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Newsletter

THAI MINISTRY OF PUBLIC HEALTH AMENDS DEFINITION OF NARCOTICS – CDB PHARMACEUTICAL AND PRIVATE OPERATIONS REMAIN PROHIBITED

- In 2019, Thailand became the first Southeast Asian country to legalize the medical use of cannabis;
- In 2020, the Thai FDA amended the definition of Category 5 narcotics, to permit the use of certain
 parts of cannabis plants (among other 'narcotics') to develop medical cannabis and hemp products
 and for research purposes;
- In 2021, additional regulations were released for the purpose of issuing permits related to hemp cultivation and use;
- Thai authorities continue to consider abolishing prohibitions limiting production of cannabis and hemp products to government entities, allowing private companies to produce medical cannabis and hemp products; and
- Amendments have yet been introduced to legalize modern CBD pharmaceutical operations (Thai
 cannabis regulations only apply to Thai traditional medicines, herbal use and research).

Introduction

In 2019, Thailand became the first Southeast Asian nation to legalize the use of cannabis for medical use and research, as well as hemp in the production of textiles, garments and other products. Under the relevant regulations that loosened controls on cannabis and hemp, only government organizations can produce cannabis/hemp to produce related products for a five-year period until 2024. Currently, the laws continue to only apply to the production of cannabis for Thai tradition medicine and herbal use, with CBD pharmaceutical operations remaining prohibited.

In 2020, the Thai authorities, including the Thai Food and Drug Administration under the Ministry of Health, drafted amendments that, if approved, may allow private companies to begin production activities. In addition, in December 2020, a new notification issued by the Ministry of Public Health (the "Notification") became effective that amends the definition of what portion of the cannabis plant is considered a narcotic. This briefing will provide an overview of the current legal status of cannabis and hemp production and use.

Notification of the Ministry of Public Health Re: Narcotics under Category 5 of the Narcotics Act

Under the Thai Narcotics Act B.E. 2522 (1976) (the "Narcotics Act"), cannabis is classified under Category 5. The notification of the Ministry of Public Health, effective in August 2019 provides an exception for the use of specific parts or extracts of cannabis or hemp in specified quantities as additives in certain production of drugs, cosmetics and food.

The latest Notification of the Ministry of Public Health, effective on 15 December 2020, has elaborated and reclassified parts of the cannabis plant to allow the full exploitation of specific parts of the cannabis plant for medical and research purposes. Essentially, the notification exempts various components, such as stalks, stems, fibers, branches, roots, leaves, extracts containing cannabidiol (CBD) tetrahydrocannabinol (THC) content not exceeding 0.2%, or residues from extraction of cannabis containing THC not exceeding 0.2% from Category 5.

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Note that, the exemption only applies to cannabis cultivated domestically in Thailand.

Permits for production, sales, possession, and import/export of hemp

A new regulation issued by the Ministry of Public Health provides a list of permissible objectives for applicants applying for permits for the production, sale, possession, import or export of hemp (the "Ministerial Regulation"). This regulation is to become effective on 29 January 2021. An applicant for a permit for the production, sale, possession, import or export of hemp should have the following objectives:

- (i) a government's mission operation;
- utilizing fiber traditionally, culturally, or by way of life within the family with no more than 1,600 square meters of planting area per family, the objective of which cannot be subject to an application for a permit for import or export of hemp;
- (iii) commercial or industrial purposes;
- (iv) medical purposes;
- (v) education, analytics, research or seed development; or
- (vi) production of certified seeds.

If a government organization has objectives under item i), iii), iv), v) or vi) above, such governmental organization must apply for a permit for the import or export of hemp according to such specific objectives. This Ministerial Regulation also sets forth the qualifications of an applicant, the list of documents required to be filed with the application, and timelines for applications review/ consideration by the Secretary-General of the Thai FDA.

Under the Ministerial Regulation, a permit holder has the following obligations:

- procure a permanent sign board displayed to the public with a clear description in Thai specifying the permitted place for hemp cultivation for production, or the place of sale, import or export;
- analyze the quantity of tetrahydrocannabinol (THC) contained in hemp prior to removing hemp from cultivating plants in the case of the use of uncertified hemp seeds for cultivation;
- prepare accounts of receipt or distribution of hemp and report to the Secretary-General of the FDA;
 and
- notify the Secretary-General of the FDA in advance prior to transporting permitted hemp of the
 quantity of hemp to be transported, date and time of transportation, type of vehicle used, route of
 transportation and a transportation controller, etc.

If a permit holder plants hemp for the purpose of research and development or for the development of hemp seeds, such hemp seeds can be certified by registration with the Department of Agriculture in accordance with the Plant Varieties Protection Act B.E. 2542 (1999). Evidence of certification of hemp seeds for registration, and results of THC level examinations, are to be submitted to the Secretary-General of the FDA for approval.

Medical production and use of cannabis and hemp

The Ministerial Regulation carves out use of cannabis and hemp for medical use, if such use is for the following purposes:

- i) examination and analysis; or
- ii) checking addictive substances in a human body

Cannabis or hemp used for the purposes above is considered as a medical device and is subject to requirements under the Medical Device Act B.E.2551 (2008). Additionally, the utilization of such substances must comply with the objectives of the medical device in question.

The Secretary-General of the FDA or the Narcotics Control Committee are empowered to set forth rules, procedures and conditions to regulate details relevant to the permission to utilize hemp under this Ministerial Regulation. Procedures and conditions may include details as follows:

- the plan for production and utilization and destruction of hemp;
- production of hemp for use as raw materials for subsequent production of other non-hemp products;
- monitoring efficiency and safety;
- reporting of undesirable results of medicine produced from hemp; and
- adjustments to plans for exports or sale of hemp.

The Secretary-General or the Narcotics Control Committee may set forth such rules, procedures and conditions
by issuing notifications and publishing such notifications in the Royal Gazette, all of which must be completed
within 30 days from the effective date of this Ministerial Regulation, which will fall on 29 March 2021.

Conclusion

Thailand's regulations related to cannabis and hemp production, possession and use continue to evolve towards wider accessibility for both potential consumers, and business operators. Significant barriers of entry continue to exist in the market, with prohibitions remaining on use, production, and entities able to apply for permits for such production and distribution. CBD pharmaceutical production and private production continues to be difficult to navigate for foreign operators interested in entering the Thai market; however, the trend is moving towards liberalization of the cannabis and hemp sector.

If you would like to discuss any of the legal implications of the matters discussed above, please contact the authors listed in the right-hand column.

This publication is intended to highlight an overview of key issues for ease of understanding, and not for the provision of legal advice. If you have any questions about this publication, please contact your regular contact persons at Mori Hamada & Matsumoto or Chandler MHM Limited. If you should have any inquiries about the publications, or would like more information about Chandler MHM Limited, please contact bd@mhm-global.com.