

Translation

MINISTERIAL REGULATION
ON APPLICATION FOR LICENSES AND GRANT OF LICENSES TO PRODUCE, IMPORT, EXPORT,
DISPOSE OR POSSESS NARCOTICS OF CATEGORY V CONCERNING HEMP,
B.E. 2563 (2020)

By virtue of the provisions of section 6 paragraph one, section 22 paragraph two, section 23 paragraph three, and section 35 paragraph two of the Narcotics Act, B.E. 2522 (1979), and section 26/2 (2) and paragraph three, section 26/3 paragraph three, section 26/5 paragraph three, section 34/1 (1), (2), and (6), section 34/2 (1) and (6), and section 34/3 (4) of the Narcotics Act, B.E. 2522 (1979) as amended by the Narcotics Act (No. 7), B.E. 2562 (2019), the Minister of Public Health hereby issues the Ministerial Regulation as follows.

Clause 1. This Ministerial Regulation shall come into force after the expiration of thirty days from the date of its publication in the Government Gazette.

Clause 2. The Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2559 (2016) shall be repealed.

Clause 3. In this Ministerial Regulation:

“hemp” means a plant whose scientific name is *Cannabis sativa L. subsp. sativa*, and which has the characteristics as stipulated by a notification of the Narcotics Commission specifying characteristics of hemp;

“seed” means seeds, propagating materials, or any parts of hemp which can be used for cultivation or reproduction;

“certified seed” means certified seeds which have the characteristics as stipulated by a notification of the Narcotics Commission specifying characteristics of hemp, and are specified as certified seeds by the Commission in the notification published in the Government Gazette;

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“testing laboratory” means a laboratory of an agency directed by the Commission to test for tetrahydrocannabinol (THC) in accordance with the rules and procedures specified by the Commission in the notification published in the Government Gazette;

“State agency” means central administration, regional administration, local administration, State enterprises, public organizations, and other State agencies.

CHAPTER I APPLICATION FOR LICENSES

Clause 4. Application for a license to produce, dispose or possess hemp shall be in accordance with the following purposes:

(1) for the purposes of missions of State agencies, except for the missions under (2), (3), (4), (5), or (6) in respect of which the State agency shall apply for a license in accordance with such respective purpose, as the case may be;

(2) for utilization of fibers consistent with the tradition, culture, or livelihood, and only for use within the family, provided that each family is allowed to have not more than one *rai* of the cultivated land;

(3) for commercial or industrial purposes;

(4) for medical purposes;

(5) for the purposes of study, testing, research, or breeding;

(6) for the purposes of producing certified seeds.

Clause 5. An application for a license to import or export hemp shall be in accordance with the purposes specified in clause 4 (1), (3), (4), (5), or (6).

Clause 6. With respect to the application for licenses under clause 4 and clause 5, the licensing authority shall, upon consideration, grant a license in accordance with the following criteria:

(1) in cases where the applicant is a natural person, the applicant must:

(a) be of Thai nationality;

(b) be not less than twenty years of age;

(c) have a domicile in Thailand;

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(d) not be a person of unsound mind, an incompetent person, or a quasi-incompetent person;

(e) not be bankrupt;

(f) not be a person whose license issued under the law on narcotics or the law on psychotropic substances is being suspended or revoked;

(g) not previously be sentenced by a final judgment as being guilty of an offense under the law on narcotics, the law on psychotropic substances, the law on prevention of volatile substance abuse, or the law on measures for the suppression of offenders in an offense relating to narcotics;

(2) in cases where the applicant is a juristic person, the applicant must be registered under Thai law, and:

(a) it must possess the qualifications under (1) (e), (f), and (g);

(b) the representative or the person empowered to act on behalf of the juristic person must possess the qualifications under (1);

(c) at least two-thirds of its directors, partners, or shareholders must be persons of Thai nationality;

(d) it must have an office located in Thailand;

(3) in cases where the applicant is a community enterprise which is not a juristic person, the person entrusted to perform activities on its behalf must also possess the qualifications under (1);

(4) in cases where the applicant is a State agency, it must have an object related to production, import, export, disposition, or possession of hemp in accordance with its missions as prescribed in clause 4 or clause 5.

Clause 7. A person who intends to apply for a license to produce, import, export, dispose or possess hemp shall submit an application to the licensing authority in the form prescribed by the Secretary-General in the notification published in the Government Gazette, together with information, documents, or evidence as follows:

(1) national identification number, in cases where the applicant is a natural person;

(2) name and juristic person's registration number, in cases where the applicant is a juristic person;

(3) a document showing registration of the community enterprise under the law on promotion of community enterprises or acceptance of registration of the agricultural

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cooperative under the law on cooperatives, in cases where the applicant is a group of agricultural workers forming a community enterprise or a cooperative;

(4) a letter showing that the applicant is a representative or a person empowered to act on behalf of the juristic person, in cases where the applicant is a juristic person;

(5) a map showing the location and coordinates of the premises for production, import, export, disposition, or possession of hemp, and structures in the vicinity thereof, as well as documents or evidence showing the description of such premises;

(6) a detailed plan for the production, import, export, disposition, or utilization, as the case may be, and safety measures for prevention of misuse;

(7) documents or evidence to assist the consideration under clause 6;

(8) consent for the licensing authority to access the information under (1) or (2) for the purpose of verification.

Clause 8. In cases where there is a necessity for the government to prevent, suppress, or resolve problems of narcotics, or to implement international cooperation concerning narcotics, the Secretary-General may, upon consideration, exempt an applicant from notifying any of the information or submitting any of the document or evidence under clause 7.

Clause 9. An applicant for a license to produce hemp through cultivation shall submit documents or evidence showing the applicant's ownership or possessory right over the hemp cultivation site. In cases where the applicant is not the owner of the said site, a letter showing the consent of the owner of the site or a permit for utilization of the site of the State agency shall also be attached.

Clause 10. An applicant for a license to produce, import, export, dispose or possess hemp for purposes of study, testing, research, or breeding shall submit a project plan for the study, testing, research, or breeding that conforms with technical standards, and documents or evidence showing the results of a test to identify the amount of tetrahydrocannabinol (THC) in hemp. The applicant shall also submit the following documents or evidence:

(1) with regard to human research, the applicant shall submit documents or evidence showing approval of a human research ethics committee specified by the Secretary-General.

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(2) with regard to actions carried out on animals for scientific purposes, the applicant shall submit documents or evidence showing approval from the supervisory committee under the law on animals for scientific purposes.

Clause 11. The submission of applications, grant of licenses, renewal of licenses, and issuance of license replacements under this Ministerial Regulations shall be made through electronic means. However, if such action cannot be carried out through electronic means, it shall be carried out at the following places:

(1) in cases of production, disposition, or possession of hemp-

(a) in Bangkok metropolitan area, it shall be carried out at the Food and Drug Administration, Ministry of Public Health;

(b) in other provinces (*changwat*), it shall be carried out at the provincial public health office of the locality where the premises for production, disposition, or possession of hemp are situated;

(2) in cases of import or export of hemp, it shall be carried out at the Food and Drug Administration, Ministry of Public Health or any other place specified by the Secretary-General in the notification published in the Government Gazette.

CHAPTER II GRANT OF LICENSES

Clause 12. Upon receiving an application, the licensing authority shall examine the application, information, documents, and evidence to verify whether they are correct and complete. If they are correct and complete, the licensing authority shall issue a document acknowledging receipt of the application to the applicant. However, if there is any incorrectness in the application or is a lack of information, documents, or evidence, the licensing authority shall forthwith notify the applicant. In cases where rectification can be made at that moment, the licensing authority shall notify the applicant to rectify it or to submit the complete information, document, or evidence. In cases where rectification cannot be made at that moment, the licensing authority shall record such deficiency and notify the applicant to rectify the application or to submit the complete and correct information, documents or evidence within the period specified by the licensing authority. In cases where submission of an application for the license is

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done through a non-electronic means, the licensing authority and the applicant shall also sign the record.

In cases where the applicant fails to rectify the application or fails to submit the complete and correct information, documents or evidence within the period specified by the licensing authority, the applicant shall be deemed to have abandoned the proceedings. In this regard, the licensing authority shall return the application, documents, and evidence to the applicant, and also notify the applicant in writing of the grounds for the return of the application. The licensing authority shall then dispose of the matter from the docket.

Clause 13. In cases of application for production licenses, if the application, information, documents, and evidence are correct and complete, and the applicant has paid for the costs of the proceedings for licensing of narcotic products, the licensing authority shall consider the application and present his or her opinion to the Commission within one hundred and twenty days. In this connection, the following actions shall be taken:

(1) in cases of application for a license in Bangkok metropolitan area, the licensing authority shall, upon consideration, present the opinion to the Commission;

(2) in cases of application for a license in other provinces (*changwat*), the Provincial Public Health Medical Physician shall present the application to a provincial committee which consists of the Provincial Governor as chairperson, the Director of the Provincial Agricultural Extension Office, the Commander of the Provincial Police, and a representative from the relevant regional office of the Office of the Narcotics Control Board as members, and the Provincial Public Health Medical Physician as member and secretary, for consideration and preparation of the opinion to be submitted to the licensing authority for presentation to the Commission.

Clause 14. In cases of application for import or export licenses, if the application, information, documents, and evidence are correct and complete, and the applicant has paid for the costs of the proceedings for licensing of narcotic products, the licensing authority shall consider the application and present his or her opinion to the Commission within sixty days.

Clause 15. In cases of application for disposition or possession licenses, if the application, information, documents, and evidence are correct and complete, and the applicant has paid for the costs of the proceedings for licensing of narcotic products, the licensing authority shall complete the consideration of the application within forty-five days.

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Clause 16. In cases where the Commission passes a resolution approving the license or the licensing authority issues an order granting the license, the licensing authority shall issue the license to the applicant within fifteen days from the date on which such resolution is passed or such order is issued.

In cases where the Commission passes a resolution disapproving the license or the licensing authority issues an order refusing the license, the licensing authority shall notify the applicant in writing within fifteen days from the date on which the disapproval resolution is passed or the refusal order is issued, as the case may be. In this regard, the grounds and right to appeal shall also be notified.

Clause 17. A licensee who holds a license to produce, import, export, or dispose hemp shall be exempted from applying for a possession license.

Clause 18. A licensee holding a license to import or export hemp who intends to import or export hemp must obtain a license for each shipment of hemp imported or exported. In this regard, the licensee shall submit an application together with documents or evidence for the following cases:

(1) In applying for a license for each shipment of hemp imported, the licensee shall attach documents or evidence indicating the name, amount or quantity, and characteristics of the hemp as specified in the form of application, including the name and location of the place of business of the producer or person who sends hemp into the Kingdom, as well as the means for importing the hemp into the Kingdom. However, in cases where it serves the aim of the government to prevent, suppress, or resolve problems of narcotics, or to implement international cooperation concerning narcotics, the indication of name and location of the place of business of the producer or person who sends hemp into the Kingdom shall be omitted.

(2) In applying for a license for each shipment of hemp exported, the licensee shall attach documents or evidence indicating the name, amount or quantity, and characteristics of the hemp as specified in the form of application, including the name and location of the place of business of the person who imports hemp into the receiving country, as well as the means for exporting the hemp. However, in cases where regulation on control of hemp is in place in the receiving country, a license to import hemp into the receiving country or a certificate issued by the State agency of such receiving country shall also be attached.

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Clause 19. In cases of application for licenses for each shipment of hemp imported or exported, if the application, documents, and evidence under clause 18 (1) or (2) are correct and complete, and the applicant has paid for the costs of the proceedings for licensing of narcotic products, the licensing authority shall complete the consideration and issuance of the license within thirty days.

The provisions of clause 12 shall also apply to the consideration of an application under paragraph one *mutatis mutandis*.

Clause 20. A licensee who holds a license for each shipment of hemp imported or exported shall take the following actions:

(1) The licensee shall bring the hemp which is imported or exported, as the case may be, to the competent official for inspection at a food and drug inspection station of the Food and Drug Administration. The documents or evidence showing the result of a test that indicates that the hemp contains tetrahydrocannabinol (THC) in the amount not exceeding that prescribed by the notification of the Narcotics Commission specifying characteristics of hemp shall also be brought for inspection.

(2) The licensee shall import or export hemp in accordance with the type specified in the license and accordance with the amount and quantity specified in the license or certificate of the importing country. In cases where less than such amount and quantity is exported, the licensee shall notify the licensing authority to amend the license to be consistent with the quantity actually exported.

(3) In cases of import of hemp, the licensee shall arrange to obtain a phytosanitary certificate, and comply with the law on plant quarantine, and shall also arrange to obtain other documents or evidence as specified by the Secretary-General in order to present them at a plant quarantine station.

(4) In cases of importing hemp from a country with control regulation, the hemp shall be accompanied by a copy of the export license or export certificate of the authority of the said exporting country. Another copy of the export license or export certificate shall also be sent to the Food and Drug Administration.

Clause 21. In cases where there is a necessity for the government to prevent, suppress, or resolve problems of narcotics, or to implement international cooperation concerning narcotics, the Secretary-General may, upon consideration, exempt the requirements under clause

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20, in whole or in part, for a licensee who holds a license for each shipment of hemp imported or exported.

Clause 22. A licensee holding a license to produce, import, export, dispose or possess hemp who intends to renew the license shall submit the application to the licensing authority prior to the date of expiration of the license, together with the license and other information, documents, or evidence specified in the form of application for license renewal.

The provisions of clause 12, clause 13, clause 14, clause 15, and clause 16 shall also apply to the consideration of an application and license renewal under paragraph one *mutatis mutandis*.

Clause 23. In cases of loss, destruction, or significant fading of a license, the licensee shall submit an application for license replacement within fifteen days from the date on which the loss, destruction, or significant fading is known, together with the following documents or evidence:

- (1) notice of case report, in cases of loss of licenses;
- (2) license, in cases of destruction or significant fading of such license;
- (3) other information, documents, or evidence specified in the form of application for license replacement.

The provisions of clause 12 shall also apply to the consideration of an application for license replacement *mutatis mutandis*.

In cases of application for license replacement, if the application, information, documents, and evidence under paragraph one are correct and complete, the licensing authority shall issue a license replacement.

Clause 24. In cases where it is necessary for a patient who travels internationally to carry hemp into or out of the Kingdom for treatment of his or her disease, the quantity of which does not exceed that necessary for the treatment for a period of ninety days, such patient shall submit an application to the licensing authority not less than fifteen days prior to the date on which each batch of hemp will be carried into or out of the Kingdom. The application shall be accompanied by a medical prescription or a certificate issued by a medical practitioner, a dental practitioner, a practitioner of Thai traditional medicine, a practitioner of applied Thai traditional medicine, or a folk healer under the law on Thai traditional medical profession who is

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responsible for the treatment, and such other information, documents or evidence as specified in the form of application.

The submission of the application and grant of license under paragraph one shall be made through electronic means. However, if such action cannot be carried out through electronic means, the provisions of clause 11 (2) shall apply *mutatis mutandis*. The provisions of clause 12 shall also apply to the consideration of an application under paragraph one *mutatis mutandis*.

In cases where the application, information, documents, and evidence under paragraph one are correct and complete, the licensing authority shall complete the consideration and issuance of the license within seven days.

CHAPTER III IMPLEMENTATION

Clause 25. A State agency which is a licensee holding a license to produce hemp through cultivation under clause 4 (1) shall take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed cultivation site. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a hemp cultivation site, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall arrange to conduct a test to identify the amount of tetrahydrocannabinol (THC) contained in the cultivated hemp every time before removing it from the cultivation site in accordance with the rules and procedures prescribed by the Commission in the notification published in the Government Gazette. Evidence showing details of the test shall be maintained at the licensed cultivation site for not less than three years from the date of the test. In cases where tetrahydrocannabinol (THC) is detected in the amount more than that prescribed by the Commission, the licensee shall notify the competent official in order to supervise the destruction of the hemp or to take any other action as specified by the Commission in the notification published in the Government Gazette.

(3) The licensee shall cause a hemp label and information leaflet, a warning, or a cautionary label to be placed on the container or package of the hemp produced in accordance

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with the rules, procedures, and conditions specified by the Commission in the notification published in the Government Gazette as per section 34/1 (3).

(4) The licensee shall cause hemp to be stored separately from other drugs or objects, and stored in a firm place secured by a lock or other comparable protection.

(5) In cases where hemp is lost, damaged, or destroyed by any cause whatsoever, the licensee must notify the licensing authority in writing without delay.

(6) The licensee shall grow hemp at the premises and location specified in the license, and mark a boundary of the cultivation area in a clearly visible manner.

(7) The licensee shall always use certified seeds for cultivation.

(8) The licensee shall prepare the premises and control the cultivation in accordance with rules, procedures, and conditions prescribed by the Commission in the notification published in the Government Gazette.

(9) The licensee shall prepare an account on receipt and discharge of hemp as licensed, and submit monthly and annual reports to the Secretary-General within thirty days from the last day of the month or year, as the case may be. Such account shall be maintained for five years from the date of its last entry, and be made ready to be shown to a competent official at all times during the working hours. The account on receipt and discharge and the report shall be in the forms specified by the Commission in the notification published in the Government Gazette as per section 34/4 paragraph two.

(10) The licensee shall notify a competent official of the date and time when hemp will be harvested not less than fifteen days prior to the harvest, and shall, upon harvest, record the date and time of the harvest and the quantity of hemp produced in the account and monthly report for submission to the Secretary-General.

(11) The licensee shall implement the production plan or utilization plan under clause 7 (6). In cases where such production plan or utilization plan cannot be implemented, the licensee shall notify the licensing authority of its intention to amend the plan for consideration within thirty days from the date on which it appears that such plan cannot be implemented, as per the rules, procedures, and conditions prescribed by the Secretary-General in the notification published in the Government Gazette.

(12) The licensee shall put in place a tracking and tracing system in order to implement the control and supervision as licensed.

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Clause 26. A licensee who holds a license to produce hemp through cultivation for utilization of fibers consistent with the tradition, culture, or livelihood, and only for use within the family under clause 4 (2) shall comply with clause 25 (1), (3), (4), (5), (6), (8), (9), and (10).

With respect to the cultivation of hemp under paragraph one, in cases where certified seeds are not used, the licensee shall arrange to conduct a test to identify the amount of tetrahydrocannabinol (THC) contained in the cultivated hemp every time before removing it from the cultivation site in accordance with the rules and procedures prescribed by the Commission in the notification published in the Government Gazette. Evidence showing details of the test shall be maintained at the licensed cultivation site for not less than one year from the date of the test. In cases where tetrahydrocannabinol (THC) is detected in the amount more than that prescribed by the Commission, the licensee shall notify the competent official in order to supervise the destruction of the hemp or to take any other action as specified by the Commission in the notification published in the Government Gazette.

In cases where certified seeds are used, the licensee shall be exempted from complying with paragraph two.

Clause 27. A licensee who holds a license to produce hemp through cultivation for commercial or industrial purposes under clause 4 (3) shall comply with clause 25, and shall notify, in writing, the licensing authority of the schedule not less than seven days in advance before the transportation of hemp as licensed. The notification shall specify the quantity, date and time, conveyance, transportation route, and person in control of the transportation. Such notification and a copy of the license to produce hemp shall accompany the transportation.

In cases of cultivation for export as licensed, certified seeds may or may not be used.

Clause 28. A licensee who holds a license to produce hemp through cultivation for medical purposes under clause 4 (4) shall comply with clause 25 (1), (2), (3), (4), (5), (6), (7), (8), (9), (11), and (12).

Clause 29. A licensee who holds a license to produce hemp through cultivation for the purposes of study, testing, research, or breeding under clause 4 (5) shall comply with clause 25 (1), (2), (3), (4), (5), (6), (8), (9), (11) and (12), and shall notify, in writing, the licensing

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authority of the schedule not less than seven days in advance before the transportation of hemp as licensed. The notification shall specify the quantity, date and time, conveyance, transportation route, and person in control of the transportation. Such notification and a copy of the license to produce hemp shall accompany the transportation.

In cases where the licensee under paragraph one has carried out breeding activities and intends to have the seeds certified as certified seeds under clause 4 (6), the licensee shall apply for a certificate of registered plant variety under the law on plant varieties, and submit to the Food and Drug Administration a copy of the certificate of registered plant variety and the result of a test to identify the amount of tetrahydrocannabinol (THC) for submission to the Commission for consideration and declaration as certified seeds.

Clause 30. A licensee who holds a license to produce hemp through cultivation for the purposes of producing certified seeds under clause 4 (6) shall comply with clause 25, and take the following actions:

(1) The licensee shall notify, in writing, the licensing authority of the schedule not less than seven days in advance before the transportation of certified seeds as licensed. The notification shall specify the quantity, date and time, conveyance, transportation route, and person in control of the transportation. Such notification and a copy of the license to produce hemp shall accompany the transportation.

(2) The licensee shall submit to the Food and Drug Administration the result of a test to identify the amount of tetrahydrocannabinol (THC) contained in the hemp produced no later than February of the following year for consideration and renewing the status of such certified seeds as certified seeds. In cases where tetrahydrocannabinol (THC) is detected in the amount more than that prescribed by the Commission, the licensee shall notify the competent official in order to supervise the destruction of the certified seeds or to take any other action as specified by the Commission in the notification published in the Government Gazette.

Clause 31. A licensee who holds a license to produce hemp through a means other than cultivation for the purposes under clause 4 (1) and (3), or the purposes of study, testing, or research, shall comply with clause 25 (3), (4), (5), (9), (11), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed production facility. The signboard shall be made from durable material and

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include texts in Thai alphabet of appropriate size which indicate that such place is a hemp production facility, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall arrange to conduct a test to identify the amount of tetrahydrocannabinol (THC), cannabidiol (CBD), and other substances contained in the hemp produced every time before removing it from the production facility in accordance with the rules and procedures prescribed by the Commission in the notification published in the Government Gazette. Evidence showing details of the test shall be maintained at the licensed production facility for not less than three years from the date of the test. However, in cases of production for use as materials to produce other products other than hemp, actions shall be taken in accordance with the rules, procedures, and conditions set out in the law on such matter.

(3) The licensee shall produce and store hemp in the premises specified in the license.

The licensee under paragraph one who will transport hemp for the purposes under clause 4 (3), or the purposes of study, testing, or research, shall notify, in writing, the licensing authority of the schedule not less than seven days in advance before the transportation of hemp as licensed. The notification shall specify the quantity, date and time, conveyance, transportation route, and person in control of the transportation. Such notification and a copy of the license to produce hemp shall accompany the transportation.

Clause 32. A licensee who holds a license to produce hemp for dispensing medication for treatment of disease of a specific patient for medical purposes under clause 4 (4) shall comply with clause 25 (3), (4), (5), (9), (11), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed dispensary. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a dispensary, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall dispense only consumable medicinal formulae as prescribed by the Minister in the notification under section 58.

(3) The licensee shall monitor and assess the effectiveness and safety, and report undesirable events resulting from the use in the form and accordance with the procedures specified by the Commission in the notification published in the Government Gazette.

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Clause 33. A licensee who produces a medicinal formula containing hemp for medical purposes under clause 4 (4) other than dispensing medication for treatment of disease of a specific patient shall comply with clause 25 (3), (4), (5), (9), (11), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed medicine production facility. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a medicine production facility, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall produce only consumable medicinal formulae as prescribed by the Minister in the notification under section 58, and carry out the production in accordance with the rules, procedures, and conditions prescribed by the Commission in the notification published in the Government Gazette.

(3) The licensee shall arrange for a pharmaceutical practitioner, a practitioner of Thai traditional medicine specialized in Thai pharmacy, or a practitioner of applied Thai traditional medicine to control the production of medicinal drugs which contain hemp, as the case may be.

(4) The licensee shall arrange to conduct a test on medicinal drugs produced every time before removing them from the medicine production facility in accordance with the rules and procedures prescribed by the Commission in the notification published in the Government Gazette. Evidence showing details of the test shall be maintained at the licensed medicine production facility for not less than three years from the date of the test.

(5) The licensee shall monitor and assess the effectiveness and safety, and report undesirable events resulting from the use in the form and accordance with the procedures specified by the Commission in the notification published in the Government Gazette.

Clause 34. A licensee who holds a license to import hemp shall comply with clause 25 (4), (5), (9), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed hemp import facility. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a hemp import facility, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

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(2) The licensee shall arrange to obtain a certificate of the foreign producer which shows the detailed characteristics as well as the result of a quality test of the hemp imported.

(3) The licensee shall cause a hemp label and information leaflet, a warning, or a cautionary label to be placed on the container or package of the hemp imported in accordance with the rules, procedures, and conditions specified by the Commission in the notification published in the Government Gazette as per section 34/2 (3).

(4) The licensee shall implement the importation plan or utilization plan under clause 7 (6). In cases where such importation plan or utilization plan cannot be implemented, the licensee shall notify the licensing authority of its intention to amend the plan for consideration within thirty days from the date on which it appears that such plan cannot be implemented, as per the rules, procedures, and conditions prescribed by the Secretary-General in the notification published in the Government Gazette.

Clause 35. A licensee who holds a license to export hemp shall comply with clause 25 (4), (5), (9), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed hemp export facility. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a hemp export facility, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall arrange to obtain a certificate of the domestic producer which shows the detailed characteristics as well as results of the quality test of the hemp exported.

(3) The licensee shall cause a hemp label and information leaflet, a warning, or a cautionary label to be placed on the container or package of the hemp exported in accordance with the rules, procedures, and conditions specified by the Commission in the notification published in the Government Gazette as per section 34/2 (3).

(4) The licensee shall implement the exportation plan under clause 7 (6). In cases where such exportation plan cannot be implemented, the licensee shall notify the licensing authority of its intention to amend the plan for consideration within thirty days from the date on which it appears that such plan cannot be implemented, as per the rules, procedures, and conditions prescribed by the Secretary-General in the notification published in the Government Gazette.

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Clause 36. A licensee who holds a license to dispose hemp shall comply with clause 25 (4), (5), (9), and (12), and take the following actions:

(1) The licensee shall arrange to have a signboard installed at a conspicuous place at the licensed disposition facility. The signboard shall be made from durable material and include texts in Thai alphabet of appropriate size which indicate that such place is a hemp disposition facility, and show the license number, name of the licensee, and expiration date of the license as specified in the license.

(2) The licensee shall keep in place hemp labels and information leaflets, warnings, or cautionary labels which are prepared by the producer or importer and placed on the container or package of hemp, and prevent them from deteriorating.

(3) The licensee shall implement the disposition plan under clause 7 (6). In cases where such disposition plan cannot be implemented, the licensee shall notify the licensing authority of its intention to amend the plan for consideration within thirty days from the date on which it appears that such plan cannot be implemented, as per the rules, procedures, and conditions prescribed by the Secretary-General in the notification published in the Government Gazette.

(4) The licensee shall ensure that a copy of the license to dispose hemp shall accompany the transportation of hemp. However, in transporting medicinal drugs which contain hemp, a copy of such license need not be provided.

Clause 37. A licensee who holds a license to possess hemp shall comply with clause 25 (4), (5), (9), and (12), and take the following actions:

(1) The licensee shall prepare the license and make the license available to be shown to a competent official upon request.

(2) The licensee shall keep in place hemp labels and information leaflets, warnings, or cautionary labels which are prepared by the producer or importer and placed on the container or package of hemp, and prevent them from deteriorating.

(3) The licensee shall implement the utilization plan under clause 7 (6). In cases where such utilization plan cannot be implemented, the licensee shall notify the licensing authority of its intention to amend the plan for consideration within thirty days from the date on which it appears that such plan cannot be implemented, as per the rules, procedures, and conditions prescribed by the Secretary-General in the notification published in the Government Gazette.

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Clause 38. In cases where a competent official or a relevant person wishes to know the amount of tetrahydrocannabinol (THC) contained in hemp, it shall be sent to a testing laboratory for a test. If it appears from the result of the test that the amount of such substance exceeds that prescribed by the Commission, the person who submits the hemp for the test shall notify the competent official in order to supervise the destruction of the hemp or to take any other action in accordance with the rules, procedures, and conditions prescribed by the Commission in the notification published in the Government Gazette.

CHAPTER IV MISCELLANEOUS

Clause 39. In order to facilitate the notification under this Ministerial Regulation, the licensing authority may, in parallel with written notice, notify applicants and licensees through electronic means.

Clause 40. Applications, licenses, and license replacements under this Ministerial Regulation shall be in the forms specified by the Secretary-General in the notification published in the Government Gazette.

PROVISIONAL PROVISIONS

Clause 41. Within five years from the date on which this Ministerial Regulation comes into force,

(1) production of hemp through cultivation for the purposes set forth in clause 4 (1), (3), or (4) may be carried out without using certified seeds;

(2) import of seeds shall be carried out only for the production of hemp through cultivation in accordance with the purposes set forth in clause 4 (1), (3), (4), (5), or (6).

Clause 42. Subject to clause 41, within five years from the date on which this Ministerial Regulation comes into force, import of hemp under clause 5, aside from that of seeds, shall be carried out only for the following cases:

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- (1) for study, testing, research, or breeding;
- (2) for medical purposes of a State agency.

Clause 43. A certificate of license to produce, dispose or possess narcotics of category V concerning hemp which is issued under the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2559 (2016), shall be deemed a license under this Ministerial Regulation, and shall be valid until such certificate expires.

Clause 44. A certificate of license to import or export narcotics of category V which is issued under the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose, Import, Export or Possess Narcotics of Category IV or Category V, B.E. 2559 (2016) with respect to the part concerning hemp, shall be deemed a license under this Ministerial Regulation, and shall be valid until such certificate expires.

Clause 45. All applications for certificates and applications for replacements of certificates of license under the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2559 (2016) and the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose, Import, Export or Possess Narcotics of Category IV or Category V, B.E. 2559 (2016) with respect to the part concerning hemp, which are submitted prior to the date on which this Ministerial Regulation comes into force and are under consideration of the licensing authority, shall be deemed applications for license or applications for license replacement under this Ministerial Regulation *mutatis mutandis*.

In cases where such application contains a text which is different from the application under this Ministerial Regulation, the licensing authority shall have the power to order the amendment and submission of additional documents or evidence as may be necessary for compliance with this Ministerial Regulation.

Clause 46. Notifications issued under the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2559 (2016) in force on the day prior to the date on which this Ministerial Regulation comes into force, shall remain in force insofar as they are not contrary to or

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inconsistent with this Ministerial Regulation until the notification issued under this Ministerial Regulation comes into force.

Issuance of the notification under paragraph one shall be completed within thirty days from the date on which this Ministerial Regulation comes into force.

Given on the 28th Day of December B.E. 2563 (2020)

Anutin Charnvirakul

Minister of Public Health

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Remark: The grounds for the promulgation of this Ministerial Regulation are as follows. Whereas the Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2559 (2016) issued under the Narcotics Act, B.E. 2522 (1979) contains certain provisions which are not suitable with the present, and the provisions of section 26/2 (2) and paragraph three, section 26/3 paragraph three, and section 26/5 paragraph three of the Narcotics Act, B.E. 2522 (1979) as amended by the Narcotics Act (No. 7), B.E. 2562 (2019) provide that application for licenses and grant of licenses to produce, import, export, dispose or possess narcotics of category V shall be as prescribed by Ministerial Regulation, it is thus expedient to revise such Ministerial Regulation in order to promote the use of hemp to benefit the economy, to promote hemp which is of high quality and standard and is exportable, and to prevent hemp misuse. It is, therefore, necessary to issue this Ministerial Regulation.

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