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

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that in order to support the acceleration of drug availability in Indonesia for handling public health emergencies, it is necessary to regulate the emergency use authorization;

b. that the provisions regarding the exception to the obligation to have a marketing authorization for drugs to be distributed in the territory of Indonesia as regulated in the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on Criteria and Procedures for Drug Registration as amended by Regulation of the Indonesian Food and Drug Authority Number 15 of 2020 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, needs to be adjusted to the legal needs as well as the developments in science and technology in the field of medicine, especially for drug use in public health emergencies;

c. that based on the provision of Article 3 of Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority, one of the functions of the Indonesian Food and Drug Authority is implementation of drug and food control before distribution and during distribution;

d. that based on the considerations as referred to in point a, point b, and point c, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on the 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;

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. Presidential Regulation Number 80 of 2017 on the 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 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 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 (State Bulletin of the Republic of Indonesia of 2017 Number 779);
5. 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 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.

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 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 (State Bulletin of the Republic of Indonesia of 2019 Number 779) are amended as follows:

1. The provision of Article 3 is amended so that Article 3 reads as follows:

Article 3

(1) Exclusion from the provisions as referred to in Article 2 section (1) is intended for:
   a. Special Access Scheme Drug: and
   b. emergency use of Drugs during public health emergencies.

(2) Special Access Scheme Drug as referred to in section (1) point a is carried out in accordance with the provisions of legislation.

(3) Emergency use of Drugs during public health emergencies as referred to in section (1) point b is carried out through the issuance of the emergency use authorization.

(4) The issuance of the emergency use authorization as referred to in section (3) is given by the Chairperson.

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

Article 3A

(1) The Emergency Use Authorization as referred to in Article 3 section (4) only applies to the use of Drugs during public health emergencies that is intended for the treatment of patients in accordance with the provisions of legislation.

(2) Importation, production and distribution of Drugs as referred to in section (1) are carried out in accordance with the provisions of the legislation.

(3) The Pharmaceutical Industry as the holder of the emergency use authorization as referred to in section (1), is obligated to:

a. being responsible for the quality of Drugs;

b. conduct follow-up studies/clinical trials of Drugs that are in clinical trial research in the world to ensure its 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 the import, production and distribution of Drugs during the emergency use authorization to the Chairperson in accordance with the provisions of legislation.

Article II

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

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

Issued in Jakarta
on 29 September 2020

CHAIRPERSON OF INDONESIAN FOOD
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 29 September 2020

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

signed

WIDODO EKATJAHJANA

STATE OF THE REPUBLIC OF INDONESIA 2020 NUMBER 1123

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,

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

DHAHANA PUTRA