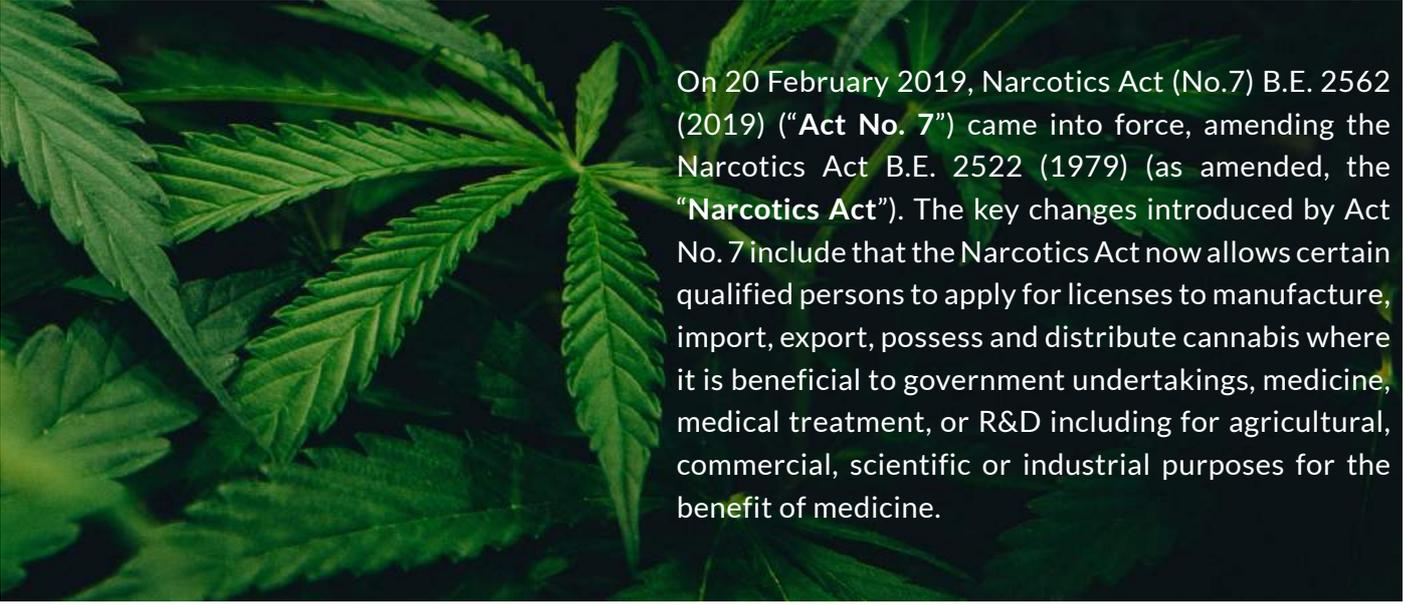


SPI Newsletter

CANNABIS – NEW BUSINESS OPPORTUNITIES IN THAILAND

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On 20 February 2019, Narcotics Act (No.7) B.E. 2562 (2019) (“**Act No. 7**”) came into force, amending the Narcotics Act B.E. 2522 (1979) (as amended, the “**Narcotics Act**”). The key changes introduced by Act No. 7 include that the Narcotics Act now allows certain qualified persons to apply for licenses to manufacture, import, export, possess and distribute cannabis where it is beneficial to government undertakings, medicine, medical treatment, or R&D including for agricultural, commercial, scientific or industrial purposes for the benefit of medicine.

More recently –

- (a) a draft Ministerial Regulation on the application for a license and the grant of approval to manufacture, distribute, import, export or possess narcotics of category 5 particular cannabis (“**Draft Ministerial Regulation**”) was approved by the Cabinet on 28 May 2019. However, the Draft Ministerial Regulation is currently being considered by the Council of the State and is subject to further amendment and approval; and
- (b) on 30 August 2019, the Narcotics Control Division of the Food and Drug Administration, Ministry of Public Health (“**TFDA**”) issued the Notification of Ministry of Public Health on the specification of name of narcotics of category 5 (No.2) B.E. 2562 (2019) (“**Notification**”) which provides a list of exempted substances that will not be deemed as narcotic substances under the Narcotics Act.

In this article, we provide a brief summary of recent legislative developments with respect to the licensing of certain activities involving cannabis for medical purposes in Thailand.

Scope of permitted activities

Cannabis is categorised as “**Narcotics Category No. 5**” under Section 7 of the Narcotics Act and is controlled under the Narcotics Act. The responsible governmental authority in relation to narcotics-related business in Thailand is the TFDA.

A qualified person may apply for a license from the TFDA pursuant to Section 26/2 of the Narcotics Act for the manufacturing, importation and exportation of cannabis (but only where it is beneficial to the government undertakings, medicine, medical treatment or R&D including for agricultural, commercial, scientific or industrial purposes for the benefit of medicine). And in relation to the distribution and possession of cannabis, a qualified person may apply for a license for those activities from the TFDA under Section 26/3 of the Narcotics Act.

Qualifications

Section 26/5 of the Narcotics Act stipulates seven categories of applicant who may apply for a license for the manufacturing, importation, exportation, distribution or possession of Narcotics Category No. 5. These categories include (1) governmental authorities, (2) medical profession practitioners, (3) higher education institutions, (4) registered agricultural practitioners who constitute community enterprise and social enterprise under the law governing agricultural cooperatives, (5) operator of international public transportation, and (6) patients who travel between countries (each subject to further specific criteria as specified under the Narcotics Act). In addition, the Minister of Public Health is empowered by Section 26/5(7) of the Narcotics Act to announce by ministerial regulation, with approval of the Narcotics Control Committee (“**Committee**”), other categories of applicant. In this regard, applicants under categories (2) (3) (4) or (7) who are juristic persons must be registered under Thai law with at least two-thirds of the directors, partners or shareholders having Thai nationality and an office in Thailand.

The transitional provision (Section 21) of Act No. 7 sets out the initial period of five years after the date that Act No. 7 is enforced (i.e. 19 February 2019), where a license for the manufacturing, importation and exportation of cannabis for the purpose of medical benefit or medical treatment shall only be issued to:

- (1) a governmental authority under Section 26/5(1); or
- (2) a cooperation between a governmental authority and other applicant mentioned in Section 26/5 (2) (3) (4) or (7) of the Narcotics Act.

Therefore, when considering Section 26/5 of the Narcotics Act together with the transitional provision of Act No. 7, it can be construed that, at present, a private sector company is not qualified to be granted a cannabis-related license. However, it remains to be seen whether a ministerial regulation regarding other types of applicant may be issued in the future which includes a private entity as one of the “other types of applicant” under Section 26/5 (7) of the Narcotics Act, which would in turn enable a cooperation between a governmental authority and the private entity to apply for a license during the 5-year initial period. We will be monitoring any developments closely in this regard.

Narcotics of Category 4 or Category 5 Ministerial Regulation

Under the Narcotics Act, the applicant must prepare and the Secretary-General of the Food and Drug Board, as a licensor, must consider the application conforming to and being in line with the criteria, methods and conditions of the application for and issuance of license prescribed in the ministerial regulations. In addition, the applicant will be responsible for expenses incurred in inspecting, analysing or assessing academic documents and other relevant expenses relating to the consideration of the application under the criteria and methods prescribed by the Committee and announced in the Royal Thai Government Gazette.



As the new ministerial regulation prescribing the abovementioned criteria, methods and conditions is still in draft form and has not yet been announced (discussed further below), the applicant must refer to the existing Ministerial Regulation on the application for license and the grant of approval to manufacture, distribute, import, export or possess narcotics of category 4 or category 5 B.E. 2559 (2016), which sets out the application process and timeframes, length of licenses, scope of permitted activities, and compliance requirements if being granted a license.

List of Exempted Substances

On 30 August 2019, the TFDA issued the Notification which provides a list of exempted substances that will not be deemed as narcotic substances under the Narcotics Act as follows:

- (1) Hemp which has been announced as narcotics of category 5 under the laws on narcotics.
- (2) Cannabidiol (CBD) extracted from cannabis with purification more than or equal to 99% and have tetrahydrocannabinol (THC) in the amount of not exceeding 0.01% by weight.
- (3) Extracts or product from extracts, having cannabidiol (CBD) as a main compound and tetrahydrocannabinol (THC) in the amount of not exceeding 0.2% by weight, which is medicine or herb product under the laws on medicine or herb product and shall only be used for the purpose of medicine or herb product.
- (4) Notwithstanding the above, within the first five years from the date on which the notification has come into force (i.e. 31 August 2019), the exemption under (1) to (3) shall be applicable only to a domestic production by the licensee under the relevant law.
- (5) Hulls, dried caudexes, dried fibre of Cannabis and other goods produced by hulls, dried caudexes and dried fibre.

Draft Ministerial Regulation on the application for a license and the grant of approval to manufacture, distribute, import, export or possess narcotics of category 5 particular cannabis

The Draft Ministerial Regulation was approved by the Cabinet on 28 May 2019, and is currently being considered by the Office of the Council of State, where it is subject to further amendment and approval. There is no timeframe specified for the consideration and approval by the Office of the Council of State.

Among other things, the Draft Ministerial Regulation briefly elaborates on “other type of applicant” but does not go as far as to include a private company in the provision. The list of “other type of applicant” depends on the objective for the application for a license to manufacture, import or export of narcotics of category 5. For example, if the objective is for the education, analysis, research of medicine, scientific or pharmacy, then “other type of applicant” includes: (i) a licensee who obtains a license to manufacture,



import or place an order into Thailand a modern medicine under the law on drugs; (ii) a licensee who obtains a license to manufacture, import or place an order into Thailand a traditional medicine under the law on drugs; (iii) a licensee who obtains a license to manufacture, import or place an order into Thailand a herb product under the law on herb products; (iv) a business operator relating to agricultural production; and (v) a business operator relating to education, analysis, research of medicine, scientific or pharmacy.

The Draft Ministerial Regulation also sets out specific qualifications if the applicant is a juristic person, which include: (i) being registered under Thai Law; (ii) having the following characteristics: Having residence or registered office in Thailand; not being bankrupted; not being an entity having suspension or withdrawal of license or certificate issued under narcotics law or psychotropic substances law; and never having been sentenced by a final judgment pursuant to narcotics law, psychotropic substances law, law relating to the prevention against abuse using of volatile substances or law relating to the measures for the suppression of offenders in an offence relating to narcotics; (iii) having the authorized representative of the applicant being of Thai nationality; and (iv) having at least two-third of directors, partners or shareholders being of Thai nationality.

Conclusion

While private entities do not presently qualify to apply for any cannabis related licenses in Thailand, there remains scope for that to change in the future, given:

- (a) the drafting in Section 26/5(7) of the Narcotics Act, which empowers the Minister of Public Health with approval of the Committee, to announce by ministerial regulation, other categories of applicant; and
- (b) the transitional provisional of Act No. 7 which allows a cooperation between a governmental authority and other applicant mentioned in Section 26/5(7) of the Narcotics Act to apply for a license during the initial 5-year period.

It is likely that further ministerial regulations and notifications will be issued in the coming months, and we will be closing monitoring any developments.

If you have any questions or would like to find out more about the regulatory landscape in Thailand with respect to cannabis for medical purposes, please contact us.

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