

Translation

**MINISTERIAL REGULATION**  
**ON APPLICATION FOR LICENSE AND ISSUANCE OF LICENSE TO PRODUCE,**  
**IMPORT OR SELL HERBAL PRODUCTS,**  
**B.E. 2563 (2020)\***

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By virtue of the provisions in section 5 paragraph one, section 17 paragraph two, section 21 paragraph two, section 23 paragraph four, section 24 paragraph two, and section 68 paragraph two of the Herbal Products Act, 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 ninety days as from the date of its publication in the Government Gazette.

**Clause 2.** Any person who wishes to operate a business of producing, importing or selling the herbal products prescribed in the Notification by the Minister under section 6 (1) shall submit an application for license to the licensing authority, together with the following information, documents or evidence:

- (1) national ID number, in the case where a natural person is the applicant;
- (2) name and registration number of the juristic person, in the case where a juristic person is the applicant;
- (3) alien work permit number under the law on foreigners' working management, or license number for the operation of business under (14) or (15) of the Schedule Three, or certificate number under the law on foreign business, in the case where the applicant is not of Thai nationality;
- (4) document indicating the qualifications of the applicant under section 19 and the person responsible for the operation as prescribed in the Notification by the Minister with the recommendation of the Committee under section 6 (13);
- (5) letter specifying that the applicant is an a representative of the juristic person or a person empowered to act on behalf of the juristic person, in the case where a juristic person is the person seeking the license;

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\* Published in the Government Gazette, Vol. 137, Issue 55a, page 3, dated 14<sup>th</sup> July B.E. 2563 (2020).

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(6) map of the location and coordinates of the place of production, importation or sale and the place of storage of the herbal products having the characteristics so prescribed in the Notification by the Minister with the recommendation of the Committee under section 6 (10), as well as buildings in the vicinity of such place;

(7) floor plan and layout of buildings within the area of the place of production, importation or sale and the place of storage of herbal products;

(8) document indicating the applicant's ownership or possessory right over the place of production, importation or sale; in the case where the applicant is not the owner of such place, a letter specifying the owner's consent must also be attached therewith;

(9) list of particulars in relation to wastewater treatment system, sewage and waste disposal, air control system, water system used for the production, in the case of an application for a license to operate a business of producing herbal products only;

(10) consent for the licensing authority to access information under (1), (2) and (3) for the purpose of inspection.

The place of production, importation or sale under paragraph one shall also include the portion of which is used as a place of storage of the herbal products being produced, imported or sold.

**Clause 3.** In the case of necessity, the applicant may use the place of production, importation, bringing or ordering into the Kingdom, sale, distribution, retention or storage of medical devices, cosmetics, drugs or food, as the case may be, having the same characteristics as the place of production, importation or sale of herbal products as prescribed in the Notification by the Minister with the recommendation of the Committee under section 6 (10), as the place of production, importation or sale of herbal products.

**Clause 4.** Upon receiving an application, the licensing authority shall examine the application together with information, documents and evidence to determine whether they are correct and complete. If they correct and complete, an application receipt shall be issued to the applicant. However, if the application is incorrect, or an information, document or evidence is absent, the applicant shall be informed promptly. In the case where such incorrectness or absence can be amended at the time, the applicant shall be notified to make amendment or submit additional information, document or evidence to complete the application. In the case where such action cannot be carried out at the time, a record of the incorrectness or absence shall be made and the applicant shall be notified to make amendment to the application or submit complete and correct information, document or evidence within the period specified by the licensing authority. In the case of application

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

Where the applicant fails to make amendment to the application or fails to submit complete and correct information, document or evidence within the period specified by the licensing authority, it shall be deemed that the applicant does not wish to proceed further and the licensing authority shall dispose of the matter from the system.

**Clause 5.** In the case where the application, together with information, document and evidence are complete and correct, and the applicant has paid for the expenses of the herbal product consideration process, the licensing authority shall complete the consideration of the application within one hundred and fifty days. Where necessary, the licensing authority may also inspect the place of production, importation, sale or storage of the herbal products. If the applicant has the qualifications and is not under any prohibition under section 19, and the place of production, importation, sale or storage of the herbal products has the characteristics prescribed in the Notification by the Minister with the recommendation of the Committee under section 6 (10), the licensing authority shall issue a order granting the license.

In the case where the licensing authority issues a refusal order, the licensing authority shall send a written notice to inform the applicant of the refusal order together with the reason thereof and the right to appeal within fifteen days as from the date the refusal order is issued.

**Clause 6.** In the case where the licensing authority issues an order granting the license, the licensing authority shall send a written notice to inform the applicant, and the applicant shall proceed to pay the license fee within sixty days as from the date the written notice is received. Once the applicant has paid the license fee, the licensing authority shall issue the license within seven days as from the date the payment is received.

In the case where the applicant fails to pay the license fee within the period under paragraph one, it shall be deemed that the applicant does not wish to receive the license and the licensing authority shall dispose of the matter from the system.

**Clause 7.** A licensee who wishes to vary a particular on the license shall submit an application for particular variation to the licensing authority, together with information, document or evidence pertaining to the particular intended to be varied, as well as other documents or evidence specified in the application for particular variation form.

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The provisions in clause 4 and clause 5 shall also apply to the consideration of the application for particular variation and the granting of permission thereof *mutatis mutandis*.

**Clause 8.** In the case where a licensee temporarily relocates or changes the place of importation, sale or storage of the herbal products due to an urgent necessity in which the seeking of permission is not possible, the licensee shall send a written notice to inform the licensing authority within seven days as from the date the relocation or change takes place, and the place relocated or changed shall be temporarily deemed the place of importation, sale or storage of the herbal products so permitted.

**Clause 9.** A licensee who wishes to renew the license shall submit an application to the licensing authority no prior to ninety days before the expiration date of the license, together with the license, information, documents or other evidence as specified in the form of the application for license renewal.

The provisions in clause 4, clause 5 and clause 6 shall also apply to the consideration of the application for license renewal and the granting of permission thereof *mutatis mutandis*.

**Clause 10.** In the case where a license is lost, destroyed or faded fundamentally, the licensee shall submit an application for license replacement within fifteen days as from the date of knowledge of the loss, destruction or fundamental fading, together with information, documents or evidence as follows:

- (1) a notice of police report, in the case of loss;
- (2) the license, in the case of destruction or fundamental fading;
- (3) other information, document or evidence as specified in the form of the application for license replacement.

The provisions in clause 4 and clause 6 shall also apply to the consideration of the application for license replacement and the issuance of license replacement *mutatis mutandis*.

In the case where the application for license replacement, together with information, documents and evidence under paragraph one are correct and complete, the licensing authority shall issue the license replacement.

**Clause 11.** A licensee who wishes to transfer the license to a transferee who has the qualifications and is not under any prohibition under section 19 shall submit an

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application for license transfer to the licensing authority, together with information, documents or evidence as follows:

- (1) the license of the transferer;
- (2) information, documents or evidence under clause 2 of the transferee;
- (3) other information, documents or evidence as specified in the form of the application for license transfer.

The provisions in clause 4 and clause 5 shall also apply to the consideration of the application for license transfer and the granting of permission thereof *mutatis mutandis*.

In the case where the licensing authority issues a permission order, the licensing authority shall issue a license to the transferee with the same validity period and conditions as the original license.

**Clause 12.** For the purpose of providing conveniences in the notification under this Ministerial Regulation, the licensing authority may also notify the applicants and the licensees through an electronic means together with the notification in writing.

**Clause 13.** Licenses to produce, import or sell herbal products, notices of temporary relocation or change of the place of importation, sale or storage of herbal products, and applications under this Ministerial Regulation shall be in accordance with the forms as prescribed by the Secretary-General and published in the Government Gazette.

**Clause 14.** Submission of application, granting of license, variation of particular on a license, license renewal, issuance of license replacement, and license transfer under this Ministerial Regulation shall be carried out mainly through an electronic means. In the period where such actions remain unable to be carried out through an electronic means, an application shall be submitted in the locality where the place of production, importation, sale or storage of herbal products is located, as follows:

- (1) in Bangkok, at the Food and Drug Administration, Ministry of Public Health;
- (2) in other provinces, at the provincial public health office, except for an application for a license to produce or import herbal products which may be submitted at the Food and Drug Administration, Ministry of Public Health;
- (3) at other places as prescribed by the Secretary-General and published in the Government Gazette.

**Clause 15.** Licenses to produce, import or sell drugs or food which are herbal products and issued under the law on drugs or the law on food before the date this

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Ministerial Regulation comes into force and have not yet expired shall remain valid until the expiration of such licenses.

Given on the 8<sup>th</sup> day of June B.E. 2563 (2020)

Anutin Charnvirakul

Minister of Public Health

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**Remarks:** The grounds for the promulgation of this Ministerial Regulation are as follows. Whereas section 17 paragraph two, section 21 paragraph two, section 23 paragraph four, section 24 paragraph two, and section 68 paragraph two of the Herbal Products Act, B.E. 2562 (2019) provide that the application for license and the issuance of license, the application for particular variation and the granting of permission thereof, the temporary relocation or change of the place of importation, sale or storage of herbal product, the application for license renewal and the granting of permission thereof, the application for and the issuance of license replacement, the application for license transfer and the granting of permission to transfer license to produce, import or sell herbal products shall be in accordance with the rules, procedures and conditions as prescribed in the Ministerial Regulation, it is therefore necessary to issue this Ministerial Regulation.

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