Translation

MINISTERIAL REGULATION
ON HERBAL PRODUCT FORMULA REGISTRATION, NOTIFICATION AND LISTING, B.E. 2563 (2020)*

By virtue of the provisions in section 5 paragraph one, section 34 paragraph four, section 38 paragraph two, section 40 paragraph four, section 41 paragraph two, section 45 paragraph four, section 48, section 49 paragraph two, and section 50 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 one hundred and eighty days as from the date of its publication in the Government Gazette.

Clause 2. In this Ministerial Regulation:

"formula registration" means herbal product formula registration;

"certificate of formula registration" means a certificate of herbal product formula registration;

"notification receipt" means an herbal product notification receipt;

"listing receipt" means an herbal product listing receipt;

"certificate" means a certificate of formula registration, a notification receipt, or a listing receipt.

Clause 3. The following persons can apply for formula registration, notification, or listing of an herbal product under this Ministerial Regulation:

(1) licensed producer or licensed importer of an herbal product;

(2) hirer of licensed producer or licensed importer of an herbal product.

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* Published in the Government Gazette, Vol. 137, Issue 55a, page 8, dated 14th July B.E. 2563 (2020).

Clause 4. Any person who wishes to register a formula as per the Notification by the Minister under section 6 (2), or notify or listing of an herbal product as per the Notification by the Minister under section 6 (3), shall submit an application to the licensing authority, together with relevant information, documents or evidence in accordance with section 36 or section 47, as the case may be.

Clause 5. Upon receiving an application for herbal product formula registration, notification or listing, the licensing authority shall issue an application receipt to the applicant for the evidentiary purpose, and shall examine the application as well as information and documents to determine whether they are correct and complete. If they are incorrect or incomplete, a record of the incorrectness or incompleteness shall be made, and the applicant shall be notified to amend the application or submit correct and complete information, documents or evidence within the period specified by the licensing authority. In the case where the application is not submitted through an electronic means, the licensing authority and the applicant shall also sign the record.

In the case where the applicant for herbal product formula registration, notification or listing fails to amend the application or submit correct and complete information, documents 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 6. In the case where the application for formula registration, together with information, documents and evidence are correct and complete, 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 three hundred and thirty days, and may issue a certificate of formula registration only when there appears to be no ground for refusal of formula registration under section 37.

In the case where the licensing authority issues an order refusing the formula registration and the Committee has approved such refusal order under section 37, the licensing authority shall send a written notice to inform the applicant, together with the reason thereof and the right to appeal within fifteen days as from the date the order is issued.

Clause 7. In the case where the licensing authority issues an order permitting the formula registration, the licensing authority shall send a written notice to inform the applicant, and the applicant shall proceed to pay the certificate of formula registration fee within sixty days as from the date the notice is received. Once the applicant has paid the

fee, the licensing authority shall issue the certificate of formula registration within seven days as from the date the payment is received.

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

Clause 8. In the case where the application for herbal product notification, together with information, documents and evidence are correct and complete, 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 two hundred and forty days, and may issue a notification receipt only when there appears to be no ground for refusal of herbal product notification under section 48 in conjunction with section 37.

In the case where the licensing authority issues an order refusing the herbal product notification and the Committee has approved such refusal order under section 48 in conjunction with section 37, the licensing authority shall send a written notice to inform the applicant, together with the reason thereof and the right to appeal within fifteen days as from the date the order is issued.

The provisions in clause 7 shall also apply to the issuance of notification receipt *mutatis mutandis*.

Clause 9. In the case where the application for herbal product documentation, together with information, documents and evidence are correct and complete, and the applicant has paid for the expenses of the herbal product consideration process, the licensing authority shall consider the application, and may issue a listing receipt only when the formula of the herbal product in the application is correct in accordance with the list annexed to the Notification of the Ministry of Public Health issued under section 6 (3) and there appears to be no ground for refusal of herbal product documentation under section 48 in conjunction with section 37.

The provisions in clause 7 and clause 8 paragraph two shall also apply to the issuance of listing receipt *mutatis mutandis*.

Clause 10. In the case where a certificate holder wishes to vary a particular on a certificate, he or she shall submit an application for particular variation to the licensing authority, together with information, documents or evidence pertaining to the particular intended to be varied as specified in the form of the application for particular variation.

The provisions in clause 5, clause 6, clause 8 paragraph one and paragraph two, or clause 9 paragraph one, as the case may be, shall also apply to the consideration of the application for particular variation and the granting of permission thereof *mutatis mutandis*.

In the case where the licensing authority issues an order permitting the particular variation under paragraph one, the licensing authority shall send a written notice to inform the applicant.

In the case of slight particular variation on a certificate which does not affect the quality, efficacy and safety of the herbal product and does not render such herbal product an herbal product prohibited from being produced, imported or sold under section 58, the certificate holder may vary the particular first before notifying the licensing authority in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

Clause 11. A certificate holder who wished to renew a certificate shall submit an application to the licensing authority no prior to ninety days before the expiration date of the certificate, together with the certificate and information, documents or evidence as specified in the form of application for certificate renewal.

The provisions in clause 5, clause 6, clause 7, clause 8, and clause 9, as the case may be, shall also apply to the consideration of the application for certificate renewal and the granting of permission thereof *mutatis mutandis*.

Clause 12. In the case where a certificate is lost, destroyed or fundamentally damaged, the certificate holder shall submit an application for certificate replacement to the licensing authority within fifteen days as from the date of knowledge of the loss, destruction or fundamental damage, together with information, documents or evidence as follows:

(1) a notice of police report, in the case of loss;

(2) the certificate or certificate number, in the case of destruction or fundamental damage;

(3) other information, documents or evidence as specified in the form of the application for certificate replacement.

The provisions in clause 5 shall also apply to the receipt of the application for certificate replacement *mutatis mutandis*.

In the case where the application, together with information, document and evidence under paragraph one are correct and complete, the licensing authority shall issue a certificate replacement, and the provisions in clause 7 shall apply *mutatis mutandis*.

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

Clause 13. For the purpose of providing conveniences in the notification under this Ministerial Regulation, the licensing authority may also notify the applicant for formula registration, the applicant for notification and the applicant for listing through an electronic means together with the notification in writing.

Clause 14. Certificates 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 15. Submission of application, issuance of certificate, certificate variation, certificate renewal, and issuance of certificate replacement 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 head office of the applicant is located, in the case where the person under clause 3 is a juristic person, or in the locality of the applicant's domicile, in the case where the person under clause 3 is a natural person, 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 or 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 16. All certificates of drug formula registration under the Drugs Act, B.E. 2510 (1967), where they are herbal products, which are issued before the Herbal Products Act, B.E. 2562 (2019) comes into force and have not yet expired, shall remain valid until the expiration of the certificates of drug formula registration as follows:

(1) certificates of drug formula registration which are registered before 1st January B.E. 2540 (1997) shall expire after five years as from the date the Drugs Act (No.6), B.E. 2562 (2019) comes into force;

(2) certificates of drug formula registration which are registered between 1st January B.E. 2540 (1997) and 31st December B.E. 2550 (2007) shall expire after seven years as from the date the Drugs Act (No.6), B.E. 2562 (2019) comes into force;

(3) certificates of drug formula registration which are registered between 1st January B.E. 2551 (2008) and the date the Herbal Products Act, B.E. 2562 (2019) comes into force shall expire after nine years as from the date the Drugs Act (No.6), B.E. 2562 (2019) comes into force.

Given on the 9th day of June, B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

Remarks: The grounds for the promulgation of this Ministerial Regulation are as follows. Whereas section 34 paragraph four, section 38 paragraph two, section 40 paragraph four, section 41 paragraph two, section 45 paragraph four, section 48, section 49 paragraph two and

section 50 paragraph two of the Herbal Products Act, B.E. 2562 (2019) provide that the application for herbal product formula registration and the issuance of certificate of herbal product formula registration, the herbal product notification and the issuance of notification receipt, the herbal product listing and the issuance of listing receipt, the application for particular variation and the granting of permission to vary particular on herbal product formula registration, notification receipt or listing receipt, the application for renewal and the granting of permission to renew certificate of herbal product formula registration, herbal product notification receipt or listing receipt, and the application for and the issuance of replacement of certificate of herbal product formula registration, herbal product notification receipt or listing receipt 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.