

REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA
NUMBER 3 OF 2015

ON

CIRCULATION, STORAGE, DESTRUCTION AND REPORTING OF NARCOTICS,
PSYCHOTROPICS AND PHARMACY PRECURSORS

BY THE BLESSINGS OF ALMIGHTY GOD

THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

- Considering :
- a. that Regulation of the Minister of Health Number 28/*Menkes/Per/I/1978* on Storage of Narcotics, Regulation of the Minister of Health Number 688/*Menkes/Per/VII/1997* on Circulation of Psychotropics, and Regulation of the Minister of Health Number 912/*Menkes/Per/VIII/1997* on Annual Need and Reporting of Psychotropics are necessary to be adjusted to legal developments and needs;
 - b. that based on the consideration as referred to in point a and to implement the provisions of Article 14 section (3), Article 36 section (2), Article 42, and Article 44 Law Number 35 Of 2009 on Narcotics, and Article 9 section (3), Article 14 section (6) and Article 15 section (2) Government Regulation Number 44 Of 2010 on Precursor, it is necessary to establish Regulation of the Minister of Health on Circulation, Storage, Destruction and Reporting of Narcotics, Psychotropics and Pharmacy Precursors;

- Observing : 1 Law Number 5 of 1997 on Psychotropics (State Gazette of the Republic of Indonesia of 1997 Number 10, Supplement to the State Gazette of the Republic of Indonesia Number 3671);
2. Law Number 35 of 2009 on Narcotics (State Gazette of the Republic of Indonesia of 2009 Number 143, Supplement to the State Gazette of the Republic of Indonesia Number 5062);
3. 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);
4. Law Number 44 of 2009 on Hospital (State Gazette of the Republic of Indonesia of 2009 Number 153, Supplement to the State Gazette of the Republic of Indonesia Number 5072);
5. Government Regulation Number 72 of 1998 on Security for Pharmaceutical Preparations and Medical Devices (State Gazette of the Republic of Indonesia of 1998 Number 138, Supplement to the State Gazette of the Republic of Indonesia Number 3781);
6. Government Regulation Number 51 of 2009 on Pharmaceutical Works (State Gazette of the Republic of Indonesia of 2009 Number 124, Supplement to the State Gazette of the Republic of Indonesia Number 5044);
7. Government Regulation Number 44 of 2010 on Precursors (State Gazette of the Republic of Indonesia of 2010 Number 60, Supplement to the State Gazette of the Republic of Indonesia Number 5126);
8. Government Regulation Number 40 of 2013 on the Implementation of Law Number 35 of 2009 on Narcotics (State Gazette of the Republic of Indonesia of 2013 Number 96, Supplement to the State Gazette of the Republic of Indonesia Number 5419);
9. Government Regulation Number 27 of 2014 on State/Regional-Owned Property Management (State Gazette of the Republic of Indonesia of 2014 Number 92,

Supplement to the State Gazette of the Republic of Indonesia Number 5533);

10. Regulation of the Minister of Health Number 1144/*Menkes/Per/III/2010* on the Organization and Work Procedures of the Ministry of Health (State Bulletin of the Republic of Indonesia of 2010 Number 585) as amended by Regulation of the Minister of Health Number 35 of 2013 (State Bulletin of the Republic of Indonesia of 2013 Number 741);
11. Regulation of the Minister of Health Number 1799/*Menkes/Per/XII/2010* on Pharmaceutical Industry (State Bulletin of the Republic of Indonesia of 2010 Number 721) as amended by Regulation of the Minister of Health Number 16 of 2013 (State Bulletin of the Republic of Indonesia of 2013 Number 442);
12. Regulation of the Minister of Health Number 1148/*Menkes/Per/VI/2011* on Pharmaceutical Wholesalers (State Bulletin of the Republic of Indonesia of 2011 Number 370) as amended by Regulation of the Minister of Health Number 34 of 2014 (State Bulletin of the Republic of Indonesia of 2014 Number 585);
13. Regulation of the Minister of Health Number 10 of 2013 on Importation and Exportation of Narcotics, Psychotropics and Pharmacy Precursors (State Bulletin of the Republic of Indonesia of 2013 Number 178);
14. Regulation of the Minister of Health Number 9 of 2014 on Clinics (State Bulletin of the Republic of Indonesia of 2014 Number 232);

HAS DECIDED:

To issue : REGULATION OF THE MINISTER OF HEALTH ON CIRCULATION, STORAGE, DESTRUCTION AND REPORTING OF NARCOTICS, PSYCHOTROPICS AND PHARMACY PRECURSORS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Ministerial Regulation:

1. Narcotics mean the substances or medicines derived from plants or non-plants, either synthetic and semi-synthetic whereas may cause a decrease or change in consciousness, loss of sense, reduction up to the elimination of pain and may create an addiction which is differentiated into categories as attached in Law on Narcotics.
2. Psychotropics mean the substances or medicines, either natural or synthetic non-narcotics as efficacious psycho-active through selective effect on the central nervous system whereas may cause the typical change in mental activity and behavior.
3. Pharmacy Precursors mean the substances or starting materials or chemicals that can be used as raw materials/supporting materials for the purpose of production process of pharmaceutical industry or intermediate product, bulk product and finished product that contains ephedrine, pseudoephedrine, norephedrine/ phenylpropanolamine, ergotamine, ergometrine, or Potassium Permanganate.
4. Distribution means each activity of distribution of Narcotics, Psychotropics and Pharmacy Precursors for the purpose of health care or sciences.
5. Consignment means each activity of giving Narcotics, Psychotropics and Pharmacy Precursors, either among the consignors and to the patients for the purpose of health care.
6. Pharmaceutical Industry means a business entity having a permit from the Minister of Health to conduct an activity of making medicines or medicine materials.
7. Pharmaceutical Wholesalers hereinafter abbreviated as PBF means a legal entity of the company having a permit for procurement, storage, distribution of medicines and/or medicine materials in a huge amount in accordance with the provisions of laws and regulations.

8. Medicine Warehouse of Government means a facility for storing and distributing pharmaceutical preparations and medical devices of Government, either Central Government and Regional Government, the Indonesian National Army/Police, State-Owned Business Entity and Regional-Owned Business Entity for purpose of health care of which in Law on Narcotics and Psychotropics referred to as Storage Facility of Government Pharmaceutical Preparations.
9. Hospital Pharmacy Unit means a functional implementation unit administering all activities of pharmaceutical services in the Hospital.
10. Clinic Pharmacy Unit means a part of clinic of which in Law on Narcotics and Psychotropics referred to as Health Center that has a duty to administer, coordinate, arrange and supervise all activities of pharmaceutical services as well as to perform pharmaceutical technical direction.
11. Pharmacy means a pharmaceutical service facility of conducting pharmaceutical practices by Pharmacist.
12. Drugstore means a facility having a permit to store non-prescription drugs and limited non-prescription drugs to be sold in retail.
13. Institute of Science means an education and training institution as well as research and development institute administered by the government or private sector that may use Narcotics, Psychotropics and Pharmacy Precursors for the purpose of development of science and technology.
14. Registered Importer for Psychotropics hereinafter referred to as Psychotropics IT means Pharmaceutical Wholesalers having a permit to import Psychotropics in order to be distributed to Pharmaceutical Industry and Institute of Science as psychotropics end-users.
15. Registered Importer for Pharmacy Precursors hereinafter referred to as Pharmacy Precursors IT means Pharmaceutical Wholesalers having a permit to import Pharmacy Precursors in order to be distributed to Pharmaceutical Industry and Institute of Science as Pharmacy Precursors end-users.
16. Head of Provincial Office means Head of Technical Implementation Unit in the scope of the National Agency of Drug and Food Control.

17. Head of Agency means Head of Non-Ministry Government Institution that has a duty to perform government duties in the field of drug and food control.
18. Director General means Director General at the Ministry of Health in charge of the direction of pharmaceutical and medical devices field.
19. Minister means the minister administering government affairs in the field of health.

Article 2

The arrangement of circulation, storage, destruction and reporting of Narcotics, Psychotropics and Pharmacy Precursors in this Ministerial Regulation includes Narcotics, Psychotropics and Pharmacy Precursors for the purpose of health care or science and technology development.

CHAPTER II CIRCULATION

Part One General

Article 3

The circulation of Narcotics, Psychotropics and Pharmacy Precursors consists of Distribution and Consignment.

Article 4

Narcotics, Psychotropics and Pharmacy Precursors circulated must meet safety requirement, efficacy and quality.

Article 5

- (1) Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs may only be circulated after obtaining the marketing approval from the Minister.
- (2) To obtain the marketing approval of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs as referred to in section (1) must be registered at the National Agency of Drug and Food Control.

- (3) The provision on procedures in obtaining the marketing approval as referred to in section (1) is performed in accordance with the provisions of laws and regulations.

Article 6

- (1) The Pharmaceutical Industry producing Narcotics and PBF or the Medicine Warehouse of Government distributing Narcotics is obligated to have a special permit from the Minister in accordance with the provisions of laws and regulations.
- (2) The special permit as referred to in section (1) is in the form of:
 - a. a Special Permit for Narcotics Production;
 - b. a Special Permit for Narcotics Import; or
 - c. a Special Permit for Narcotics Distribution.
- (3) The Institute of Science obtaining, planting, storing and using Narcotics and/or Psychotropics for science and technology purposes must have a permit from the Minister in accordance with the provisions of laws and regulations.

Article 7

The circulation of Narcotics in the form of drugs used in therapy programs and medical rehabilitation is conducted in accordance with the provisions of laws and regulations.

Part Two

Distribution

Paragraph 1

General

Article 8

The distribution of Narcotics, Psychotropics and Pharmacy Precursors is obligated to meet Good Distribution Practice in accordance with the provisions of laws and regulations.

Article 9

- (1) The distribution of Narcotics, Psychotropics and Pharmacy Precursors may only be conducted according to:
 - a. a Purchase order; or
 - b. a Medicine Use Report and A Request Form for the orders from the Public Health Center.
- (2) The Purchase order as referred to in section (1) point a may only be valid for each Narcotic, Psychotropic, or Pharmacy Precursor.
- (3) The purchase order of Narcotics may only be used for 1 (one) kind of Narcotic.
- (4) The purchase order of Psychotropics or Pharmacy Precursors may only be used for 1 (one) or several kinds of Psychotropics or Pharmacy Precursors.
- (5) The purchase order as referred to in section (3) and section (4) must be separated from the order of other goods.

Paragraph 2

Distribution of Category I Narcotics

Article 10

- (1) The distribution of Category I Narcotics may only be conducted by the state-owned PBF Company having a Special Permit of Narcotics Import to the Institute of Science for the purpose of science and technology development, including for laboratory needs.
- (2) The distribution of Narcotics as referred to in section (1) may only be conducted according to the purchase order from the responsible Pharmacist and/or the Head of Institute of Science by using the sample as set out in the Form 1 attached.

Paragraph 3

Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the Form of Raw Materials

Article 11

- (1) The distribution of Narcotics in the form of raw materials may only be conducted by the State-owned PBF Company

having a Special Permit of Narcotics Import to Pharmaceutical Industry and/or Institute of Science.

- (2) The distribution of Narcotics as referred to in section (1) may only be conducted according to the purchase order from the responsible Pharmacist for production and/or the Head of Institute of Science by using the sample as set out in the Form 1 attached.

Article 12

- (1) The distribution of Psychotropics in the form of raw materials may only be conducted by PBF having a permit as Psychotropics IT to Pharmaceutical Industry and/or Institute of Science.
- (2) The distribution of Psychotropics as referred to in section (1) may only be conducted according to the purchase order from the responsible Pharmacist for production and/or the Head of Institute of Science by using the sample as set out in the Form 2 attached.

Article 13

- (1) The distribution of Pharmacy Precursors in the form of substance/starting materials/chemicals or intermediate product/bulk product may only be conducted by PBF having a permit of Pharmacy Precursors IT to Pharmaceutical Industry and/or Institute of Science.
- (2) The distribution of Pharmacy Precursors as referred to in section (1) may only be conducted according to the purchase order from the responsible Pharmacist for production and/or the Head of Institute of Science by using the sample as set out in the Form 3 attached.

Paragraph 4

Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of Drugs

Article 14

- (1) The Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs may only be conducted by:

- a. The Pharmaceutical Industry to PBF and the Medicine Warehouse of Government;
 - b. PBF to other PBF, Pharmacy, Hospital Pharmacy Unit, Clinic Pharmacy Unit, the Medicine Warehouse of Government and Institute of Science;
 - c. The State-owned PBF having a Special Permit of Narcotics Import to Pharmaceutical Industry, for Distribution of Narcotics;
 - d. The Medicine Warehouse of Central Government to the Medicine Warehouse of Local Government, Public Hospital Pharmacy Unit, and National Army or Police Hospital Pharmacy Unit; and
 - e. The Medicine Warehouse of Local Government to Local Hospital Pharmacy Unit, Local Clinic Pharmacy Unit and the Public Health Center.
- (2) Other than to other PBF, Pharmacy, Hospital, Medicine Warehouse of Government and Institute of Science as referred to in section (1) point b, PBF may distribute Pharmacy Precursors of limited non-prescription category of drug to Drugstore.

Article 15

The Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs by Pharmaceutical Industry to PBF may only be conducted by Pharmaceutical Industry of the marketing approval owner.

Article 16

- (1) The Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs may only be conducted according to the purchase order from the responsible Pharmacist or the Head of Institute of Science for research and development needs by using the sample as set out in the Form 1, Form 2 and Form 4 attached.
- (2) Excluded from the provision as referred to in section (1), for Distribution to the Medicine Warehouse of Government, the purchase order may be signed by the appointed Pharmacist.

- (3) In the event that Distribution of Pharmacy Precursors from PBF to Drugstore, may only be conducted according to the purchase order from Pharmaceutical Technical Staff by using sample as set out in the Form 4 attached.

Article 17

- (1) The delivery of Narcotics, Psychotropics and Pharmacy Precursors made by Pharmaceutical Industry, PBF, or the Medicine Warehouse of Government must be completed with:
 - a. the purchase order;
 - b. the invoice and/or delivery order, at least containing:
 1. the name of Narcotics, Psychotropics and Pharmacy Precursors;
 2. the dosage form;
 3. the strength;
 4. the packaging;
 5. the amount;
 6. the expire date; and
 7. the batch number.
- (2) The delivery of Narcotics, Psychotropics and Pharmacy Precursors as referred to in section (1) conducted through the transportation service may only carry Narcotics, Psychotropics and Pharmacy Precursors in accordance with the amount stated in the purchase order, invoice, and/or delivery order carried at the time of delivery.

Part Three

Consignment

Paragraph 1

General

Article 18

- (1) The Consignment of Narcotics, Psychotropics and Pharmacy Precursors may only be conducted in the form of drugs.

- (2) In the event that the Consignment as referred to in section (1) is made to the patient, it must be performed by Pharmacist at pharmaceutical service facilities.
- (3) The Consignment as referred to in section (2) is conducted directly according to the standard of pharmaceutical services.
- (4) Excluded from the provision as referred to in section (2), the consignment of Pharmacy Precursors included in limited non-prescription category of drug at Drugstore is conducted by Pharmaceutical Technical Staff.

Paragraph 2

Consignment of Narcotics and Psychotropics

Article 19

- (1) The Consignment of Narcotics and/or Psychotropics may only be conducted by:
 - a. the Pharmacy;
 - b. the Public Health Center;
 - c. the Hospital Pharmacy Unit;
 - d. the Clinic Pharmacy Unit; and
 - e. the doctor.
- (2) The Pharmacy as referred to in section (1) point a may only consign Narcotics and/or Psychotropics to:
 - a. another Pharmacy;
 - b. the Public Health Center;
 - c. the Hospital Pharmacy Unit;
 - d. the Clinic Pharmacy Unit;
 - e. the doctor; and
 - f. the patient.
- (3) The Consignment of Narcotics and/or Psychotropics as referred to in section (2) point a to point d may only be conducted to meet the shortage of amount of Narcotics and/or Psychotropics based on prescription already received.
- (4) The Consignment as referred to in section (3) must be based on written request letter signed by the responsible

Pharmacist by using sample as set out in the Form 5 attached.

- (5) The Pharmacy, the Public Health Center, the Hospital Pharmacy Unit, and the Clinic Pharmacy Unit may only consign Narcotics and/or Psychotropics to the patient based on doctor's prescription.

Article 20

- (1) The Consignment of Narcotics and Psychotropics by Pharmacy to the Doctor may only be conducted in the event that:
 - a. the doctor conducts the individual practice by giving Narcotics and Psychotropics through injection; and/or
 - b. the doctor conducts the assignment or practice at remote area of which there is no pharmacy or in accordance with the provisions of laws and regulations.
- (2) The Consignment as referred to in section (1) must be based on a written request letter signed by the doctor handling the patient by using the sample as set out in the Form 6 attached.

Article 21

- (1) The Consignment of Narcotics and Psychotropics by the doctor to the patient may only be conducted in the event that:
 - a. the doctor conducts the individual practice by giving Narcotics and Psychotropics through injection;
 - b. the doctor helps the patient in emergency condition by giving Narcotics through injection;
 - c. the doctor helps the patient in emergency condition by giving Psychotropics; or
 - d. the doctor conducts an assignment in a remote area where there is no pharmacy based on an assignment letter from the authorized official.
- (2) The assignment Letter as referred to in section (1) point d includes as a permit of Storage for Narcotics and Psychotropics for treatment purposes.

Paragraph 3
Consignment of Pharmacy Precursors

Article 22

- (1) The Consignment of Pharmacy Precursors may only be conducted by:
 - a. the Pharmacy;
 - b. the Public Health Center;
 - c. the Hospital Pharmacy Unit;
 - d. the Clinic Pharmacy Unit;
 - e. the doctor; and
 - f. the Drugstore.
- (2) The Pharmacy may only consign Pharmacy Precursors of prescription drug category to:
 - a. another Pharmacy;
 - b. the Public Health Center;
 - c. the Hospital Pharmacy Unit;
 - d. the Clinic Pharmacy Unit;
 - e. the doctor; and
 - f. the Patient.
- (3) The Pharmacy, the Public Health Center, the Hospital Pharmacy Unit, and the Clinic Pharmacy Unit may only consign Pharmacy Precursors of prescription drug category to the patient based on doctor's prescription.
- (4) The Consignment of Pharmacy Precursors of prescription drug category as referred to in section (2) point a until point d may only be conducted to meet the shortage of amount of Pharmacy Precursors of prescription drug category based on the prescription already received.
- (5) The Consignment of Pharmacy Precursors of the limited non-prescription category of drug by the Pharmacy to another Pharmacy, the Public Health Center, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, and the Drugstore may only be conducted to meet the shortage of daily need for Pharmacy Precursors of the limited non-prescription category of drug required for the treatment.
- (6) The Consignment of Pharmacy Precursors by the Pharmacy to a doctor may only be conducted if necessary to conduct

the duty/practice at remote area of which there is no pharmacy or in accordance with the provisions of laws and regulations.

Article 23

- (1) The Consignment as referred to in Article 22 section (4), section (5), and section (6) must be based on written request letter signed by Pharmacist/Pharmaceutical Technical Staff of person in charge or the doctor handling the patient by using sample as set out in the Form 7, Form 8, and Form 9 attached.
- (2) Excluded from the provision as referred to in section (1), the consignment of Pharmacy Precursors of the limited non-prescription category of drug by Pharmacy to Drugstore, may only be conducted according to a written request letter signed by Pharmaceutical Technical Staff by using sample as set out in the Form 8 attached.
- (3) The Consignment of Pharmacy Precursors of the limited non-prescription category of drug to the patient must consider the rationality of amount consigned according to therapy needs in accordance with the provisions of laws and regulations.

CHAPTER III
STORAGE

Part One
General

Article 24

The storage place for Narcotics, Psychotropics, and Pharmacy Precursors at production, distribution and pharmaceutical service facilities must be able to keep the safety, efficacy and quality of Narcotics, Psychotropics and Pharmacy Precursors.

Article 25

- (1) The storage place for Narcotics, Psychotropics, and Pharmacy Precursors may be in the form of warehouse, room, or special cabinet.

- (2) The storage place for Narcotics is prohibited to be used to store goods other than Narcotics.
- (3) The storage place for Psychotropics is prohibited to be used to store goods other than Psychotropics.
- (4) The storage place for Pharmacy Precursors in the form of raw materials is prohibited to be used to store goods other than Pharmacy Precursors in the form of raw materials.

Article 26

- (1) The special warehouse as referred to in Article 25 section (1) must meet these following conditions:
 - a. walls are made of bricks and have doors with iron bars and 2 (two) different keys;
 - b. ceilings may be made of concrete walls or iron bars;
 - c. if it has window or ventilation, must be with iron bars;
 - d. the warehouse is not allowed to be entered by another person without permission from the responsible Pharmacist; and
 - e. warehouse keys are controlled by the responsible Pharmacist and other authorized officer.
- (2) The special room as referred to in Article 25 section (1) must meet these following conditions:
 - a. walls and ceilings made of solid materials;
 - b. if any window or ventilation, it must be with iron bars;
 - c. one door with 2 (two) different keys;
 - d. special room key controlled by the responsible Pharmacist/the appointed Pharmacist and other authorized officer; and
 - e. It cannot be entered by other persons without permission from the responsible Pharmacist/the appointed Pharmacist.
- (3) The special cabinet as referred to in Article 25 section (1) must meet these following conditions:
 - a. made of solid materials;
 - b. not easily moved and has 2 (two) different keys;
 - c. must be placed in a special room at the corner of the warehouse for the Medicine Warehouse of Government;

- d. put in a safe place and unseen by public for the Pharmacy, the Hospital Pharmacy Unit, the Public Health Center, the Clinic Pharmacy Unit and the Institute of Science ; and
- e. keys of special cabinet are controlled by the responsible Pharmacist/the appointed Pharmacist and other authorized officer.

Article 27

The storage for Narcotics, Psychotropics, and Pharmacy Precursors is obligated to meet the Good Manufacturing Practice, the Good Distribution Practice and/or the standard of pharmaceutical services in accordance with the provisions of laws and regulations.

Part Two

Storage for Narcotics or Psychotropics

Article 28

- (1) The Pharmaceutical Industry producing Narcotics must have the storage place for Narcotics in the form of special warehouse, consisting of:
 - a. the special warehouse dedicated only for Narcotics in the form of raw materials; and
 - b. the special warehouse dedicated only for Narcotics in the form of drugs.
- (2) The Special warehouse as referred to in section (1) is under control of the responsible Pharmacist.

Article 29

- (1) The Pharmaceutical Industry producing Psychotropics must have the storage place for Psychotropics in the form of special warehouse or special room, consisting of:
 - a. the special warehouse or the special room dedicated only for Psychotropics in the form of raw materials; and
 - b. the special warehouse or the special room dedicated only for Psychotropics in the form of drugs.

- (2) The Special warehouse or the special room as referred to in section (1) is under control of the responsible Pharmacist.

Article 30

- (1) PBF distributing Narcotics must have the storage place for Narcotics in the form of special warehouse.
- (2) In the event that PBF distributes Narcotics in the form of raw materials and drugs, the special warehouse as referred to in section (1) must consist of:
 - a. the special warehouse dedicated only for Narcotics in the form of raw materials; and
 - b. the special warehouse dedicated only for Narcotics in the form of drugs.
- (3) The Special warehouse for the storage place for Narcotics as referred to in section (1) and section (2) is under control of the responsible Pharmacist.

Article 31

- (1) PBF distributing Psychotropics must have the storage place for Psychotropics in the form of special warehouse or special room.
- (2) In the event that PBF distributes Psychotropics in the form of raw materials and drugs, special warehouse or special room as referred to in section (1) must consist of:
 - a. the special warehouse or the special room of Psychotropics in the form of raw materials; and
 - b. the special warehouse or the special room of Psychotropics in the form of drugs.
- (3) The special warehouse or the special room for the storage place for Psychotropics as referred to in section (1) and section (2) is under control of the responsible Pharmacist.

Article 32

- (1) The Medicine Warehouse of Government storing Narcotics or Psychotropics must have the storage place for Narcotics or Psychotropics in the form of special room or special cabinet.

- (2) The special room or the special cabinet for the storage place for Narcotics or Psychotropics as referred to in section (1) is under control of the responsible Pharmacist or the appointed Pharmacist.

Article 33

- (1) The Pharmacy, the Hospital Pharmacy Unit, the Public Health Center, the Clinic Pharmacy Unit, and the Institute of Science must have the storage place for Narcotics or Psychotropics in the form of special cabinet.
- (2) The Special cabinet as referred to in section (1) is under control of the responsible Pharmacist.

Article 34

The individual practice doctor using Narcotics or Psychotropics for treatment purpose must store Narcotics or Psychotropics in a safe place and has the key under the control of the doctor.

Part Three

Storage for Pharmacy Precursors

Article 35

- (1) The Pharmaceutical Industry using Pharmacy Precursors in the form of raw materials to produce Pharmacy Precursors or PBF distributing Pharmacy Precursors in the form of raw materials must have the storage place for Pharmacy Precursors in the form of special warehouse or special room.
- (2) The Special warehouse or the special room as referred to in section (1) is under control of the responsible Pharmacist.

Article 36

- (1) The Pharmaceutical Industry producing Pharmacy Precursors in the form of drugs, PBF distributing Pharmacy Precursors in the form of drugs, or the Medicine Warehouse of Government must store Pharmacy Precursors in the form of drugs in a warehouse as a safe storage of drugs based on risk analysis.

- (2) The Pharmacy, the Public Health Center, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, and the Institute of Science must store Pharmacy Precursors in the form of drugs in a safe storage place for drugs based on risk analysis.

CHAPTER IV DESTRUCTION

Article 37

The destruction of Narcotics, Psychotropics and Pharmacy Precursors may only be conducted in the event that:

- a. they are produced without meeting applicable standard and requirements and/or cannot be re-processed;
- b. they have been expired;
- c. they may not meet conditions to be used in health care and/or for scientific development, including its residual use;
- d. their marketing approval is cancelled; or
- e. they are related to criminal act.

Article 38

- (1) The destruction as referred to in Article 37 point a until point d is conducted by the Pharmaceutical Industry, PBF, the Medicine Warehouse of Government, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, the Institute of Science, the doctor or the Drugstore.
- (2) Narcotics, Psychotropics and Pharmacy Precursors meeting the criteria of destruction as referred to in Article 37 point a until point d in the Public Health Center must be returned to the Medicine Warehouse of Local Government.
- (3) The Medicine Warehouse of Government conducting destruction must make deletion in accordance with the provisions of laws and regulations in the field of State/Regional-Owned Property Management.
- (4) The destruction of Narcotics, Psychotropics and Pharmacy Precursors related to criminal act as referred to in Article 37 point e is conducted by the authorized government institution in accordance with the provisions of laws and regulations.

Article 39

The destruction of Narcotics, Psychotropics and Pharmacy Precursors must be performed by:

- a. not polluting the environment; and
- b. not harming the health of the people.

Article 40

The destruction of Narcotics, Psychotropics and Pharmacy Precursors is performed with these following phases:

- a. a person in charge of production/distribution/ pharmaceutical service facilities/head of the institution/ individual practice doctor addresses the notification letter and request for witness to:
 1. The Ministry of Health and the National Agency of Drug and Food Control, for the Medicine Warehouse of Central Government;
 2. The Provincial Health Office and/or the Provincial Office of Drug and Food Control for the Importer, the Pharmaceutical Industry, PBF, the Institute of Science, or the Medicine Warehouse of Provincial Government; or;
 3. The Regency/Municipal Health Office and/or the Provincial Office of Drug and Food Control, for the Pharmacy, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, the Medicine Warehouse of Regency/Municipal Government, the doctor, or the Drugstore.
- b. the Ministry of Health, the National Agency of Drug and Food Control, the Provincial Health Office, the Provincial Office of Drug and Food Control, and the Regency/Municipality Health Office determines the officer in its department to become witness of destruction in accordance with such request letter as a witness.
- c. the Destruction is witnessed by the officer already determined as referred to in point b.
- d. Narcotics, Psychotropics and Pharmacy Precursors in the form of raw materials, intermediate products and bulk

products must be taken sampling for testing purposes by the authorized officer before destruction is performed.

- e. Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs must be clarified with the truth in an organoleptic way by a witness before destruction is performed.

Article 41

In the event that Destruction of Narcotics, Psychotropics and Pharmacy Precursors is performed by the third party, it is obligated to be witnessed by the owner of Narcotics, Psychotropics and Pharmacy Precursors and witness as referred to in Article 40 point b.

Article 42

- (1) A person in charge of production/distribution/pharmaceutical service facilities/head of the institution/individual practice doctor conducting the destruction of Narcotics, Psychotropics and Pharmacy Precursors must make a Record of Destruction.
- (2) The Record of Destruction as referred to in section (1), at least contains:
 - a. the day, date, month and year of destruction;
 - b. the place of destruction;
 - c. the name of the person in charge of production/distribution/pharmaceutical service facilities/head of the institution/individual practice doctor;
 - d. the name of medical officer as witness and another witness of such agency/facility;
 - e. the name and amount of Narcotics, Psychotropics and Pharmacy Precursors destructed;
 - f. the method of destruction; and
 - g. the signature of a person in charge of production facilities/distribution facilities/pharmaceutical service facilities/head of the institution/individual practice doctor and witness.

- (3) The Record of Destruction as referred to in section (1) is made in 3 (three) copies and its carbon copy is sent to the Director General and Head of Agency/Head of Provincial Office using the sample as set out in the Form 10 attached.

CHAPTER V
RECORDING AND REPORTING

Part One
Recording

Article 43

- (1) The Pharmaceutical Industry, PBF, the Medicine Warehouse of Government, the Pharmacy, the Public Health Center, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, the Institute of Science, or the individual practice doctor conducting production, Distribution, or Consignment of Narcotics, Psychotropics and Pharmacy Precursors are obligated to make recording on the receipts and/or disbursements of Narcotics, Psychotropics and Pharmacy Precursors.
- (2) The Drugstore conducting the consignment of Pharmacy Precursors in the form of drugs is obligated to make recording on the receipts and/or disbursements of Pharmacy Precursors in the form of drugs.
- (3) The recording as referred to in section (1) and section (2) at least contains:
 - a. the name, dosage form, and strength of Narcotics, Psychotropics and Pharmacy Precursors;
 - b. the amount of preparation;
 - c. the date, number of document and source of acceptance ;
 - d. the amount received;
 - e. the date, number of document and destination of distribution/consignment;
 - f. the amount distributed/consigned;
 - g. the batch number and expire date of each acceptance or distribution/consignment; and
 - h. the initials or identity of the appointed officer.

- (4) The recording as referred to in section (1) and section (2) must be made in accordance with document of acceptance and document of distribution including document of import, export and/or consignment.

Article 44

All documents for recording, acceptance, distribution and/or consignment including the purchase order of Narcotics, Psychotropics and Pharmacy Precursors are obligated to be kept separate at least 3 (three) years.

Part Two Reporting

Article 45

- (1) The Pharmaceutical Industry producing Narcotics, Psychotropics and Pharmacy Precursors is obligated to make, keep, and submit the report on the production and distribution of finished product of Narcotics, Psychotropics and Pharmacy Precursors every month to the Director General with a carbon copy sent to the Head of Agency.
- (2) PBF conducting Distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs is obligated to make, keep, and submit the report of the receipt and distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs every month to the Head of Provincial Health Office with a carbon copy sent to the Head of Agency/Head of Provincial Office.
- (3) The Medicine Warehouse of Central Government is obligated to make, keep and submit the receiving report and distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs to the Director General with a carbon copy sent to the Head of Agency.
- (4) The Medicine Warehouse of Local Government is obligated to make, keep and submit the receiving report and distribution of Narcotics, Psychotropics and Pharmacy Precursors in the form of drugs to the Head of Provincial

Health Office or the Regency/Municipality with a carbon copy sent to the Head of Provincial Office.

- (5) The reporting as referred to in section (1) until section (4) at least consists of:
 - a. the name, dosage form, and strength of Narcotics, Psychotropics, and/or Pharmacy Precursors;
 - b. the amount of stocks at the beginning and end of month;
 - c. the date, number of document and source of acceptance;
 - d. the amount received;
 - e. the date, number of document and destination of distribution;
 - f. the amount distributed; and
 - g. the batch number and expire date of each acceptance or distribution and initial and end stock.
- (6) The Pharmacy, the Hospital Pharmacy Unit, the Clinic Pharmacy Unit, the Institute of Science, and the individual practice doctor are obligated to make, keep and submit the receiving report and consignment/use of Narcotics and Psychotropics, every month to the Head of Regency/Municipal Health Office with a carbon copy sent to the Head of Provincial Office.
- (7) The reporting as referred to in section (6) at least contains of:
 - a. the name, dosage form, and strength of Narcotics, Psychotropics, and/or Pharmacy Precursors;
 - b. the amount of stocks at the beginning and end of month;
 - c. the amount received; and
 - d. the amount consigned.
- (8) The Public Health Center is obligated to make, keep and submit the receiving report and consignment /use of Narcotics and Psychotropics in accordance with the provisions of laws and regulations.
- (9) The report as referred to in section (1) until section (4) and section (6) may use reporting system of Narcotics, Psychotropics, and/or Pharmacy Precursors electronically.

- (10) The report as referred to in section (1) until section (4) and section (6) is submitted not later than the 10th day of the month.
- (11) Further provisions on the procedures of reporting Narcotics, Psychotropics, and/or Pharmacy Precursors are regulated by the Director General.

CHAPTER VI DIRECTION AND SUPERVISION

Article 46

The Minister, the Head of the National Agency of Drug and Food Control, the Head of Provincial Office, the Head of Provincial Health Office, and the Head of Regency/Municipal Health Office makes direction and supervision toward the implementation of this Ministerial Regulation according to their own duty, function and authority.

Article 47

Violations against provisions in this Ministerial Regulation are subject to an administrative sanction in accordance with the provisions of laws and regulations.

CHAPTER VII TRANSITIONAL PROVISIONS

Article 48

At the time when this Ministerial Regulation comes into force, every Pharmaceutical Industry, PBF, Medicine Warehouse of Government, Pharmacy, Public Health Center, Hospital Pharmacy Unit, Clinic Pharmacy Unit, or Institute of Science in conducting Storage of Narcotics, Psychotropics, and/or Pharmacy Precursors must adjust to the provision of storage as regulated in this Ministerial Regulation not later than 3 (three) years since this Ministerial Regulation comes into force.

CHAPTER VIII
CLOSING PROVISIONS

Article 49

At the time when this Ministerial Regulation comes into force:

1. Regulation of the Minister of Health Number 28/*Menkes/Per/I/1978* on Storage of Narcotics;
2. Regulation of the Minister of Health Number 688/*Menkes/Per/VII/1997* on the Distribution of Psychotropics; and
3. Regulation of the Minister of Health Number 912/*Menkes/Per/VIII/1997* on Annual Need and Reporting of Psychotropics;

are repealed and declared ineffective.

Article 50

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

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

Issued in Jakarta
on January 5, 2015

MINISTER OF HEALTH
OF THE REPUBLIC OF INDONESIA,

Signed

NILA FARID MOELOEK

Promulgated in Jakarta
on January 16, 2015

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

Signed

YASONNA H. LAOLY

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2015 NUMBER 74

Jakarta, 30 November 2016

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,



WIDODO EKATJAHJANA

PURCHASE ORDER OF NARCOTICS

Number :

The undersigned below:

Name :

Position :

Is making order of Narcotics to:

Name of Distributor :

Address :

Telephone :

and Narcotics being ordered are:

(State the name of drug, dosage form, strength/potency, the amount in number and letter)

Such Narcotics will be used for:

Name of Facility :

(Pharmaceutical Industry/PBF/Pharmacy/Public Health Center/Hospital Pharmacy Unit/Clinic Pharmacy Unit/Medicine Warehouse of Government/Institute of Science) *

Facility Address :

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist/Head of Institute of Science

SIKA/SIPA/NIP No.

*) delete if inapplicable

Notes:

- One Purchase Order is only valid for one type of Narcotic
- The Purchase Order is made at least 3 (three) copies

PURCHASE ORDER OF PSYCHOTROPICS

Number :

The undersigned below:

Name :

Position :

Is making order of Psychotropics to:

Name of Distributor :

Address :

Telephone :

and Psychotropics being ordered are:

(State the name of drug, dosage preparation, strength/potency, the amount in number and letter)

Such Psychotropics will be used for:

Name of Facility :

(Pharmaceutical Industry/PBF/Pharmacy/Public Health Center/Hospital Pharmacy Unit/Clinic Pharmacy Unit/Medicine Warehouse of Government/Institute of Science) *

Facility Address :

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist/Head of Institute of Science

SIKA/SIPA/NIP No.

*) delete if inapplicable

Notes:

The Purchase Order is made at least 3 (three) copies

PURCHASE ORDER OF RAW MATERIALS FOR PHARMACY PRECURSORS

Number :

The undersigned below:

Name :

Position :

Is making order of Raw Materials for Pharmacy Precursors to:

Name of Distributor :

Address :

Telephone :

and Raw Materials for Pharmacy Precursors being ordered are:

(State the name of raw materials and the amount in number and letter)

Such Raw Materials for Pharmacy Precursors will be used for:

Name of Facility :

(Pharmaceutical Industry/Institute of Science) *

Facility Address :

Name of city, date, month, year

Buyer

Signature and stamp

Name of the responsible Pharmacist/

Head of Institute of Science

SIKA/SIPA/NIP No.

*) delete if inapplicable

Notes:

The Purchase Order is made at least 3 (three) copies.

PURCHASE ORDER OF DRUGS FOR PHARMACY PRECURSORS

Number :

The undersigned below:

Name :

Position :

Is making order of Drugs for Pharmacy Precursors to:

Name of Distributor :

Address :

Telephone :

and Drugs for Pharmacy Precursors being ordered are:

(State the name of drug, dosage form, strength/potency, the amount in number and letter)

Such Drug for Pharmacy Precursors will be used for:

Name of Facility :

(Pharmaceutical Industry/PBF/Pharmacy/Public Health Center/Hospital Pharmacy Unit/Clinic Pharmacy Unit/Drugstore/Medicine Warehouse of Government/Institute of Science) *

Facility Address :

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist/Pharmaceutical Technical Staff of Person in Charge /Head of Institute of Science

SIKA/SIPA/SIKTTK/NIP No.

*) delete if inapplicable

Notes:

The Purchase Order is made at least 3 (three) copies

REQUEST LETTER FOR NARCOTICS/PSYCHOTROPICS

The undersigned below:

Name :

Position :

Name of Facility :

(Pharmacy/Public Health Center/Hospital Pharmacy Unit/Clinic Pharmacy Unit) *

Is making request for Narcotics/Psychotropics* to:

Name of Facility : Pharmacy.....

Address :

And Narcotics/Psychotropics* being requested are:

(State the name of drug, dosage form, strength/potency, the amount in number and letter)

That will be used to meet the shortage of Narcotics/Psychotropics* in serving the prescription of:

(State number of prescription, date of prescription, name of patient, amount in prescription, name of service facility issuing such prescription)

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist

SIK /SIPA No.

*) delete if inapplicable

Notes:

- A Request Letter is only valid for one prescription.
- Request Letter is made at least 3 (three) copies.
- Attach the copy of prescription.

REQUEST LETTER FOR NARCOTICS/PSYCHOTROPICS

The undersigned below:

Name :
Position :
SIP No. :

Is making request for Narcotics/Psychotropics* to:

Name of Facility : Pharmacy.....
Address :

And Narcotics/Psychotropics* being requested are:

(State the name of drug, dosage form, strength/potency, the amount in number and letter)

Such Narcotics/Psychotropics* will be used for doctor practices:

Name of Doctor :
Address of Service :

Name of city, date, month, year
Buyer

Signature and stamp

Name of Pharmacist
SIP No.

*) delete if inapplicable

Notes:

- One Request Letter is only valid for one type of Narcotics/Psychotropics.
- The Request Letter is made at least 3 (three) copies.

REQUEST LETTER FOR PHARMACY PRECURSORS OF PRESCRIPTION
CATEGORY OF DRUG

The undersigned below:

Name :

Position :

Name of Facility :

(Pharmacy/Public Health Center/Hospital Pharmacy
Unit/Clinic Pharmacy Unit) *

Is making request for Pharmacy Precursors of Prescription Category of Drug to:

Name of Facility : Pharmacy.....

Address :

And Pharmacy Precursors of Prescription Category of Drug being requested are:
(State the name of drug, dosage form, strength/potency, the amount in number and letter)

That shall be used to meet the shortage of Pharmacy Precursors of Prescription Category of Drug in serving the prescription of:

(State number of prescription, date of prescription, name of patient, amount in prescription, name of service facility issuing such prescription)

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist

SIK /SIPA No.

*) delete if inapplicable

Notes:

- One Request Letter is only valid for one prescription
- The Request Letter is made at least 3 (three) copies
- Attach the copy of prescription

REQUEST LETTER FOR PHARMACY PRECURSORS OF THE LIMITED
NON-PRESCRIPTION CATEGORY OF DRUG

The undersigned below:

Name :

Position :

Name of Facility :

(Pharmacy/Public Health Center/Hospital Pharmacy
Unit/Clinic Pharmacy Unit/Drugstore) *

Is making request for Pharmacy Precursors of the Limited Non-Prescription
Category of Drug to:

Name of Facility : Pharmacy.....

Address :

And Pharmacy Precursors of the Limited Non-Prescription Category of Drug
being requested are:

(State the name of drug, dosage form, strength/potency, the amount in number
and letter)

That shall be used to meet the shortage of Pharmacy Precursors of the Limited
Non-Prescription Category of Drug required for the treatment dated.....

Name of city, date, month, year

Buyer

Signature and stamp

Name of Pharmacist/Pharmaceutical Technical
Staff

SIK/SIPA/SIKTTK No.

*) delete if inapplicable

Notes:

- One Request Letter is only valid for one Precursor Substance of the Limited
Non-Prescription Category of Drug.
- The Request Letter is made at least 3 (three) copies.

REQUEST LETTER FOR PHARMACY PRECURSORS

The undersigned below:

Name :

Position :

SIP No. :

Is making request for Pharmacy Precursors to:

Name of Facility : Pharmacy.....

Address :

And Pharmacy Precursors being requested are:

(State the name of drug, dosage form, strength/potency, the amount in number and letter)

Such Pharmacy Precursors shall be used for doctor practice:

Name of Doctor :

Address of Service :

Name of city, date, month, year

Buyer

Signature and stamp

Name of Doctor

SIP No.

Notes

- One Request Letter is only valid for one type of Precursor Substance.
- The Request Letter is made at least 3 (three) copies.

RECORD OF DESTRUCTION OF NARCOTICS

Number :...../ .../20...

On this day... date... month...of ...pursuant to Regulation of the Minister of Health of the Republic of Indonesia Number... of ...on Circulation, Storage and Destruction of Narcotics, Psychotropics and Pharmacy Precursors, we, the undersigned below:

Name of Pharmacist/Director :

SIPA/SIK No. :

Name of Facility :

Facility Address :

In the presence of the witnesses :

1. Name : (write the name of witness from the Ministry of Health)

Position :

NIP :

2. Name : (write the name of witness from National Agency of Drug and Food Control)

Position :

NIP :

3. Name : (write the name of witness from the facility concerned)

Position :

SIPA/SIKTTK :

Declare truly that at....., taken place in....., we have destroyed some amount of Narcotics as mentioned in the attachment.

We do this kind of destruction by means of.....

This Record is made in 4 (four) copies and sent to:

1. The Ministry of Health of RI c.q. Directorate General of Development of Pharmaceutical and Medical Devices
2. National Agency of Drug and Food Control of RI
3. Health Office of.....Province
4. Files

Thus, we truly make this Record in order to be used accordingly.

Acknowledged by:
Director, Person in Charge/Head

Name of City, Date, Month, Year

Signature and stamp

Signature and stamp
(Name of Pharmacist/Director)
SIK/SIPA/NIP

Witnesses:

1. The Officer of Ministry of Health of RI,
Signature
(.....)
2. The Officer of National Agency of Drug and Food Control of RI
Signature
(.....)
3. The Officer of Facility concerned
Signature
(.....)

Attachment to the Record of Destruction of Narcotics:

Number :...../...../ 20

List of Narcotics being destroyed:

Sequential No.	Name of Drug	Unit	Amount	Price	Remark (Damaged/Expired)

Acknowledged by:
Director,

Name of City, Date, Month, Year
Person in Charge/Director

Signature and stamp

Signature
(Name of Pharmacist/Director)
SIK/SIPA/NIP

Witnesses:

1. The Officer of Ministry of Health of RI,

Signature

(.....)

2. The Officer of National Agency of Drug and Food Control of RI

Signature

(.....)

3. The Officer of Facility concerned

Signature

(.....)