REGULATION OF THE MINISTER OF HEALTH OF
THE REPUBLIC OF INDONESIA
NUMBER 10 OF 2013
ON
IMPORTATION AND EXPORTATION OF NARCOTICS,
PSYCHOTROPICS AND PHARMACY PRECURSORS

BY THE BLESSINGS OF THE ALMIGHTY GOD

THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

Considering : a. that control arrangements of the importation and exportation of psychotropics in the Regulation of Minister of Health Number 785/ *Menkes*/Per/VII/1997 and the importation and exportation of Pharmacy Precursors in the Regulation of Minister of Health Number 168/*Menkes*/Per/II/2005 need to be adjusted to its legal development and requirement;

b. that based on the consideration as referred to in point a and to implement the provision of Article 22 Law Number 35 of 2009 on Narcotics, Article 20 Law Number 5 of 1997 on Psychotropics, Article 10 section (4) point a and point c in Government Regulation Number 44 of 2010 on Precursors, it is necessary to establish the Regulation of Minister of Health on the Importation and Exportation of Narcotics, Psychotropics and Pharmacy Precursors;

Observing : 1. Law Number 8 of 1976 on the Ratification of 1961 Narcotics Single Convention including its changing Protocols (State Gazette of the Republic of Indonesia of 1976 Number 36, Supplement to the State Gazette of the Republic of Indonesia Number 3085);

2. Law Number 8 of 1996 on the Ratification of Convention on Psychotropic Substances 1971 (State Gazette of the Republic of Indonesia of 1996 Number 100, Supplement to the State Gazette of the Republic of Indonesia Number 3657);
3. 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);
4. Law Number 7 of 1997 on the Ratification of the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (State Gazette of the Republic of Indonesia of 1997 Number 17, Supplement to the State Gazette of the Republic of Indonesia Number 3673);
5. 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);
6. 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);
7. 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);
8. 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);

9. 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);
10. Presidential Decree Number 103 of 2001 on Position, Task, Function, Authority, Organizational Structure and Work Procedures of Non-Department Government Institution as frequently amended, last by Presidential Regulation Number 64 of 2005;
11. Regulation of the Minister of Health Number 1144/*Menkes*/Per/VIII/2010 on the Organization and Work Procedures of the Ministry of Health (State Bulletin of the Republic of Indonesia of 2010 Number 585);

HAS DECIDED:

To Enact : REGULATION OF THE MINISTER OF HEALTH ON THE IMPORTATION AND EXPORTATION OF NARCOTICS, PSYCHOTROPICS AND PHARMACY PRECURSORS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Minister Regulation:

1. Narcotics mean the substances or medicines derived from plants or non-plants, either synthetic and semi-synthetic that 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 and synthetic non-narcotics as efficacious psycho-active through selective effect on the central nervous system that may cause the typical change in mental activity and behavior.
3. Precursors mean the substances or starting materials that may be used in the making of Narcotics and Psychotropics.

4. 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 efedrin, pseudoefedrin, norefedrin/fenylpropanolamine, ergotamine, ergometrin, or potassium permanganat.
5. Importation means an activity of importing Narcotics, Psychotropics and/or Pharmacy Precursors into the Indonesian customs teritorry.
6. Exportation means an activity of exporting Narcotics, Psychotropics and/or Pharmacy Precursors from the Indonesian customs teritorry.
7. Approval Letter of Import, hereinafter abbreviated as SPI means an approval letter for the importation of Narcotics, Psychotropics and/or Pharmacy Precursors.
8. Approval Letter of Export, hereinafter abbreviated as SPE means an approval letter for the exportation of Narcotics, Psychotropics and/or Pharmacy Precursors.
9. Psychotropics Producer Importer, hereinafter referred to as Psychotropics IP means pharmaceutical industry using Psychotropics as raw materials of production process that obtains permit to import its own Psychotropics.
10. Producer Importer for Pharmacy Precursors, hereinafter referred to as Pharmacy Precursors IP means pharmaceutical industry using Pharmacy Precursors as raw materials or supporting materials for production process having a permit to import its own Pharmacy Precursors.
11. 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.
12. 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.

13. Producer Exporter for Psychotropics, hereinafter referred to as Psychotropics EP means pharmaceutical industry having a permit as psychotropics exporter.
14. Producer Exporter for Pharmacy Precursors, hereinafter referred to as Pharmacy Precursors EP means pharmaceutical industry having a permit as Pharmacy Precursors exporter.
15. Registered Exporter for Psychotropics, hereinafter referred to as Psychotropics ET means pharmaceutical wholesalers having a permit as Psychotropics exporter.
16. Registered Exporter for Pharmacy Precursors, hereinafter referred to as Pharmacy Precursors ET means pharmaceutical wholesalers having a permit as Pharmacy Precursors exporter.
17. Pharmaceutical Industry means a business entity having a permit from the Minister of Health to conduct an activity of making medicines or medicine materials.
18. 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 laws and regulations.
19. 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.
20. Head of the National Agency of Drug and Food Control, hereinafter referred to as Head of Agency means Head of Agency of which its duties and responsibilities in the field of drug and food control.
21. Director General means Director General at the Ministry of Health in charge of the direction of pharmaceutical and medical devices field.

22. Minister means the minister administering government affairs in the field of health.

Article 2

Importation and exportation of Narcotics, Psychotropics, and/or Pharmacy Precursors may only be performed for the purpose of health services or development of science and technology.

CHAPTER II
IMPORTATION OF NARCOTICS, PSYCHOTROPICS AND PHARMACY PRECURSORS

Part One
General

Article 3

(1) Importation of Narcotics may only be performed by 1 (one) state-owned PBF company already had a special permit as importer from the Minister.
(2) The Minister delegates the granting of a special permit as referred to in section (1) to the Director General.
(3) In the event that the state-owned PBF company as referred to in section (1) may not be able to conduct its function in performing the importation of Narcotics, Director General may give a special permit to other state-owned PBF company.

Article 4

(1) Importation of Psychotropics and/or Pharmacy Precursors may only be performed by Pharmaceutical Industry, PBF, or Institute of Science.
(2) Pharmaceutical Industry and PBF as referred to in section (1) must have a permit as Psychotropics IP/Pharmacy Precursors IP or as Psychotropics IT/Pharmacy Precursors IT from the Minister.
(3) Institute of Science as referred to in section (1) may not require a permit as Psychotropics and/or Pharmacy Precursors importer.

(4) The Minister delegates the granting of permit as referred to in section (2) to the Director General.

Part Two
Implementation of Import

Article 5

(1) Importation of Narcotics, Psychotropics, and/or Pharmacy Precursors may only be performed after having SPI from the Minister.
(2) SPI as referred to in section (1) is valid for every time of import implementation.
(3) The Minister delegates the granting of SPI as referred to in section (1) to the Director General .

Article 6

The State-owned PBF company having a special permit as Narcotics importer may only be able to distribute the imported Narcotics to Pharmaceutical Industry that already had a special permit to produce Narcotics or Institute of Science.

Article 7

(1) Psychotropics IP and/or Pharmacy Precursors IP may only import Psychotropics and/or Pharmacy Precursors for the need of its own production process and it is not allowed to trade and/or transfer it.
(2) Institute of Science may only import Psychotropics and/or Pharmacy Precursors for its own need and it is not allowed to trade and/or transfer it.

Article 8

(1) Psychotropics IT and/or Pharmacy Precursors IT may only import Psychotropics and/or Pharmacy Precursors based on orders from Pharmaceutical Industry or Institute of Science.
(2) Psychotropics and/or Pharmacy Precursors as referred to in section (1) is required to be distributed directly to the ordering Pharmaceutical Industry or Institute of Science.
(3) The ordering Pharmaceutical Industry or Institute of Science is not allowed to trade and/or transfer Psychotropics and/or Pharmacy Precursors.

Article 9

(1) Pharmaceutical Industry that already had a special permit to produce Narcotics is required to submit an annual needs plan for production process signed by Responsible Pharmacist for Production at the latest on January 10 every year.
(2) Psychotropics IP and/or Pharmacy Precursors IP is required to submit the annual needs plan for production process signed by Responsible Pharmacist for Production at the latest on January 10 every year.
(3) Psychotropics IT and/or Pharmacy Precursors IT is required to submit the annual needs plan for the ordering Pharmaceutical Industry, signed by Responsible Pharmacist for PBF at the latest on January 10 every year.

Article 10

In each import implementation, state-owned PBF Company having a special permit as Narcotics Importer, Psychotropics IP/Pharmacy Precursors IP, and Psychotropics IT/Pharmacy Precursors IT is required to the original sheet of approval letter of import to the local customs officer for filling out a control card of import realization.

Article 11

(1) The state-owned PBF company performing Narcotics Import is required to inspect such imported Narcotics after arriving at warehouse.
(2) Inspection of Narcotics as referred to in section (1) is required to be witnessed by the authorized official from the agency having duties and responsibilities in the field of drug and food control.

Part Three

Requirements and Procedures for Obtaining an Importer Permit

Article 12

(1) To obtain a permit as Psychotropics or Pharmacy Precursors importer, Pharmaceutical Industry or PBF

proposes an application to the Director General through *online* to *http://e-pharm.kemkes.go.id* followed by supporting documents, as follows:

a. a copy of business permit of Pharmaceutical Industry and/or PBF;
b. a copy of Company Registration (TDP);
c. a copy of Tax Registration Number (NPWP); and
d. a copy of Work Permit of Responsible Pharmacist for Production.

(2) In order to propose the verification process of documents through online, the applicant must gives copies of supporting documents as referred to in section (1) to the Director General not exceeding 3 (three) working days upon receiving the online application.

(3) Not exceeding within a period of 7 (seven) working days upon receiving documents as referred to in section (2), Director General issues a permit or rejects such permit application attached with objective reasons.

(4) Form of permit for Psychotropics IP/Pharmacy Precursors IP and/or Psychotropics IT/Pharmacy Precursors IT permit as referred to in section (3) is set out in Form 1, Form 2, Form 3, or Form 4 as attached.

Article 13

(1) A permit for Psychotropics IP/Pharmacy Precursors IP or a permit for Psychotropics IT/Pharmacy Precursors IT is valid for a period of 3 (three) years and can be renewed by meeting the requirements.

(2) A permit for Psychotropics IP/Pharmacy Precursors IP or permit for Psychotropics IT/Pharmacy Precursors IT is declared invalid if the validity period of supporting documents as referred to in Article 12 section (1) has expired or having been repealed in accordance with laws and regulations.

Part Four

Requirements and Procedures for Obtaining SPI

Article 14

(1) Prior to proposing an application of SPI, the importer must propose an application of Monitoring Result Analysis to the Head of Agency.

(2) The provision on requirements and procedures of application of Monitoring Result Analysis as referred to in section (1) is regulated by the Head of Agency Regulation.

Article 15

(1) To obtain SPI for the purpose of health services, the state-owned PBF having a special permit as Narcotics Importer, Psychotropics IP/Pharmacy Precursors IP, or Psychotropics IT/Pharmacy Precursors IT proposes an application to the Director General through *online* to *http://e-pharm.kemkes.go.id* followed by supporting documents, as follows:
   a. A statement letter of having never been conducted the Importation of Narcotics, Psychotropics, or Pharmacy Precursors or a copy of the last SPI;
   b. the last import realization report;
   c. a report of usage realization for production;
   d. a copy of annual needs plan signed by the Responsible Pharmacist;
   e. a copy of purchase order to the exporter at exporting country;
   f. a copy of purchase order from Pharmaceutical Industry, if the applicant is Psychotropics IT/Pharmacy Precursors IT;
   g. a copy of purchase order from Pharmaceutical Industry, if the applicant is state-owned PBF having a special permit as Narcotics Importer;
   h. a copy of marketing approval letter for Narcotics, Psychotropics, or Pharmacy Precursors that shall be imported;
   i. a copy of special permit of Narcotics Importer or Psychotropics IP/Pharmacy Precursors IP permit or Psychotropics IT/Pharmacy Precursors IT permit;
   j. a copy of control card; and
   k. Monitoring Result Analysis.

(2) Excluded from supporting documents as referred to in section (1) point b, point c, and point i for Pharmaceutical Industry or PBF that may never been imported Narcotics, Psychotropics, or Pharmacy Precursors.

(3) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (1) and section (2) to the Director General not exceeding 3 (three) working days upon receiving such online application.

(4) Not exceeding within a period of 7 (seven) working days upon receiving documents as referred to in section (3), Director General issues an approval or rejection of SPI attached with objective reasons.

(5) Form of SPI as referred to in section (4) is set out in Form 5, Form 6, Form 7, Form 8, or Form 9 as attached.

Article 16

(1) SPI is valid for 3 (three) months and can be renewed at maximum of 2 (two) times.

(2) To obtain a renewal of SPI, the state-owned PBF having a special permit as Narcotics Importer, Psychotropics IP/Pharmacy Precursors IP, or Psychotropics IT/Pharmacy Precursors IT proposes an application to the Director General through *online* to *http://epharm.kemkes.go.id* by stating the reason for renewal and attached with supporting documents, as follows:

a. the original SPI;

b. a copy of special permit as Narcotics Importer or Psychotropics IP/Pharmacy Precursors IP permit or Psychotropics IT/Pharmacy Precursors IT permit; and

c. a copy of control card.

(3) Application for SPI renewal as referred to in section (1) must be proposed not exceeding 10 (ten) days prior to the expiry of SPI.

(4) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (2) to the Director General not exceeding 3 (three) working days upon receiving online application.

(5) Not exceeding within a period of 7 (seven) working days upon receiving documents as referred to in section (2), Director General issues an approval or rejection for SPI renewal attached with objective reasons.

Article 17

(1) The state-owned PBF company having a special permit as Narcotics Importer may propose an application for SPI Narcotics for the purpose of science and technology development, diagnostic reagents and laboratory reagents based on orders from Institute of Science.

(2) Application for SPI Narcotics as referred to in section (1) is proposed to the Director General through *online* to *http://epharm.kemkes.go.id* followed by supporting documents, as follows:

a. a purchase order from Institute of Science;
b. a statement letter of Narcotics need signed by the Head of Institute of Science;
c. a copy of purchase order to exporter;
d. a copy of special permit as Narcotics importer;
e. a research protocol for research purposes;
f. a statement letter of having never been conducted Narcotics Import for the purpose of Institute of Science concerned or the last import realization and stock report; and
g. Monitoring Result Analysis.

(3) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (2) to the Director General not exceeding 3 (three) working days upon receiving an online application.

(4) Not exceeding within a period of 7 (seven) working days upon the receipt of supporting documents as referred to in section (3), Director General issues an approval or rejection of SPI followed by objective reasons.

(5) Form of SPI Narcotics document as referred to in section (4) is set out in Form 5 as attached.

Article 18

(1) Psychotropics IT or Pharmacy Precursors IT may apply for SPI Psychotropics or SPI Pharmacy Precursors for the purpose of science and technology development, diagnostic reagents and laboratory reagents based on orders from the Institute of Science.

(2) Application for SPI Psychotropics or SPI Pharmacy Precursors as referred to in section (1) is proposed to the Director General through *online* to *http://e-pharm.kemkes.go.id* followed by supporting documents, as follows:

a. a purchase order from the Institute of Science;
b. a statement letter of the need for Psychotropics or Pharmacy Precursors signed by the head of Institute of Science;
c. a copy of purchase order to exporter;
d. a copy of letter of permit for Psychotropics IT or Pharmacy Precursors IT;
e. a research protocol for research purpose;
f. a statement letter of having never been conducted the Importation of Psychotropics or Pharmacy Precursors for the purpose of Institute of Science concerned or the last import realization and stock report; and
g. Monitoring Result Analysis.

(3) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (2) to the Director General not exceeding 3 (three) working days upon receiving online application.

(4) Not exceeding within a period of 7 (seven) working days upon the receipt of supporting documents as referred to in section (3), Director General issues an approval or rejection of SPI followed by objective reasons.

(5) Form of SPI Psychotropics or SPI Pharmacy Precursors document as referred to in section (4) is set out in Form 7 and Form 9 as attached.

Article 19

(1) Other than conducting the Importation of Psychotropics or Pharmacy Precursors through Psychotropics IT or Pharmacy Precursors IT, the Institute of Science may perform direct importation.

(2) Institute of Science that will perform direct importation of Psychotropics or Pharmacy Precursors as referred to in section (1) must apply for SPI to the Director General by attaching:
   a. an application letter;
   b. a statement letter of the need for Psychotropics or Pharmacy Precursors signed by the head of Institute of Science;
   c. a copy of purchase order to exporter;
   d. a research protocol for research purpose;
   e. a statement letter of having never been conducted the importation of Psychotropics or Pharmacy Precursors for the purpose of Institute of Science or the last import realization and stock report; and
   f. Monitoring Result Analysis.

(3) Not exceeding within a period of 7 (seven) working days upon receiving documents as referred to in section (1), Director General issues an approval or rejection of SPI followed by objective reasons.

(4) Form of SPI Psychotropics or SPI Pharmacy Precursors document as referred to in section (2) is set out in Form 10 and Form 11 as attached.

CHAPTER III

EXPORTATION OF NARCOTICS, PSYCHOTROPICS AND PHARMACY PRECURSORS

Part One

General

Article 20

(1) The exportation of Narcotics may only be conducted by 1 (one) the state-owned PBF company already had a special permit as an exporter from the Minister.

(2) The Minister delegates the granting of special permit as referred to in section (1) to the Director General.

(3) In the event that the state-owned PBF company as referred to in section (1) may not be able to perform its function in conducting the exportation of Narcotics, Director General may give a special permit to other state-owned PBF Company.

Article 21

(1) The exportation of Psychotropics and/or Pharmacy Precursors may only be performed by Pharmaceutical Industry or PBF.

(2) Pharmaceutical Industry or PBF as referred to in section (1) must have a permit as Psychotropics EP/ Pharmacy Precursors EP or as Psychotropics ET/ Pharmacy Precursors ET from the Minister.

(3) The Minister delegates the granting of permit as referred to in section (2) to the Director General .

Part Two

Implementation of Export

Article 22

(1) The exportation of Narcotics, Psychotropics, and/or Pharmacy Precursors may only be performed upon receiving SPE from the Minister.

(2) SPE as referred to in section (1) is valid for each time of export implementation.

(3) The Minister delegates the granting of SPE as referred to in section (1) to the Director General .

Article 23

(1) In order to implement the export, the exporter having a special permit as a Narcotics Exporter, Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET is required to give information in written to the Director General and sent its copy to the Head of Agency containing:

a. an estimation of export implementation date;
b. a type of transportation (sea/air) including the name and flight number/name and ship number;
c. details of delivery (name of harbour/airport of importing country and transit if any); and
d. an estimation of arrival date at importing country.

(2) Information as referred to in section (1) is submitted not exceeding 7 (seven) working days prior to its export implementation date.

Part Three

Requirements and Procedures of Obtaining Exporter Permit

Article 24

(1) To obtain a permit as Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET, Pharmaceutical Industry or PBF applies to the Director General through *online* to *http://e-pharm.kemkes.go.id* followed by supporting documents, as follows:
a. a copy of business permit of Pharmaceutical Industry or PBF;
b. a copy of Company Registration (TDP);
c. a copy of Tax Registration Number (NPWP); and
d. a copy of Work Permit of the Responsible Pharmacist.

(2) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (1) to the Director General not exceeding 3 (three) working days upon receiving online application.

(3) Not exceeding within a period of 7 (seven) working days upon the receipt of supporting documents as referred to in section (2), Director General issues an approval or rejection of permit followed by objective reasons;

(4) Form of permit as Psychotropics EP/ Pharmacy Precursors EP or Psychotropics ET/ Pharmacy Precursors ET as referred to in section (3) is set out in Form 12, Form 13, Form 14, or Form 15 as attached.

Article 25

(1) A permit for Psychotropics EP/ Pharmacy Precursors EP or Psychotropics ET/ Pharmacy Precursors ET is valid for a period of 3 (three) years and can be renewed by meeting the requirements.

(2) A permit for Psychotropics EP/ Pharmacy Precursors EP or Psychotropics ET/ Pharmacy Precursors ET is declared invalid if the validity period of supporting documents as referred to in Article 24 section (1) has expired or has been repealed in accordance with laws and regulations.

Part Four

Requirements and Procedures for Obtaining Approval Letter of Export

Article 26

(1) Prior to applying for SPE, the exporter should apply for Monitoring Result Analysis to the Head of Agency.

(2) The provision on requirements and procedures of application for Monitoring Result Analysis is regulated by the Regulation of Head of Agency.

Article 27

(1) To obtain SPE, state-owned PBF having a special permit as Narcotics Exporter, Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET applies to Director General through *online* to *http://e-pharm.kemkes.go.id* followed by supporting documents, as follows:

a. a statement letter of having never been conducted export or a copy of the last SPE and/or the last export realization report;
b. a copy of export plan for 1 (one) year;
c. the original SPI from importing country;
d. a copy of purchase order from importer;
e. a copy of marketing approval letter for or special approval letter for the export of Narcotics, Psychotropics, or Pharmacy Precursors that will be exported;

f. a copy of special permit as Narcotics exporter, Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET; and

g. Monitoring Result Analysis.

(2) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (1) to the Director General not exceeding 3 (three) working days upon receiving online application.

(3) Not exceeding within a period of 7 (seven) working days upon receiving documents as referred to in section (2), Director General issues an approval or rejection of SPE followed by objective reasons.

(4) Form of SPE document as referred to in section (3) is set out in Form 16, Form 17, Form 18, Form 19, or Form 20 as attached.

Article 28

(1) SPE is valid for 3 (three) months and can be renewed at maximum of 2 (two) times.

(2) To obtain SPE renewal, the state-owned PBF having a special permit as Narcotics Exporter, Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET applies to the Director General through *online* to *http://epharm.kemkes.go.id* by stating the reason for such renewal and followed by supporting documents, as follows:

a. the original SPE; and

b. a copy of special permit as Narcotics exporter, Psychotropics EP/ Pharmacy Precursors EP, or Psychotropics ET/ Pharmacy Precursors ET.

(3) an application for SPE renewal as referred to in section (2) must be proposed not exceeding 10 (ten) days prior to the expiry of SPE.

(4) In order to propose the verification process of documents through online, the applicant must give copies of supporting documents as referred to in section (2) to the Director General not exceeding 3 (three) working days

upon receiving online application.

(5) Not exceeding within a period of 7 (seven) working days upon the receipt of supporting documents as referred to in section (3), Director General issues an approval or rejection of SPE renewal followed by objective reasons.

CHAPTER IV
THE CHANGE IN SPI/SPE

Article 29

(1) In the event that there is a change in supporting data submitted in accordance with the provision of Article 15, Article 17, Article 18, Article 19, and Article 27, then SPI or SPE must be updated.

(2) Procedures of updating SPI or SPE are valid with *mutatis mutandis* following the provision of Article 15, Article 17, Article 18, Article 19, and Article 27.

CHAPTER V
FEES

Article 30

(1) Toward application for a permit as importer/exporter of Psychotropics and/or Pharmacy Precursors or its renewal and the application for SPI/SPE Narcotics, Psychotropics, and/or Pharmacy Precursors or its renewal as well as the application for Monitoring Result Analysis, shall be subject to fees as non-tax state income in accordance with the laws and regulations.

(2) In the event that such application for permit as referred to in section (1) is rejected, then such fees already paid may not be withdrawn by the applicant.

CHAPTER VI
RECORDING AND REPORTING

Article 31

The state-owned PBF company conducting the Importation and/or Exportation of Narcotics, or Pharmaceutical Industry,

PBF, Institute of Science conducting the Importation and/or Exportation of Psychotropics and/or Pharmacy Precursors is required to make a recording and keep the record on the importation and exportation of Narcotics, Psychotropics, or Pharmacy Precursors which are under its control.

Article 32

(1) The state-owned PBF company already had a special permit as importer/Narcotics Exporter is required to submit a report on realization of Narcotics Import/Export to the Director General through online and/or in written each time of Importation/Exportation.
(2) Psychotropics IP/ Pharmacy Precursors IP, Psychotropics IT/ Pharmacy Precursors IT, Psychotropics EP/ Pharmacy Precursors EP, Psychotropics ET/ Pharmacy Precursors ET are required to submit a report on realization of Impor/Export for Psychotropics and/or Pharmacy Precursors to the Director General through online and/or in written each time of Importation/Exportation.
(3) The report as referred to in section (1) and section (2) is received not later than 3 (three) days for Narcotics and 7 (seven) days for Psychotropics and Pharmacy Precursors upon the receipt of Narcotics, Psychotropics and/or Pharmacy Precursors by importer or the implementation of export of Narcotics, Psychotropics and/or Pharmacy Precursors with a copy sent to the Head of Agency.
(4) The form of written report as referred to in section (3) is set out in Form 21, Form 22, Form 23, Form 24, and Form 25 as attached.

Article 33

(1) Institute of Science performing the importation of Psychotropics and/or Pharmacy Precursors both directly and through Psychotropics IT/ Pharmacy Precursors IT is required to submit a report on realization of the importation of Psychotropics and/or Pharmacy Precursors to the Director General with a copy sent to the Head of Agency in written each time of importation.

(2) The report as referred to in section (1) is received not later than 7 (seven) days upon receiving the Import of Psychotropics and/or Pharmacy Precursors with a copy sent to the Head of Agency.

(3) The form of report on import realization as referred to in section (1) is set out in Form 26 as attached.

CHAPTER VII
DIRECTION AND SUPERVISION

Article 34

Direction and supervision toward the implementation of this Minister Regulation shall be performed by the Minister and the Head of Agency according to their own duties, functions and authorities based on laws and regulations.

CHAPTER VIII
SANCTIONS

Article 35

(1) A breach toward the provision of this Minister Regulation shall be subject to administrative sanctions.

(2) Administrative sanctions as referred to in section (1) shall be in form of:
   a. a written warning;
   b. a temporary discontinuation of activity; or
   c. repeal of permit as Importer or Exporter of Narcotics, Psychotropics, and/or Pharmacy Precursors as regulated in this Minister Regulation.

(3) The repeal of permit as Importer or Exporter of Narcotics, Psychotropics and/or Pharmacy Precursors as referred to in section (2) is made by Director General.

CHAPTER IX
TRANSITIONAL PROVISIONS

Article 36

(1) The application for a permit as importer/exporter of Psychotropics and/or Pharmacy Precursors, or the

application for SPI/SPE of Narcotics, Psychotropics, and/or Pharmacy Precursors already filed prior to this Minister Regulation shall be continuously processed in accordance with regulation or provision enacted prior to this Minister Regulation coming into force.

(2) The permit for importer/exporter or SPI/SPE issued in accordance with regulation or provision enacted prior to this Minister Regulation coming into force shall be declared to remain effective until its validity period expires.

CHAPTER X
CLOSING PROVISIONS

Article 37

At the time when this Minister Regulation comes into force:

a. Regulation of the Minister of Health Number 785/*Menkes*/Per/VII/1997 on Export and Import of Psychotropics; and
b. Regulation of the Minister of Health Number 168/*Menkes*/Per/II/2005 on Pharmacy Precursors, to the extent due to the Import and Export of Precursor Substances;

are repealed and declared ineffective.

Article 38

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

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

Issued in Jakarta
On January 18, 2013

MINISTER OF HEALTH
OF THE REPUBLIC OF INDONESIA

signed

NAFSIAH MBOI

Promulgated in Jakarta
On January 30, 2013

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA

signed

AMIR SYAMSUDIN

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2013 NUMBER 178

Jakarta, 30 June 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