

Notification of the National Herbal Policy Committee

Re: Criteria, Procedures and Conditions for Filing Operator Application,
B.E. 2563 (2020)

Whereas it is deemed expedient to prescribe the criteria, procedures and conditions for filing an application to be an operator under the Herbal Product Act, B.E. 2562 (2019),

By virtue of section 10 (9) and section 76 paragraph two of the Herbal Product Act, B.E. 2562 (2019), the National Herbal Policy Committee hereby notifies as follows:

Clause 1 This notification is called the "National Herbal Policy Committee Re: Criteria, Procedures and Conditions for Filing Operator Application, B.E. 2563 (2020)".

Clause 2 This notification shall come into force from the day following the date of its publication in the Government Gazette onward.

Clause 3 In this notification,

"operator" means an operator who is engaged in the production of herbs or in the production of herbal products under the Notification of the National Herbal Policy Committee Re: Determination of Types of Operators;

"certificate" means a certificate of operator;

"operator registry" means a registry of operators who have been granted the certificate of operator under this notification;

"Director-General" means the Director-General of the Department of Thai Traditional and Alternative Medicine.

Clause 4 An applicant for operator registration must have the qualifications and none of the prohibited characteristics as follows:

(1) in case of an ordinary person, must be an operator who is a Thai national;

(2) in case of a registered juristic person with head office located in Thailand, must have shareholders who are Thai nationals more than fifty percent of all shareholders;

(3) has never been ordered to execute or refrain from any act to prevent any violation of this law;

(4) is not under a suspension or revocation order of a certificate of registration, licence, notification receipt or listing receipt under this law.

Clause 5 An application for operator registration shall file an application via the following methods:

(1) electronic (online) submission via the websites or IT systems of the Department of Thai Traditional and Alternative Medicine or Department of Agricultural Extension; or

(2) electronic (online) submission to the Department of Thai Traditional and Alternative Medicine or a Provincial Public Health Office or a Provincial Agriculture Office; or

(3) any other submission methods as prescribed and notified by the Director-General of the Department of Thai Traditional and Alternative Medicine.

Clause 6 An applicant shall complete an operator application form, attach supporting documents and evidences and send them via electronic (online) submission, and send such supporting documents and evidences (if any) with certified true copy signature via registered mail to the Director-General of the Department of Thai Traditional and Alternative Medicine within three days.

For the application under paragraph one, upon completion and submission of the application form together with the supporting documents and evidences via electronic (online) submission, the applicant shall print out a copy of the operator application form and keep it as evidence.

Clause 7 Officials of the Department of Thai Traditional and Alternative Medicine shall complete checking details of the application and supporting documents and evidences within fifteen days from the day following the date of receiving the application.

If the application form as well as the documents and evidences are found to be complete and accurate, the Department of Thai Traditional and Alternative Medicine shall promptly issue the certificate of operator to the applicant via an electronic system.

Clause 8 If the checking of details of the application form, supporting documents and evidences found them to be incomplete or inaccurate, the Director-General shall be told to send a letter, via registered mail with acknowledgement of receipt or an electronic mail, to the applicant informing him or her to completely and accurately correct them within fifteen days from the day following the date of receiving such letter or electronic mail. If the applicant has not done so within the prescribed period, it shall be deemed that the applicant has abandoned the operator application.

Clause 9 If after checking, it is found that an applicant lacks any qualification or has any prohibited characteristic as prescribed in this notification, the Director-General shall issue a refusal order of the application together with a written explanation to the applicant via registered mailed with acknowledgement of receipt within seven days from the day following the date of issue of the refusal order.

Clause 10 An applicant shall have the right to lodge an appeal in writing by specifying the facts of the matter, legal argument(s) or reasons, and submitting supporting evidences (if any) to the Director-General within fifteen days from the day following the date of receiving of the refusal order by post.

The Director-General shall complete the consideration and decision of an appeal within thirty days from the day following the date of the appeal submission. The decision of the Director-General shall be final.

In the case where the appeal period under paragraph one has expired, the Director-General shall dispose of the application from the system.

Clause 11 In the case where a certificate is lost, substantially damaged, faded, or destroyed, the operator may print out a new certificate from the electronic system.

Clause 12 If an operator who has been granted a certificate wishes to change details of the notified particulars, the operator shall apply for a new operator application.

Notification of change under paragraph one shall be submitted, *mutatis mutandis*, in accordance with the criteria, procedures and conditions prescribed in Clause 5 to Clause 10.

Clause 13 The Department of Thai Traditional and Alternative Medicine shall prepare an operator registry for dissemination and linkage with relevant agencies via the Department's IT system.

Clause 14 Operator application form, certificate of operator form, and operator registry form shall be as prescribed by the Director-General.

Clause 15 The Permanent Secretary of Public Health shall have charge and control of the execution of this notification and shall have the power to make decision over the implementation of this notification, and such decision shall be final.

Issued on 30 March B.E. 2563 (2020)

(Anutin Charnvirakul)

Deputy Prime Minister

Chairperson of the National Herbal Policy Committee