators, forcing them to make do with low holdings.

Cultivation in Greenhouses and Climatic Conditions

In Israel, most cannabis cultivation is carried out in greenhouses, and is subject to seasonal conditions and the variables of nature. In fact, some farms can grow only during certain months of the year, and mainly during the winter. The scorch-

ing heat of the Israeli summer forces growers to use expensive cooling mechanisms in cultivation rooms, which often forces breaks until the end of the warm season to avoid heavy electricity costs.

Both in Israel and around the world, raising capital for cannabis companies under current market conditions is challenging, and is compounded by the significant price declines that cannabis has endured across the globe, which have also affected the local market. Additionally, cannabis patients' preferences often fluctuate according to personal taste and participation in forums and groups on various media, which is particularly significant in the very small Israeli market. Rapid changes in patients' tastes and preferences often require companies to adapt quickly, sometimes leaving them with unsold inventory.

Lack of Personalised Treatment

Despite global and ongoing research, it is difficult to adapt cannabis strains to patients based on their individual needs, which is a challenge for both cannabis companies and patients alike. However, it is important to emphasise that the field remains determined to continue research and eventually bridge this gap.

1.5 Legal Risks

As stated, the Israeli cannabis industry is still considered new, and has not yet stabilised. Against this normative backdrop, companies face the following legal risks:

Legislation Changes

As detailed in 1.1 **Primary Laws & Regulations**, Israeli legislation regarding cannabis consists of a hierarchy of many legislative documents. These include the Ordinance, regulations and government decisions that change and are updated from time to time. Government reso-

lutions and the legal landscape are constantly changing, meaning that one of the current major legal risks is long-standing uncertainty, particularly considering the frequent turnover of governments and lack of governmental stability.

Liability and Criminal Record

As part of the process of obtaining approval to operate in the medical cannabis field, the operator is required to present a list of all those involved in their company. This list includes all interested parties, signatories, and managers/office holders, as well as any employees or subcontractors working in the field on behalf of the operator. The list is forwarded to the Israeli police, who examine the involved parties and their registration as well as any information available in the police systems. If disqualifying information arises, the operator will receive notice that their application has been rejected. As part of the application review process, the IMCA and the police are not required to disclose to the operator the reason for disqualification.

The IMCA's Extensive Enforcement Power

There are many guidelines that operators must meet across all the links of the value chain, including cultivation, manufacturing, storage, distribution, marketing, and dispensaries. The frequent regulatory changes, introduced at the discretion of the IMCA and the Ministry of Health, have led companies to cease their activities due to non-compliance with new restrictions and demands.

This reality of swift changes creates a certain risk for operators and constitutes a major consideration in entering the cannabis arena, since, if they do not meet new mandatory requirements, they may be required to destroy their goods and sometimes even cease activities.

Cannabis and Driving

In Israel, the legal status of medical cannabis patients behind the wheel is complicated. From a legal standpoint, it is strictly forbidden to drive while under the influence of cannabis or cannabis metabolites. That said, the prohibition comes with no clear provisions regarding the time that a driver should wait from the moment they consume medical cannabis until driving is permitted again. The issue has not yet been regulated by legislation. However, the Ministry of Health is set to publish regulations that will allow patients to drive under certain conditions, depending on the length of time that has passed since the cannabis was consumed and the amount of cannabis present in the patient's body. As long as such regulations have not come into effect, driving is prohibited for any person (including licensed patients) under the influence of cannabis or its metabolites.

Advertising Medical Cannabis Products

Under the law, it is illegal to advertise medical cannabis products without the written approval of the IMCA and outside of non-medical mediums. But it should be clarified that, in some cases, and at the discretion of the IMCA, certain content can be considered for advertising. The rationale behind this prohibition is to protect public safety by avoiding the creation of a recreational retail atmosphere that encourages the use of cannabis for non-medical purposes.

This makes the operation of cannabis-based business challenging, as one must retain a competitive advantage without the aids of advertisement and marketing materials. However, it should be noted that while specific products may not be advertised, there are no limitations on advertising the cannabis companies themselves.

Importing Medical Cannabis

Under the current regulatory framework, importing cannabis into Israel is permitted, and imported products constitutes a high percentage of the products on the shelves. However, to import cannabis into Israel, one must meet the requirements of Procedure 109, which defines the import procedures in all aspects required. Under this framework, the import of cannabis end products is permitted only if they were manufactured under GMP IMC or EU-GMP standards, provided that they were transported, stored and maintained in proper transportation and storage conditions as defined by the IMCA. Compliance with these rules poses an additional challenge for those working in importation.

These risks are in addition to the hurdles presented in **1.4 Challenges for Market Participants**.

1.6 Enforcement & Penalties

Since cannabis is defined as a dangerous drug in the state of Israel, any unlicensed or unapproved operation with cannabis constitutes a violation of the criminal law and carries a criminal punishment in accordance with the Penal Law, 5737-1977.

Accordingly, both companies and prospective patients must comply with the Ordinance, the Regulations and IMCA Procedures. Failure to comply with the aforementioned constitutes a criminal offence that may lead to sanctions.

Enforcement and Penalties for Individuals

The entities tasked with enforcing compliance are mentioned in **1.2 Regulatory Bodies** above.

The Administrative Offences Regulations mentioned in **1.1 Primary Laws & Regulations** impose a monetary fine of ILS500 on individu-

als found with up to 15 grammes for personal use. Additionally, using cannabis in a public place will result in a fine of ILS1,000. Soldiers, prison guards and police officers were excluded from the Regulations, meaning that, for them, any amount of cannabis possession constitutes a criminal offence. In addition, following the Regulations, President Herzog and the Minister of Justice called on citizens who were convicted of using or possessing cannabis for personal consumption to appeal to the authorities to have their criminal records expunged. The Administrative Offences Regulations also stipulate that possessing a quantity larger than 15 grammes for personal use may hold a penalty of up to three years in prison. Additionally, a penalty of up to 20 years in prison applies for importing, trafficking, supplying or any other transaction involving cannabis.

Enforcement and Penalties for Operators

In accordance with the provisions of Procedure 107, all interested parties, signatories, managers/office holders, employees and any subcontractors engaging in the field on behalf of the operator must comply with the Ordinance, Regulations and Procedures and their licence, as mentioned in **1.1 Primary Laws & Regulations**.

The operator is required to detail any changes to the details of the involved parties indicated above to the IMCA.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

There are no common cross-jurisdictional applicable.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

There are several elements that affect access to obtaining a licence to operate or use medical cannabis, as follows.

Lack of Authorised Doctors to Issue Medical Cannabis Licences

There are over 140,000 medical cannabis patients in the State of Israel today. However, there are only 65 doctors who are authorised to issue and renew licences for these patients, of whom a much smaller number do so in practice. This situation causes many delays and difficulties in obtaining and renewing licences.

Lack of Insurance Reimbursement

Currently, medical cannabis is not defined as a registered medication in the Israeli Medication Registry. Therefore, most insurance companies will not reimburse expenses for the purchase of medical cannabis and its ancillary products. The few insurance companies that do reimburse patients do so only for oncology patients.

Likelihood of Increasing Patient Access

There is high likelihood that patient access to medical cannabis will increase as regulations become more favourable. As mentioned in **1.1 Primary Laws & Regulations**, the Reform eased and simplified all regulatory and licensing processes for patients.

The most significant change brought on by the Reform was the introduction of a prescription-based model rather than the previous licence-based model for the following:

- cancer;
- Crohn's disease;

- AIDS;
- multiple sclerosis;
- Parkinson's disease;
- Tourette's syndrome;
- epilepsy;
- autism;
- dementia; and
- those given the prognosis of less than six months to live.

Additionally, the Reform eliminated cannabis as a "last-resort treatment" for the following indications:

- cancer;
- stomach illnesses;
- AIDS;
- multiple sclerosis;
- Parkinson's disease;
- epilepsy; and
- dementia.

Previously, patients had to demonstrate that other conventional forms of treatment were ineffective over long periods of time although now, for some indications, the period required for demonstration is shorter.

Both milestones show a trend in broadening patient access to medical cannabis, and there is a high likelihood that this trend will continue.

3.2 Non-controlled Cannabinoids in Food

Currently, cannabis is defined in the Ordinance as "Any plant or part of a plant of the cannabis family and any part thereof, including its roots but excluding oil produced from its seeds" (the first addition to the Ordinance).

Thus, all parts of the cannabis plant are considered dangerous drugs, and are completely

prohibited for use or consumption in any way, including in food and cosmetics. Despite the above, according to publications by the Ministry of Health regarding the Reform, it is possible that, as of early June 2024, only cannabis with psychoactive components with a concentration of more than 0.2% THC (and the rest of its family of cannabinoids) will remain in the Ordinance. Thus, cannabinoids with less than 0.2% of psychoactive components will no longer be covered under the IMCA regulation, but rather under the food and cosmetics regulation.

3.3 Decriminalisation

In Israel, the recreational use of cannabis is strictly prohibited. The legislative source of the criminal prohibition is the Ordinance, which defines the rules regarding the various types of offences (possession, cultivation, commerce, etc.) and determines the various penalties for these offences.

"Decriminalisation" Regulations

The prohibition notwithstanding, in recent years there has been a change in attitudes in state institutions regarding minor drug offences (personal use of cannabis). Thus, in April 2019, the Dangerous Drugs Law (Special Fine Offence – Temporary Order), 5778–2018, came into effect, which states that an offence of consuming or possessing cannabis for personal use will result in an administrative monetary fine only. If another offence is committed within five years from the date of the first offence, the fine will be higher. These fines will be considered a special fine offence under the Criminal Procedure Law (Combined Version), 5742–1982.

After three years, with the expiration of the order, the Knesset officially approved the Administrative Offences Regulations, which stated that possession of cannabis for personal use (up

to 15 grammes) will result in an administrative offence only (see **1.6 Enforcement & Penalties**).

Export to Non-medical Markets

The Reform includes easements in cannabis exports. Prior to the Reform's entry into effect, cannabis could be exported only in accordance with Israeli rules and standards and only for medical purposes. In accordance with the Reform, the words "for medical use and research" were deleted from Procedure 110, which defines the guidelines for the approval process of applications for export of a dangerous cannabis drug.

This change marks a significant and positive milestone for exporters, as it dramatically expands their market reach. Additionally, exporters are no longer bound by stringent regulations, as there is no longer a need to comply specifically with Israeli standards, although they still require an import permit from the receiving country.

In conclusion, over the years, many bills have been and continue to be submitted, aimed at regulating recreational use. This increase in legislative pressure demonstrates an upward trend in favour of legalisation.

Disclaimer: While the above discusses legal issues, and is grounded in expert legal knowledge, it does not constitute legal advice or act in replacement of it. Moreover, it is only applicable at the time of publication of this guide (May 2024), as the legal landscape is constantly evolving.

Trends and Developments

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Herzog Fox & Neeman combines an interdisciplinary approach with its extensive team of hundreds of legal personnel. The firm's expertise allows it to provide businesses with tailored solutions to legal issues, promoting both organic and M&A-based growth. Services include approval and licensing; representation before regulators; local and international M&A; corporate law; investment transactions; commercial agreements; IPOs; dual listings; mass financing; ongoing consultation to public and private companies; tax consultation; medical patents

and trade marks; employment agreements; and general financing matters. Herzog Fox & Neeman's cannabis desk offers a range of strategic and legal services, both locally and internationally. The firm advises clients on all stages of the supply chain – from cultivation, manufacturing, marketing and distribution to sale. The office maintains direct contact with regulatory cannabis bodies in Israel and overseas, leading foreign firms servicing the cannabis industry, and research and pharma entities at the forefront of cannabis technology.

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Introduction – Pathway to Legalisation?

For years, the legalisation of cannabis has been gaining traction gradually in Israeli discourse. However, despite winning support both in the court of public opinion and among many lawmakers over the years, various efforts towards full legalisation have stalled in parliament. While Israel's medico-regulatory approach to cannabis has driven imperative research and development, it has challenged broad access to those in need and limited commercial opportunities for local industry as its regulation remains very tight. However, reforms implemented this year, bi-partisan support and increased demand all point to a major shift, offering the potential for easements for patients as well as commercial opportunities across the entire value chain.

Short Overview – History of Regulation and Status Quo

Under the 1961 Single Convention on Narcotic Drugs (the "Convention"), of which Israel is a signatory, and its Dangerous Drugs Ordinance (DDO), cannabis is classified as a "dangerous drug" in Israel. Nonetheless, both allow for the medical or scientific use of cannabis under strict supervision and regulation.

In 2011, Government Res. No 3069 established a regulatory authority in Israel responsible for all aspects pertaining to the supervision, control, and regulation of cannabis with respect to its propagation, cultivation, post-harvest processing, distribution, delivery, possession, transportation, destruction, consumption, and research, under the Ministry of Health. In 2013, these responsibilities and associated powers were transferred to the newly established Israel Medical Cannabis Authority (IMCA).

In terms of patient reimbursement in Israel, cannabis patients are entitled to partial or full reimbursement under the discretion of the Ministry of Defence and the National Insurance Institute (social security).

Although the Ministry of Health has granted patients licences to use cannabis for medical purposes under certain conditions, it maintains that cannabis is not a medicine, and that its efficacy and safety as a medicine have not yet been sufficiently demonstrated. It also contends that cannabis should be handled like any other complementary medical product that is subject to regulation in order to protect public health and welfare.

However, Procedure 106 of the IMCA, which sets out a list of medical conditions that merit treatment with medical cannabis products, and was published along with its inception, states that there is evidence that cannabis could aid patients afflicted with certain medical conditions and alleviate their suffering. Medical disorders are periodically reviewed and updated for inclusion. They currently include Tourette's syndrome, multiple sclerosis, cancer, pain, nausea, seizures, muscular spasms, epilepsy and post-traumatic stress disorder.

Pursuant to Procedure 106, medical cannabis licences were granted to patients by a select number of IMCA-approved doctors which, at times, presented a complex bureaucratic situation as bottlenecks were created due to high demand and the limited number of authorised doctors.

A framework for regulating the cannabis industry for medical purposes and establishing a reliable source of cannabis supply in accordance with agreed-upon standards was adopted in 2013 with Government Res No 1050 ("Resolution 1050").

The "Road Map," also known as Government Res. No 1587 ("Resolution 1587"), was enacted by the Israeli government in 2016, establishing a uniform licensing procedure for all cannabis-related activity. Based on the Road Map, each operation in the medical cannabis field, including propagation, cultivation, manufacturing, storage, distribution, and pharmaceutical services, must comply with the provisions of applicable laws and have IMCA approval.

The aim of the resolution was to regulate the use of cannabis for medical purposes and establish professional authorisation criteria for its use in

treating medical conditions. The "Road Map" resulted in the following:

- it gave cannabis medical status;
- it ensured medical-grade product quality through proper supervision;
- inessential barriers for patients were removed and accessibility eased;
- the number of authorised doctors was increased;
- the number of operators engaged in cultivation and supply was extended; and
- it introduced supervision of proper medical practice and use labels.

Of special note is the fact that, for some medical conditions, the resolution examined the transition from a licensing regime to a prescription regime.

In April 2019, the Ministry of Health's Medicalisation Reform entered into force enacting a new reform regarding the issuance of licences and the use of medical cannabis. The reform created a shift away from the grower-to-patient distribution model in favour of a comprehensive value-chain model that covers not only the growing of medical cannabis but also manufacturing, storage, distribution, transportation, and exclusive pharmaceutical services. The new model nevertheless retained the licence-for-use requirement.

The Medicalisation Reform also defined new procedures and standards of quality and security, resulting in many farmers suddenly finding themselves no longer compliant. This led to their closure by the IMCA and to the destruction of much of their produce, resulting in a noticeable deficit in medical cannabis supply, negatively affecting patients and their therapeutic continuity. The result was the approval of a cannabis importation procedure and the easing of gov-

ernmental controls relating to the importation of medical cannabis products. As part of the Medicalisation Reform, the Israeli government also approved the export of medical cannabis.

Following the full implementation of the Medicalisation Reform, patient numbers climbed and eventually doubled, hitting 59,431 by February 2020.

Additionally in 2019, a three-year provisional ruling decriminalised adult usage of non-medical cannabis. The order stipulated that the private possession of cannabis would now be punishable by a specific fine offence, according to the procedures of Criminal Procedure Law, of ILS1,000 in total for the first infraction and roughly ILS2,000 for the second. If an adult repeatedly breaks the law, authorities may, at their discretion, launch criminal proceedings.

After the interim order came to an end in 2022, the Administrative Offences Regulations (Administrative Fine-Possession and Use of Cannabis for Self-Consumption) were formally passed by the Israeli parliament. These regulations completely abolished the criminal record for the offence of cannabis possession for personal use (in an amount of up to 15 grammes) and state that such possession will result in an administrative offence with imposition of a fine of ILS500, and that using cannabis in a public place will result in a fine of ILS1,000.

Furthermore, the regulations eliminated the distinction between the first infraction and subsequent offences (resulting in a greater punishment). The proposed laws also impose an administrative fine on those with criminal records; however, juveniles, inmates, and military personnel were left out of these decriminalised measures.

In accordance with the Administrative Offences Regulations, the President and the Minister of Justice invited those who had been found guilty of using or possessing cannabis for personal use to contact the authorities and request that their criminal records be expunged.

This shift from criminal to merely administrative punishment was perceived by the public as a significant step toward a less stringent regime.

Currently, CBD is regulated by the DDO, and is still perceived as a dangerous drug. In 2024, Israel intends to remove CBD and other non-THC cannabinoids, such as THCV and HHC, from the DDO. This initiative was also seen as encouraging by the public.

It is widely accepted that 2024 will be a year of significant cannabis reforms as the Ministry of Health published a draft for public comments entitled “Enabling Reform Outline” in August 2023, in which regulations and IMCA procedures were amended to ease and simplify all regulatory and licensing processes for practitioners, patients, entrepreneurs and operators.

The Enabling Reform is the broadest medical cannabis regulation to date. Perhaps the most anticipated change was the shift away from the licence model. Medical cannabis will become available through prescription for some medical conditions, like any other medicine, and will not be limited to a small number of IMCA-approved doctors, which is expected to eliminate the previous bottlenecks.

On 1 April 2024, the move away from licences to prescriptions came into force for cancer, Crohn’s disease, AIDS, multiple sclerosis, Parkinson’s disease, Tourette’s syndrome, epilepsy, autism, dementia, and for those with terminal illnesses

and a prognosis of less than six months to live. All these patients are now able to obtain prescriptions from their doctors without a licence. Opponents contend that ignoring the needs of patients left outside the scope of this stipulation, eg, those suffering from PTSD, fibromyalgia, and chronic pain, could spur the use of substitutes from the opiate family of drugs.

As of April 2024, there are above 140,000 registered cannabis patients in Israel. As seen with the introduction of previous cannabis reforms, a further drastic increase in patients is expected as additional parts of the Enabling Reform enter into force incrementally.

Key Players and Characteristics

Israel boasts one of the world's most extensive and well-organised medical cannabis markets, with one of the highest patient per capita ratios.

The value chain in Israel is divided into the building blocks of cultivation, production, storage and distribution, transportation, and dispensation (pharmacies).

In addition to the various stakeholders described above, a number of government entities are involved in the ecosystem, as follows.

- The Ministry of Defence, the Ministry of Health, and the National Insurance Institute (social security) handle patient reimbursement, financing, and serve as recommending bodies;
- The Ministry of Agriculture preliminarily handles applications for a cannabis growing/breeding farm licence; the Israel Land Authority restricts the use of agricultural land for commercial purposes; and the Planning Administration ensures that licence applicants meet planning and building law requirements.

After the initial stages of an application for an occupation licence are cleared, the Israeli police are tasked with assuring that an applicant's record, including their criminal record, does not contain information that disqualifies them from receiving the licence.

The relatively large and growing quantity of cannabis patients in Israel has also boosted stakeholders in pharmatech, agritech and startups, attracted domestic and foreign investors, and driven further medical research in academia and hospitals.

The characteristics of the market are substantially influenced by Israel's:

- well-established clinical trial system;
- early foothold in cannabis research;
- advanced R&D capabilities;
- very significant concentration of startups; and
- universal healthcare system that continues to offer the market as it expands.

The Israeli medical cannabis market is supplied through local production as well as imports from, among other countries, Canada, Portugal, Lesotho, Uganda and South Africa. The market is undoubtedly a significant player in terms of import volumes, despite the small size of the country. Israel also exports cannabis, a trend that is expected to continue as the Israeli government eases exports for medical cannabis and allows for the export of non-medical cannabis, as per the Enabling Reform.

Future Developments and Trends

The local market is set to respond to the aforementioned top-to-bottom Enabling Reform and encourage several trends pertaining to both patients and the local industry.

In terms of patient trends, significant growth is expected, as the market will become more accessible to many given the transition to a prescription model, as the pre-reform licensing mechanism created bottlenecks and required patients to navigate heavy bureaucracy.

The Enabling Reform is set to allow cannabis as a first-line treatment for some, as opposed to merely a treatment of last resort, offering better access, as the period required to demonstrate that other conventional forms of treatment were ineffective is shortened. Additionally, the Enabling Reform will expand the pool of those eligible for treatment, eliminating some age limits, including children with certain chronic conditions.

As of April 2024, the number of registered cannabis patients stood at just over 140,000. The regulatory changes, as well as the outcomes of the war, which led to an increase in PTSD cases and patients with chronic pain, are expected to significantly increase an already growing number of patients by approximately 70%.

In terms of easements for the local industry, significant simplifications for market participants in medical cannabis are underway. These include cannabis exportation, which is set to significantly increase as the Enabling Reform will approve outbound cannabis for both recreational and medical markets, and will align with EU-GMP standards (without needing to comply with Israel's standards) which will further extend the global reach of market participants, as mentioned in **3.3 Decriminalisation** of Law and Practice for Israel's Medical Cannabis & Cannabinoid Regulation 2024. Furthermore, the reform is also set to encourage cannabis innovation and research through the simplification of the entire process.

These promising steps forward in the local industry are expected to boost the number of local cannabis companies, and their specialties, value, and quality, whether their focus be on products, medical devices, delivery systems, agritech, or R&D.

Experts also foresee that the Enabling Reform will reduce the demand for illicit cannabis, which has been seen worldwide.

Additionally, the ongoing ambiguity surrounding CBD regulation is set to be addressed. The country's CBD industry is subject to significantly harsher regulations than North America and Europe, which is why many view this as a major step forward.

Commercial Opportunities and Challenges

The current and prospective regulatory environment presents both opportunities and challenges in the local market.

In alignment with Israel's mature and robust technological infrastructure, commercial opportunities in medical cannabis largely surround the areas of R&D, medical devices, delivery systems, agritech, genetics, and cannabinoid development. These opportunities have attracted myriad local and international players in pharmatech, hospitals, academia, tech startups, and among investors.

Additionally, as Israel offers comfortable regulatory conditions for clinical research, many countries, including the US, Canada, Australia, and Germany, among others, have outsourced their research to Israel, meaning that clinical trials are underway in this promising field where there is still much to discover.

The current regulatory environment does, however, continue to pose challenges for entrepreneurs and patients alike, as regulation tries to catch up and adapt to a global and fast-developing industry. The local industry is eager to perform, and is outpacing sluggish or outdated regulation, while political instability serves as an additional hurdle. However, as mentioned, the Enabling Reform is set to propel commercial activity as restrictions ease.

In line with the rest of the world, local market participants are also being tested by a tightened investment environment as we witness a slowdown in capital markets, private equity, and venture capital investments hurting the entire cannabis sector. Moreover, cannabis companies around the world are struggling as product oversupply has led to a significant decline in both wholesale and retail cannabis prices, which also affects local industry. However, many view this current lull as a sign of market correction, echoing trends in other young industries.

Conclusion – Market Outlook and Expert Opinion on Legalisation

The changes seen in the medical cannabis industry in recent years, as well as the maturity of the market, which, once volatile and unpredictable, has now stabilised, offer an optimistic outlook for patients and market participants alike.

The Enabling Reform is widely viewed as a transformative measure due to its extensive reach, aimed at enhancing accessibility for those in need while simplifying the previously complex regulatory landscape, once characterised by convoluted bureaucracy and supervision under numerous authorities, leading many market participants to endure hardship or financial strain.

Local experts are divided on the subject of legalisation. Several of them endorse it, considering it a positive, unavoidable step that could lead to the creation of a globally recognised domestic industry. Proponents cite the trends of increased job creation, increased investments for a sector in need, and a decline in use among youths and in overall crime that has been linked to legalisation elsewhere. They also note the developments seen in states that have since legalised cannabis due to tax revenues generated that are then redirected towards various public services and infrastructure projects.

On the other hand, critics point out public health concerns due to misuse, overconsumption, and over-accessibility to young people that only regulation can curb, since cannabis can impair or harm if abused or consumed in an uninformed manner.

In light of the above, the question arises as to the path Israel will take if legalisation can happen, which would certainly constitute a major milestone in the timeline of the country's cannabis programme.

In conclusion, Israel's regulatory shifts and market response will be interesting to follow in the coming months as patients and market participants alike anticipate much awaited change.

Disclaimer: While the above discusses legal issues, and is grounded in expert legal knowledge, it does not constitute legal advice or act in replacement of it. Moreover, it is only applicable at the time of publication of this guide (May 2024), as the legal landscape is constantly evolving.