REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 13 OF 2021
ON
THIRD 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 the approval of the Emergency Use Authorization as stipulated in the Regulation of the Head Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration as amended several times, most recently by Regulation of the Food and Drug Authority Number 27 of 2020 on Second Amendment to Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration, needs to be adjusted to the criteria and/or requirements for safety, efficacy, and quality in order to grant the Emergency Use Authorization;

b. that based on the provisions of Article 3 section (1) point d of Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority, the Indonesian Food and Drug Authority has the function of carrying out supervisory duties in pre-market and supervising during the post-market;

c. that based on the considerations as referred to in point a and point b, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on the Third 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 6 of 2018 on Health Quarantine (State Gazette of the Republic of Indonesia of 2018 Number 128, Supplement to the State Gazette of the Republic of Indonesia Number 6236);
2. Government Regulation Number 5 of 2021 on the Implementation of Risk-Based Business Licensing (State Gazette of the Republic of Indonesia of 2021 Number 15, (Additional State Gazette of the Republic of Indonesia Number 6617);
3. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);
4. Presidential Regulation Number 99 of 2020 on Vaccine Procurement and Vaccination in Combating the Corona Virus Disease 2019 (COVID-19) Pandemic (State Gazette of the Republic of Indonesia of 2020 Number 227) as amended by Presidential Regulation Number 14 of 2021 on Amendments to Presidential Regulation Number 99 of 2020 on Vaccine Procurement and Vaccination in Combating the Corona Virus Disease 2019 (COVID-19) Pandemic (State Gazette of the Republic of Indonesia of 2021 Number 66);
5. 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;
6. Regulation 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 1745) as amended by Regulation of the Indonesian Food and Drug Authority Number 27 of 2020 on Second Amendment to 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 2020 Number 1123);

7. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Working Procedure of the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1002);

HAS DECIDED:

To issue: REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THIRD 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) as amended by Regulation of the Indonesian Food and Drug Authority Number 27 of 2020 on Second Amendment to 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 2020 Number 1123) are amended as follows:

1. The provision of Article 1 is amended so that Article 1 reads as follows:

Article 1

In this Authority Regulation:

1. Drug Registration hereinafter referred to as Registration means the procedure for registration and evaluation of Drugs to obtain approval.

2. Drug means a finished product including Biological Product, which is a substance or combination of substances used to affect or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, treatment, recovery, and improvement of health, and contraception for humans.
3. Biological Product means a product containing biological materials derived from a human, animal, or microorganisms prepared in a conventional way, including extraction, fractionation, reproduction, cultivation, or through biotechnology methods, among others fermentation, genetic engineering, cloning, including but not limited to enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, DNA recombinant products, and immunosera.
4. Contraceptive mean a Drug or device containing a drug that is intended to prevent conception.
5. Narcotic mean a Drug derived from a plant or non-plant, both synthetic and semi-synthetic, which can cause a decrease or change in consciousness, loss of sense, alleviate and relieve of pain and can create an addiction, which is differentiated into categories as stipulated in the Law on Narcotics.
6. Psychotropic mean a drug both natural and synthetic, non-Narcotics, which has psychoactive properties through selective effect on the central nervous system that causes distinctive changes in mental activity and behavior.
7. Marketing Authorization means a form of Registration approval to be distributed in the territory of Indonesia.
8. Emergency Use Authorization abbreviated as EUA means an approval for the use of Drugs in a public health emergency situation for those that have not yet obtained marketing authorization or for those that have obtained marketing authorization for other use or indication.

9. Marketing Authorization Holder means an Applicant who has obtained a Marketing Authorization for Drugs submitted for Registration.
10. Label means information printed on the packaging.
11. Summary of Product Characteristics/Brochure means complete information approved by the Chairperson regarding the description of Drugs, efficacy, and safety of Drugs from the data of clinical trial results, and other information that is considered necessary and serves as a source of information for healthcare professional and a reference in the preparation of Product Information for Patients.
12. Product Information means a complete description of Drugs approved by the Chairperson, including efficacy, safety, route of administration and other information deemed necessary that is listed in the Summary of Product Characteristics/Brochures and/or Patient Information Leaflet.
13. Patient Information Leaflet means information for patients approved by the Chairperson regarding the efficacy, safety, and route of administration and other information deemed necessary by using Indonesian that is easy to understand and comprehended by patients.
14. Applicant means Pharmaceutical Industry that has obtained licensing in Pharmaceutical Industry in accordance with the provisions of legislation.
15. Pharmaceutical Industry means a business entity that has a license from the Minister of Health to carry out Drug product or drug substances manufacturing activities.
16. Domestic Pharmaceutical Industry means a Pharmaceutical Industry located in the territory of Indonesia.
17. New Registration means a Registration for Drugs that have not obtained a Marketing Authorization in Indonesia.
18. Variation Registration means the Registration of changes in aspects of administration, efficacy, safety, quality, and/or Product Information and Drug Labels that have been Marketing Authorization in Indonesia.

19. Major Variation Registration means a Variation Registration that has a significant impact on the aspects of efficacy, safety and/or quality of Drugs.
20. Minor Variation Registration means a Variation Registration that does not belong to the category of Major Variation Registration or Notification Variation Registration.
21. Notification Variation Registration means a Variation Registration that has minimal or no impact at all on aspects of efficacy, safety, and/or quality of Drugs, and does not change the information on the Marketing Authorization.
22. Renewal registration means the registration of extension of the Marketing Authorization validity period.
23. Biosimilar Product means a Biological Product with a similar profile of efficacy, safety, and quality to approved Biological Products.
24. Good Manufacturing Practice, hereinafter abbreviated as GMP means a method of Drugs manufacturing that aims to ensure that the quality of drugs produced is in accordance with the requirements and purposes of use.
25. Active Pharmaceutical Ingredients means a component of drugs that have pharmacological effects.
26. Excipient means a component of drugs that do not have pharmacological effects.
27. Composition means a qualitative and quantitative arrangement of Active Pharmaceutical Ingredients in Drugs.
28. Formula means a qualitative and quantitative arrangement of Active and Excipient Substances in Drugs.
29. New Drug means a Drug with a New Chemical Entity, new dosage form, new strength, or new combination having never been approved in Indonesia.
30. Branded Generic Drug means a Drug with trade names containing Active Pharmaceutical Ingredients with the same Composition, strength, dosage form, route of administration, indications, and posology with originator drugs that have been approved in Indonesia.

31. Generic Drug means a drug with the name according to International Nonproprietary Names Modified determined by the World Health Organization or the name specified in the national health program.
32. First Generic Drug means the first Generic Drug registered in Indonesia with the same Active Pharmaceutical Ingredients as the Originator Drug approved in Indonesia.
33. Local Drug mean a drug made or packaged primary by the Pharmaceutical Industry in Indonesia.
34. Contract Giver means the Pharmaceutical Industry that delegates the work of manufacturing drugs based on a contract.
35. Contract Acceptor means the Pharmaceutical Industry that accepts Drug manufacturing works based on a contract.
36. Imported Drug means a drug made by the pharmaceutical industry abroad in the form of a Finished Product or a Bulk Product in primary packaging to be distributed in Indonesia.
37. Finished Product means a product having gone through all stages of the manufacturing process.
38. Bulk Product means an ingredient having been processed and only requiring packaging to become Drugs.
39. Contract Drug means a drug whose manufacture is delegated to other Pharmaceutical Industries.
40. Licensed Drug means a Drug made by Domestic Pharmaceutical Industry on the basis of a License.
41. License means the delegation of right and authority to use the results of research and development related to efficacy, safety, quality, and technology transfer in the manufacture, and/or use of trade names and marketing of a Drug.
42. Patent Protected Drug means a Drug that obtains patent protection based on the applicable Patent Law in Indonesia.
43. Investigational New Drug means a Drug product or drug substances in the form of a new molecule or new Formula, Biological Product/biotechnology being developed and manufactured by a research institution or Pharmaceutical Industry in Indonesia and/or abroad for use in the nonclinical and/or clinical trial stages in Indonesia with the aim of obtaining a Marketing Authorization in Indonesia.

44. Orphan Drug means an indispensable Drug for the treatment of rare diseases and it has been proven its7 safety and effectiveness.
45. Form means a registration form.
46. Day means a work day.
47. Chairperson means the Chairperson of the Indonesian Food and Drug Authority.

2. The provision of Article 3 is amended to read as follows:

Article 3

(1) Exclusion from the provisions as referred to in Article 2 section (1) is intended for Special Access Scheme Drug.
(2) Special Access Scheme Drug as referred to in section (1) is carried out in accordance with the provisions of the legislation.

3. The provision of Article 3A is amended to read as follows:

Article 3A

(1) In the event of a public health emergency, the Marketing Authorization as referred to in Article 2 section (1) may be in the form of an EUA.
(2) EUA as intended in section (1) only applies to the use of Drugs during a public health emergency which is intended for the treatment of patients in accordance with the provisions of legislation.
(3) To obtain the EUA as referred to in section (1), the Applicant must register their product -
(4) The EUA as referred to in section (1) is granted by the Chairperson

4. Between Article 3A and Article 4, 1 (one) article is inserted, namely Article 3B, so that it reads as follows:

Article 3B

(1) Drugs as referred to in Article 3A section (2) must meet the following criteria of:
   a. in accordance with the declaration of public health emergencies by the government;
   b. any sufficient scientific evidence related to the safety and efficacy aspects of Drugs in order to prevent, diagnose, or treat serious and life-threatening diseases/conditions based on non-clinical, clinical data, and related guidelines on management of disease;
   c. having quality that meets the applicable standards and Good Manufacturing Practices
   d. having a greater benefit than risk (risk-benefit analysis) based on a review of non-clinical and clinical data of drugs for the proposed indication; and
   e. no alternative treatment/management that is adequate and approved for the diagnosis, prevention or treatment of the disease that cause public health emergency.

(2) Importation, production, and distribution of Drugs for EUA as referred to in Article 3A section (1) is carried out in accordance with the provisions of legislation.

(3) Pharmaceutical Industry that has EUA as referred to in Article 3A section (1) is obligated to:-
   a. be responsible for the quality of Drugs;
   b. conduct follow-up studies/clinical trials on drugs currently under clinical trial research in the world to ensure their effectiveness and safety;-
   c. conduct pharmacovigilance monitoring and adverse event/adverse drug reaction reporting to the Chairperson in accordance with the provisions of legislation; and
   d. report the realization of importation, production, and distribution of Drugs during the emergency use authorization to the Chairperson in accordance with the provisions of legislation.

(4) Further provisions regarding EUA as referred to in Article 3A section (1) are implemented in accordance with the technical implementation instructions stipulated by the Chairperson of the Indonesian Food and Drug Authority.

Article II

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

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

Issued in Jakarta
on 28 April 2021

CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 29 April 2020

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 2021 NUMBER 461

Jakarta, 8 May 2023
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,

DIREKTUR JENDERAL PERATURAN PERUNDANG-UNDANGAN KEMENTERIAN HUKUM DAN HAK ASASI MANUSIA

ASEP N. MULYANA