REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 15 OF 2019
ON
AMENDMENT TO REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 24 OF 2017 ON CRITERIA AND PROCEDURES FOR DRUG REGISTRATION

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering:
a. that in order to realize the acceleration of public services, the provisions regarding the criteria and procedures for drug registration, especially regarding the drug evaluation pathway and the approvable letter as stipulated in Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration are no longer in accordance with the development of legal needs as well as developments in science and technology in the field of Medicine so that it needs to be amended;
b. that based on the considerations as referred to in point a, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on Amendment to Regulation of the

Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration;

Observing :

1. Law Number 36 of 2009 on Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);
2. Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);
3. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration as amended by Regulation of the Minister of Health Number 1120/Menkes/Per/XII/2008 on Amendment to Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration;
4. Regulation of the Indonesian Food and Drug Authority Number 26 of 2017 on Organization and Working Procedures of the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2017 Number 1745);

HAS DECIDED:

To issue: REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON AMENDMENT TO REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 24 OF 2017 ON CRITERIA AND PROCEDURES FOR DRUG REGISTRATION.

Article I

Several provisions in Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration (State Bulletin of the Republic of Indonesia of 2017 Number 1692) are amended as follows:

1. The provision of Article 37 is amended so it reads as follow:

Article 37

(1) Evaluation pathway consists of:

a. 7 (seven) Days pathway covering Registration for Export-Only Drug;

b. 10 (ten) Days Pathway covering Renewal Registration;

c. 40 (forty) Days pathway covering Minor Variation Registration;

d. 50 (fifty) Days pathway covering the first registration of Investigational New Drugs by the Pharmaceutical Industry investing in Indonesia;

e. 75 (seventy-five) Days pathway covering the first registration of the First Generic Drugs by the pharmaceutical industry investing in Indonesia and Variation Registration of New Drugs and Biological Products related to quality that have been approved in at least 1 (one) country with an established evaluation system;

f. 100 (one hundred) Days pathway covering:

1. New Registration of New Drugs and Biological Products indicated for the treatment of serious diseases that threaten human life (life saving), and/or are easily transmitted to others, and/or there is no or lack of other safe and effective therapeutic options;

2. New Registration of New Drugs and Biological Products based on justification indicated for serious and rare diseases (Orphan Drug) in Indonesia;

3. New Registration of New Drugs, Biological Products, Generic Drugs, and Branded Generic Drugs is intended for national health programs equipped with supporting documents for program requirements or the results of prequalification of the World Health Organization;

4. The first Registration of New Drugs and Biological Products by the pharmaceutical industry investing in Indonesia;
5. New Registration of New Drugs and Biological Products that have gone through the Investigational New Drugs developed by a research institution or the Pharmaceutical Industry in Indonesia, made by the Pharmaceutical Industry in Indonesia and at least 1 (one) clinical trial conducted in Indonesia.
6. New Registration of Generic Drugs that have the same Formulas, source of raw materials, Drug specifications, quality, packaging specifications, manufacturing process, that have and use the same manufacturing facility as Branded Generic Drugs that have been approved or vice versa;
7. Major Variation Registration with new indications/posology for Drugs intended as referred to in point 1) to point 5);
8. Major Variation Registration regarding quality and Product Information;

g. 120 (one hundred and twenty) Days pathway covering New Registration of New Drugs and Major Variation Registration with new indications/posology that have been approved in at least 1 (one) country with an established evaluation system;

h. 150 (one hundred and fifty) Days pathway including New Registration of Generic Drugs and Branded Generic Drugs that are not included in the evaluation pathway as referred to in point f;

i. 300 (three hundred) Days pathway covering New Registration of New Drugs and Biological Products as well as Major Variations Registration with new indications/posology that are not included in the evaluation path as referred to in point d and point e.

2. The provisions of section (2), section (3), and section (5) of Article 45 are amended so that Article 45 reads as follows:

Article 45

(1) The evaluation as referred to in Article 44 is carried out on efficacy and safety data based on scientific evidence and guidelines for the assessment of safety efficacy by the Efficacy-Safety Evaluation Team.

(2) The National Committee for Drug Evaluation conducts discussions on the results of the evaluation as referred to in section (1) and provides recommendations for decisions to the Chairperson.

(3) In the event that a detailed technical clarification and/or explanation is needed on the registration document as referred to in Article 27 clause section (1), the National Committee for Drug Evaluation can request clarification from the Applicants through a hearing.

(4) For the implementation of the hearing as referred to in section (3), the Chairperson delivers a written notification to the Applicants.

(5) The Chairperson submits the decision on the results of the evaluation as referred to in section (2) in writing to the Applicants not later than 30 (thirty) Days from the implementation of the National Committee for Drug Evaluation periodic meeting.

3. The provisions of Article 49 are amended so Article 49 reads as follow:

Article 49

(1) The Chairperson in issuing a decision on the application for registration submitted by the Applicant is given based on the following considerations:
   a. evaluation results of Registration documents and/or recommendations issued by the National Committee for Drug Evaluation, Efficacy-Safety Evaluation Team, Quality Evaluation Team, Product Information and Label Evaluation Team; and/or
   b. results of on-site inspection at the Drug manufacturing facility (in situ).

(2) The decision as referred to in section (1) is in the form of:
   a. approval; or
   b. rejection.

(3) The decision in the form of approval as referred to in section (2) point a is given by the Chairperson to Applicants who meet the administrative requirements and provisions as referred to in Article 4.

(4) The decision in the form of rejection as referred to section (2) point b is given by the Chairperson to Applicants that based on the evaluation and/or assessment does not fulfill the administrative requirements and provisions as referred to in Article 4.

4. The provision of Article 50 is deleted.

5. The provision of section (2) of Article 51 is amended and 1 (one) section namely section (3) is added so that Article 51 reads as follows:

Article 51

(1) Approval as referred to in Article 49 section (2) point a is notified in writing to the Applicants in the form of:
   a. Marketing Authorization;
   b. Export-only approval; or
   c. Variation Registration approval.

(2) The Marketing Authorization as referred to in section (1) point a is issued if the results of commercial scale Drug manufacture meet the requirements.

(3) Exempted from the provisions as referred to in section (1) point a, the Drugs that have not been manufactured on a commercial scale may be issued an approvable letter in preparing the commercial scale Drug manufacture.

6. Several provisions in Annex XIII are amended so that they become as listed in the Annex as an integral part of this Agency Regulation.

Article II

This Agency Regulation comes into force on the date of its promulgation.

In order that every person may know hereof, it is ordered to promulgate this Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 17 July 2019

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 18 July 2019

DIRECTOR GENERAL OF LEGISLATION
OF THE MINISTRY OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2019 NUMBER 779

Jakarta, 17 October 2022
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia
DIRECTOR GENERAL OF LEGISLATION AD INTERIM,

DHAHANA PUTRA

ANNEX TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 15 OF 2019
ON
AMENDMENT TO REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 24 OF 2017 ON CRITERIA AND PROCEDURES FOR DRUG REGISTRATION

PRE-REGISTRATION DOCUMENT REQUIREMENTS

A. ADMINISTRATIVE DOCUMENTS

1. Cover letter.
2. Certificates and other administrative documents in accordance with Annex VI.
3. Documents for determining the 100 (one hundred) Days pathway.
   3.1. Justification that the Drug is indicated for serious and rare diseases (Orphan Drug), and/or
   3.2. Justification that the Drug is indicated for the treatment of serious diseases that threaten human life (lifesaving), and/or easily transmitted to others, and/or there is no or lack of other treatment options that are safe and effective, and/or
   3.3. Supporting documents for public health programs.
4. Documents for determining the 120 (one hundred and twenty) Days pathway.

   Supporting documents for Registration requirements that have been approved in the reference country with a well-known evaluation system:

   1.1. Information on Marketing Authorization status from other country and accompanied by valid evidence.
   1.2. Full Assessment Report (AR) document is available in English from the reference country authority body, with the proposed indication and posology requirements similar to those approved in the reference country. If the Drug has been approved in more

than one country, a comparison matrix should be provided and the one approved is the most stringent.

The Registration conditions with the reference country:

4.2.1. Criteria for selecting a reference country:

4.2.1.1. The country that will be the reference is a country with a well-known evaluation system and has published AR in English, and

4.2.1.2. It has become a reference country by many other countries.

Based on the above criteria, the reference countries are the European Union, US, Australia, Canada, UK and Japan.

4.2.2. All aspects related to Drug quality, including but not limited to source of raw materials, formula, manufacturing site, release and shelf life specifications, must be identical to those approved in the reference country.

4.2.3. The proposed Drug is not a Drug that requires specific evaluation related to differences in disease patterns, resistance patterns and/or national program policies, such as anti-infective, antiviral (Hepatitis C; HIV), anti-malarial, and Tuberculosis Drugs.

4.2.4. A declaration letter stating that all aspects of Drug quality are identical to those approved in the reference country, including a statement that the Drug Master File (DMF) submitted to the Indonesian FDA is identical to that submitted to the reference country, if required.

4.2.5. The Drug has been approved in the reference country with approval in the last 5 (five) years.

5. Documents for determining the 300 (three hundred) Days pathway For New Registration of New Drugs, Biological Products, or Registration of Major Variation with new indications/new posology that are not included in the 100 (one hundred) Days and 120 (one hundred and twenty) Days pathway, an evaluation will be carried out through the 300 (three hundred) Days pathway.

6. Drug documents related to patents (if necessary)

6.1. Patent-related declaration letter.

6.2. Results of patents searches from the Directorate General of Intellectual Property.

6.3. Results of patent self-assessment.

B. QUALITY DOCUMENTS

1. Quality overall summary.
2. Information on animal-derived ingredients used in the manufacturing process of Active Pharmaceutical Ingredients and Drugs.
3. DMF or equivalent document from the manufacturer of Active Pharmaceutical Ingredients for Active Pharmaceutical Ingredients that have never been used for the manufacturing of approved Drugs in Indonesia (if necessary).
4. Equivalence data (summary/protocol) or justification if it is not required for an equivalence test.

C. NON-CLINICAL DOCUMENTS (if necessary)

1. Non-clinical overview.
2. Non-clinical tabulated summary.

D. CLINICAL DOCUMENT (if necessary)

1. Clinical overview.
2. Tabulated study synopses.

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO