THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA

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The Original document is written in Bahasa Indonesia, and subsequently translated into English. In the event of a discrepancy between the two versions, Bahasa Indonesia version shall take precedence.

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 14 OF 2019 ON THE RECALL AND THE DESTRUCTION OF DRUGS THAT FAIL TO MEET STANDARDS AND/OR REQUIREMENTS FOR SAFETY, EFFICACY, QUALITY AND LABEL

BY THE BLESSINGS OF ALMIGHTY GOD

THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that the public needs to be protected from health risks in response to the circulation of drugs that fail to meet standards and/or requirements for safety, efficacy, quality, and labels;

b. that the provisions regarding the criteria and procedures for recalling drugs that fail to meet the standards and/or requirements as regulated in the Regulation of the Chairperson of Regulation of the Indonesian Food and Drug Authority Number HK.04.1.33.12.11.09938 OF 2011 on Criteria and Procedures for the Recall of Drugs Not Fulfilling Standards and/or Requirements, have been no longer in accordance with the development of legal needs as well as developments in science and technology in the field of Drugs, therefore those need to be replaced;

c. that based on the considerations as referred to in point a and point b, it is necessary to issue a Regulation of the Indonesian Food and Drug Authority on Recall and the Destruction of Drugs Not Fulfilling Standards and/or Requirements for Safety, Efficacy, Quality, and Labels;

Observing : 1. Law No. 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 the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);

3. Regulation of the Indonesian Food and Drug Authority Number 26 of 2017 on Organization and Work Procedure of the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2017 Number 1745);

4. Regulation of the Indonesian Food and Drug Authority Number 12 of 2018 on Organization and Work Procedure of Technical Implementing Units within the Indonesian Food and Drug Authority Environment (State Bulletin of the Republic of Indonesia of 2018 Number 784);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THE RECALL AND THE DESTRUCTION OF DRUGS THAT FAIL TO MEET STANDARDS AND/OR REQUIREMENTS FOR SAFETY, EFFICACY, QUALITY AND LABEL.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Agency Regulation:

1. Drug Recall means the process of recalling any drug in circulation that fail to meet the standards and/or requirements of safety, efficacy, quality and label.
2. Drug destruction means an act of destroying and eliminating drugs, packaging and/or labels thereof, that fail meet the standards and/or requirements of safety, efficacy, quality and labels thus preventing them from being further used.
3. Drug means a finished medicine including Biological Products, which is an ingredient or combination of ingredients used to influence or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, healing, recovery, and improvement of health, and contraception for humans.
4. Marketing Authorization Holder means any pharmaceutical industry that has received Marketing Authorization approval for registered Drugs.
5. Good Manufacturing Practices (*Cara Pembuatan Obat yang Baik*), hereinafter abbreviated as CPOB, means a method of manufacturing Drugs which aims to ensure that the quality of Drugs products is in accordance with the requirements and purposes of use.
6. A batch means a number of Drugs which have uniformity in characteristics and quality and are produced in one manufacturing cycle on a certain manufacturing order.
7. Rapid Vigilance System means a rapid notification from the Indonesian Food and Drug Authority to other state authorities or vice versa regarding drugs that fail to meet standards and/or requirements for safety, efficacy, quality, and labels.

8. Supervisory Officer, hereinafter referred to as Officer, means a civil servant within the Indonesian Food and Drug Authority who is assigned to supervise the implementation of recall activities and drug.
9. Days means work days.
10. Letter of Recall means an instruction or order for the Drug Recall from the Chairperson of the Indonesian Food and Drug Authority to the Marketing Authorization Holder or from the Marketing Authorization Holder to distribution facilities and pharmaceutical service facilities.
11. The Chairperson of the Agency means the Chairperson of the Indonesian Food and Drug Authority.

Article 2

(1) Marketing Authorization Holder is obligated to guarantee that the drug circulated in the territory of Indonesia has been in compliance with the standards and/or requirements for safety, efficacy, quality, and label.
(2) Standards and/or requirements for safety, efficacy and quality, as referred to in section (1) refer to:
    a. parameters as stated in the Indonesian Pharmacopoeia or other standard books in accordance with the provisions of llegislation;
    b. registration documents that have been approved; and/or
    c. fulfillment of CPOB.
(3) Standard and/or label requirements as referred to in section (1) refer to the approved registration documents.

CHAPTER II
RECALL OF DRUGS
Part One
General

Article 3

(1) Marketing Authorization Holder is obligated to recall Drugs that fail to meet the standards and/or requirements of safety, efficacy, quality and label.
(2) The recall as referred to in section (1) may apply to 1 (one), several, or the entire Batch.

Part Two
Recall Criteria

Article 4

(1) The Recall as referred to in Article 3 takes the form of:
    a. Mandatory recall; or
    b. Independent recall.
(2) The mandatory recall as referred to in section (1) point a is a recall ordered by the Chairperson of the Agency.
(3) The mandatory recall as referred to in section (1) point a is conducted based on:
    a. the results of sampling and testing;
    b. Rapid Vigilance System;
    c. the results of verification of public complaints;
    d. the results of studies on the safety and/or efficacy of Drugs; and/or
    e. findings of inspection results.
(4) An Independent recall as referred to in section (1) point b refers to a recall initiated by the Marketing Authorization Holder.
(5) The independent recall as referred to in section (1) point b is conducted based on the detection of risk by The Marketing Authorization Holder regarding safety, efficacy, quality, and drug labels in circulation.

(6) The Marketing Authorization Holder carries out an independent recall as referred to in section (1) point b by issuing a recall instruction.

(7) Independent recall instructions as referred to in section (4) is submitted to distribution facilities and pharmaceutical service facilities.

(8) The recall instructions as referred to in section (7) is submitted as a copy to the Chairperson of the Agency and the Director General serving at the Ministry of Health who is in charge of the field of Pharmaceuticals.

Article 5

(1) In the event that the independent recall is conducted as referred to in Article 4 section (1) point b, the Marketing Authorization Holder is obligated to submit information on the plan of the Drug Recall to the Chairperson of the Agency.

(2) The information as referred to in section (2) at minimum contain the following information:
   a. Drug identity;
   b. reasons for recall;
   c. the stipulation of recall class; and
   d. recall range.

Part Three

The Classification of Drug Recall

Article 6

The Recall of Drugs that fail to meet the standards and/or requirements as referred to in Article 3 is classified into:

a. The Recall of Class I Drugs;

b. The Recall of Class II Drugs; and

c. The Recall of Class III Drugs.

Paragraph 1
The Recall of Class I Drugs

Article 7

(1) The Recall of Class I Drugs as referred to in Article 6 point a is conducted for Drugs which, if consumed, c cause death, permanent disability, fetal defects, or serious effects on health.
(2) The Recall of Class I Drugs as referred to in section (1) is conducted if:
    a. Drugs fail to meet safety requirements;
    b. Drugs are contaminated with microbes on sterile preparations;
    c. Drugs are contaminated with pathogenic microbes in the required oral preparations;
    d. Drugs are contaminated with chemicals that cause serious health effects;
    e. the label does not describe the content and/or the strength of the active substance properly;
    f. Drugs mixed with other drugs in one container; and/or
    g. Multi-component drugs containing the wrong active substance.

Paragraph 2
The Recall of Class II Drugs

Article 8

(1) The Recall of Class II Drugs as referred to in Article 6 point b is implemented for Drugs which, if consumed, may cause illness or mistreatment which may cause temporary effects on health followed by recovery.
(2) The Recall of Class II Drugs as referred to in section (1) may be conducted if:

a. Drugs does not guarantee sterility in the production of sterile preparations;
b. the label is considered incomplete or misprinted related to efficacy and/or quality in addition to recall considerations as referred to in Article 7 section (2);
c. the brochures or leaflets provide false or incomplete information;
d. the products are contaminated with microbes in non-sterile drug preparations according to requirements and/or specifications;
e. the products are contaminated with chemical or physical substances (excessive impurities or particulates, cross-contamination); and/or
f. The drug fails to meet the specifications for uniformity of content, weight diversity, dissolution, potency, level, degree of acidity (pH) of sterile preparations, description, water content, or other stability parameters.

Paragraph 3
The Recall of Class III Drugs

Article 9

(1) The Recall of Class III Drugs as referred to in Article 6 point c is conducted for Drugs that do not cause significant harm to health and are not included in the Recall of Class I Drugs as referred to in Article 7 and the Recall of Class II Drugs as referred to in Article 8.
(2) The Recall of Class III Drugs as referred to in section (1) may be conducted, if:
a. the label is considered incomplete or misprinted related to other than safety, efficacy and/or quality;
b. Drugs fail to meet the specifications for disintegration time, volume transferred, or degree of acidity (pH) of non-sterile preparations;

c. the packaging is damaged which may affect safety, efficacy and/or quality; and/or

d. Drugs fail to meet the standards and/or requirements, are not classified as Drugs, and must be recalled based on class I Drug Recall and Class II Drug Recall.

Part Four
The Scope of Recall

Article 10

(1) The Drug Recall covers:
   a. distribution facilities;
   b. pharmaceutical service facilities;
   c. health service facilities; and
   d. the public.

(2) The Drug Recall covers distribution facilities, pharmaceutical service facilities and health service facilities as referred to in section (1) which it includes:
   a. pharmaceutical wholesalers;
   b. government pharmaceutical installations;
   c. pharmacies;
   d. hospital pharmacy installation;
   e. community health centers;
   f. clinics;
   g. drug stores;
   h. doctors; and
   i. midwife practices.

(3) The Chairperson of the Agency may change the scope of Drug Recalls as referred to in section (2) based on considerations of risk studies.

Article 11

(1) The distribution facilities as referred to in Article 10 section (2) which fall within the recall scope is obligated to conduct recalls in accordance with the instructions of the Marketing Authorization Holder.

(2) In addition to implementing the provisions as referred to in section (1), distribution facilities is obligated to make returns and reports.

(3) The returns and the report as referred to in section (2) is made in accordance with technical guidelines regarding the proper distribution of Drugs.

Article 12

(1) Pharmaceutical service facilities that are within the scope of the recall is obligated to carry out the return in accordance with the instructions of the Marketing Authorization Holder.

(2) In addition to implementing the provisions as referred to in section (1), pharmaceutical service facilities is obligated to conduct reporting.

(3) The reporting as referred to in section (2) is conducted in accordance with technical guidelines on how to manage Drugs in pharmaceutical service facilities.

Article 13

The procedure for Drug Recall from government-owned pharmaceutical installations, government-owned hospital-pharmacy installations, and public health centers shall be carried out in accordance with the provisions of legislation.

Article 14

(1) Health service facilities that are within the scope of the recall is obligated to carry out the return in accordance with the instructions of the Marketing Authorization Holder.

(2) In addition to implementing the provisions as referred to in section (1), health service facilities is obligated to conduct reporting.

(3) The reporting as referred to in section (2) is carried out in accordance with the provisions of legislation.

Article 15

The Drug Recall amid the public as referred to in Article 10 section (1) point d is conducted through publication.

Part Five

Reporting

Article 16

(1) The implementation of Drug Recall as referred to in Article 4 is required to be reported to the Chairperson of the Agency.

(2) The report as referred to in section (1), includes:

a. the initial report on the implementation of Drug Recall;

b. the periodic reports on the implementation of Drug Recall; and

c. final report on the results of drug recall.

Article 17

(1) The initial report as referred to in Article 16 section (2) point a contains at least information and completeness of data and/or documents as follows:

a. the number of Drugs produced for the batch to recall;

b. the remaining stock of drugs that have not been circulated;

c. he number of Drugs circulated in each distribution facility, pharmaceutical service facility, and/or health service facility for the batch being withdrawn;

d. a copy of the recall instruction from the Marketing Authorization Holder to distribution facilities, pharmaceutical service facilities, and/or health service facilities; and

e. publication implementation.

Article 18

Periodic reports as referred to in Article 16 section (2) point b at least contains information and completeness of data and/or documents as follows:

a. the results of investigations and supporting data in making final conclusions;
b. the progress of corrective and preventive actions which are taken to prevent recurrence; and
c. the data progress of recall result.

Article 19

The final report on the results of Drug Recall as referred to in Article 16 section (2) point c is equipped with the following information and/or documents:

a. the data of recall result; and
b. the implementation of corrective and preventive actions which are taken to prevent recurrence.

Part Six

The Period for Submitting Drug Reports

Article 20

(1) The initial report on the implementation of Drug Recall as referred to in Article 16 section (2) point a is required to be submitted within the maximum period of:
    a. 1 x 24 (one times twenty four) hours since the date of the recall letter in the case of the Recall of Class I Drugs;
    b. 5 (five) Days since the date of the recall letter for the Recall of Class II Drugs; and
    c. 10 (ten) Days since the date of the recall letter for the Recall of Class III.
(2) The final report on the implementation of Drug Recall as referred to in Article 16 section (2) point c is required to be submitted with the following conditions:
    a. The drug recall at a distribution facility is conducted within the maximum period of:

1. 10 (ten) Days since the date of the recall letter for the Recall of Class I;
2. 20 (twenty) Days since the date of the recall letter for the Recall of Class II Drugs; and
3. 40 (forty) Days since the date of the recall letter for the Recall of Class III.

b. The drug recall at pharmaceutical service facilities and health service facilities shall be conducted within the maximum period of:
1. 40 (forty) Days since the date of the recall letter for the Recall of Class I;
2. 80 (eighty) Days since the date of the recall letter for the Recall of Class II Drugs; and
3. 120 (one hundred and twenty) Days since the date of the recall letter for the Recall of Class III.

Article 21

The Marketing Authorization Holder is obligated to monitor and evaluate the effectiveness of the implementation of Drug Recall.

Part Seven
Publication

Article 22

(1) The Marketing Authorization Holder is obligated to carry out the publication related to Drug Recall and ensure its effectiveness.
(2) The publication as referred to in section (1) shall be carried out through printed and electronic media.
(3) The publication as referred to in section (1) is required to be carried out under the following conditions:
a. the Recall of Class I Drugs classification within a maximum period of 1 x 24 (twenty four) hours since the date of the recall letter;
b. the Recall of Class II Drugs classification within a maximum period of 3 (three) days since the date of the recall letter; and

c. the Recall of Class III Drugs classification within a maximum period of 5 (five) days since the date of the recall letter.

Article 23

(1) The publication is made based on the results of a risk assessment which states that Drug Recall must be informed to the public.
(2) The publication as referred to in section (1) may be carried out by the Chairperson of the Agency or authorized official for the purpose of protecting the society.

Article 24

In the event that the Chai of Agency and/or Distribution Permit Holder make publication as referred to in Article 22 and Article 23, the publication of Drug Recall is required to contain the following information:

a. the identity of the drug that fails to meet the recall standards and/or requirements and the scope of its circulation;
b. Recalled batch;
c. the reasons for the Recall of the Drug that fails to meet standards and/or requirements;
d. the Recall scope of the Drug that fails to meet standards and/or requirements; and
e. the guidance information for the public or health workers if they find, have and/or have consumed the drug.

CHAPTER III

PUBLIC PARTICIPATION

Article 25

The public may participate in supervising the implementation of Drug Recall conducted by the Marketing Authorization Holder.

Article 26

The roles of the society in monitoring the implementation of the Drug Recall as referred to in Article 25, include:

a. reporting that the drug circulation that has been recalled by the Marketing Authorization holder or the National Agency of Drug and Food Control is still in circulation; and
b. participating in the dissemination of information related to Drug Recall conducted by the Marketing Authorization Holder or the Indonesian Food and Drug Authority in accordance with the provisions of legislation.

CHAPTER IV
DESTRUCTION

Article 27

(1) Drugs that fail to meet the standards and/or requirements, have been recalled from circulation, or are still in the warehouse of the Marketing Authorization Holder, is required to be destroyed.
(2) Destruction of Drugs as referred to in section (1) is carried out on:
    a. Drugs;
    b. packaging; and/or
    c. labels.
(3) In the event that that Drug destruction be carried out on the packaging as referred to in section (2) point b and on the label as referred to in section (2) point c however such packaging and label do not affect the quality of the Drug, the Drug may be repackaged.
(4) The Marketing Authorization Holder is responsible for repackaging as referred to in section (3).
(5) The repackaging referred to in section (3) is required to be implemented in accordance with the provisions of CPOB.

(6) The Destruction of Drugs as referred to in section (1) shall be carried out by taking into account that the drugs:
   a. do not cause a decrease in health for humans; and
   b. do not pollute the environment.

(7) The Drug Destruction as referred to in section (6) is carried out in accordance with the provisions of legislation.

Article 28

(1) The Destruction of Drugs as referred to in Article27 is conducted by the Marketing Authorization Holder witnessed by the Officer.

(2) The Marketing Authorization Holder is obligated to make a Destruction Record related to the activity as referred to in section (1).

(3) The destruction record as referred to in section (2) contains at least the following information:
   a. the day, date and place/location of destruction;
   b. the party that destroyed/the Marketing Authorization Holder;
   c. the witnessing officer;
   d. the name of the Drugs;
   e. the form of preparation;
   f. the distribution license number;
   g. the amount of the drug;
   h. the batch number;
   i. the destruction method; and
   j. names and signatures of the parties who destroy it and witnesses.

Article 29

(1) The implementation of Drug Destruction as referred to in Article 27 is required to be reported to the Chairperson of the Agency.

(2) The report as referred to in section (1) is equipped with the destruction record as referred to in Article 28 section (2) and visual documentation.

(3) Visual documentation as referred to in section (2) may be in the form of photos and/or video recordings of the destruction.

CHAPTER V
ADMINISTRATIVE SANCTIONS

Article 30

(1) The Marketing Authorization Holder that violates Article 2 section (1), Article 3 section (1), Article 5 section (1), Article 11 section (1) and section (2), Article 12 section (1) and section (2), Article 14 section (1) and section (2), Article 16 section (1), Article 20 section (1) and section (2), Article 21, Article 22 section (1) and section (3), Article 24, Article 27 section (1) and section (5), Article 28 section (2) and Article 29 section (1) is subject to administrative sanctions in the form of:
   a. warning;
   b. stern warning;
   c. temporary cessation of drug manufacturing;
   d. freezing of marketing authorization;
   e. revocation of marketing authorization;
   f. freezing of CPOB certificates; and/or
   g. revocation of the CPOB certificate.

(2) Temporary cessation of drug manufacturing as referred in section (1) pointc for all activities or part of activities.

(3) The administrative sanctions as referred to in section (1) isimposed on the Marketing Authorization Holder by the Chairperson of the Agency.

Article 31

The procedure for the imposition of administrative sanctions as referred to in Article 30 is implemented in accordance with the Decision of the Chairperson of the Agency which regulates the follow-up on the results of supervision.

CHAPTER V
TRANSITIONAL PROVISIONS

Article 32

At the time this Agency Regulation was promulgated, the recall and destruction activities of drugs that fail to meet standards and/or requirements for safety, efficacy, quality, and labels, which are in the process of such drug recall and destruction based on the provisions of the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.04.1. 33.12.11.09938 of 2011 on the Criteria and Procedures for Drugs Recall that Fail to Meet Standards and/or Requirements, remains to be implemented based on the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.04.1.33.12.11.09938 of 2011 on Criteria and Procedures for Recall of Drugs that Fail to Meet the Standards and/or Requirements.

CHAPTER VI
CLOSING PROVISIONS

Article 33

At the time this Agency Regulation comes into force, Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.04.1.33.12.11.09938 of 2011 on Criteria and Procedures for Recall of Drugs that Fail to Meet the Standards and/or Requirements (State Bulletin of the Republic of Indonesia of 2011 Number 551) is repealed and declared ineffective.

Article 34

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

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

Issued in Jakarta
on 17 July 2019

THE CHAIRPERSON OF THE INDONESIAN OF
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 18 July 2019

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

Signed.

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2019 NUMBER 778