# GUIDELINE FOR MANAGEMENT OF PARTICULAR MEDICINES THAT ARE OFTENLY MISUSED

## (Regulation of the Head of Medicine and Food Supervisory Bodty of R.I Number 7 Year 2016, dated May 9, 2016)

WITH THE BLESSING OF THE ONE AND ONLY GOD

HEAD OF MEDICINE AND FOOD SUPERVISORY BODY

OF THE REPUBLIC OF INDONESIA

Considering:

a. whereas, to protect the people from misusing and using wrong Medicine, it is necessary to initiate more careful supervision;

b. whereas, oftenly used particular Medicine need to be managed appropriately by pharmaceutical industry, pharmacy whole saler, drug store, Hospital Pharmaceutical Installation, and pharmaceutical clinic to prevent deviation and faulty action;

c. whereasm based on the consideration referred to in letter a and letter b it is necessary to stipulate Regulation of the Head of Medicines and Food Supervisory Body on guideline in managing oftenly used Medicines / drugs;

In view of:

1. Ordonance on prescribed drug (Sterkwerkende Geneesmiddelen Ordonnantie; Staatsblad Year 1949; 419);

2. Law Number 36 Year 2009, concerning Health (Statute Book of the Republic of Indonesia Year 2009 Number 144, Supplement to Statute Book of the Republic of Indonesia Number 5063);

3. Government Number 72 Year 1998, concerning safeguard of pharmaceutical preparation and healthcare apparatus (Statute Book of the Republic of Indonesia Year 1998 Number 138, Supplement to Statute Book

of the Republic of Indonesia Number 3781);

4. Government Number 51 Year 2009, concerning pharmaceutical work (Statute Book of the Republic of Indonesia Year 2009 Number 124, Supplement to Statute Book of the Republic of Indonesia Number 5044);

5. Presidential Decree Number 103 Year 2001, concerning Capacity, Duty, Function, Authority, Organizational Chart, and Working System of non-Department Government Institution as amended several times and lately amended by Presidential Regulation Number 145 Year 2015;

6. Presidential Decree Number 110 Year 2001, concerning Organizational Unit and Duty of Echelon I of Non-Department Government Institution as amended several times and lately amended by Presidential Regulation Number 4 Year 2013;

7. Regulation of the Minister of Trade Number 70/MDag/Per/9/2015, concerning Importer Identification Number;

8. Regulation of the Minister of Health Number 922/Menkes/Per/X/1993, concerning terms and conditions for issuing License for Drug Store as amended by Decision of the Minister of Health Number 1332/Menkes/SK/X/2002;

9. Regulation Minister Minister of Health Number 1799/Menkes/Per/XII/2010 concerning Industri Farmasi as amended by Regulation Minister Minister of Health Number 16 Year 2013 (State Gazette the Republic of Indonesia Year 2013 Number 442);

10. Regulation Minister Minister of Health Number 1148/Menkes/Per/VI/2011 concerning Pharmaceutical Wholesaler as amended by Regulation of Minister of Health Number 34 Year 2014 (State Gazette the Republic of Indonesia Year 2014 Number 109

11. Regulation of Minister of Health Number Year 2014, concerning Clinic (State Gazette the Republic of Indonesia Year 2014 Number 232);

12. Regulation of Minister Minister of Health ber 35 Year 2014 concerning Standard of Pharmaceutical

service at Drug Store (State Gazette the Republic of Indonesia Year 2014 Number 1162);

13. Regulation of Minister of Health Number 58 Year 2014, concerning Standard Pharmaceutical Service at Hospital (State Gazette the Republic of Indonesia Year 2014 Number 1223);

14. Decision of Head of Medicine and Food Supervisory Body Number 02001/SK/KBPOM Year 2001, concerning Organization and work procedure of Medicine and Food Supervisory Body as amended by Decision of Head of Medicine and Food Supervisory Body Number HK.00.05.21.4231 Year 2004;

15. Regulation of Head of Medicine and Food Supervisory Body Number HK.03.1.34.11.12.7542 Year 2012, concerning technical guideline on distribution of Genuine Medicine (State Gazette the Republic of Indonesia Year 2012 Number 1268);

16. Regulation of Head of Medicine and Food Supervisory Body Number HK.03.1.33.12.12.8195 Year 2012, concerning application of guideline on preparation of genuine medicines (State Gazette the Republic of Indonesia Year 2013 Number 122);

17. Regulation of Head of Medicine and Food Supervisory Body Number 14 Year 2014 concerning Organization and work procedure of Technical Operating Unit within Medicine and Food Supervisory Body (State Gazette the Republic of Indonesia Year 2014 Number 1714);

18. Regulation of Head of Medicine and Food Supervisory Body Number 12 Year 2015, concerning supervision on Imported Medicine and Food into the territory of Indonesia (State Gazette the Republic of Indonesia Year 2015 Number 1373);

19. Regulation of Head of Medicine and Food Supervisory Body Number 13 Year 2015 concerning supervision on imported medicine and food into the territory of Indonesia (State Gazette of the Republic of Indonesia Year 2015 Number 1374);

DECIDES

To stipulate:

REGULATION OF HEAD OF MEDICINE AND FOOD SUPERVISORY BODY CONCERNING GUIDELINE FOR PARTICULAR MEDICINE OFTENLY MISUSED.

## CHAPTER I

## GENERAL PROVISION

### Article 1

What is meant in this Regulation of Head of Medicine and Food Supervisory Body:

1. Particular medicines that are often misused hereinafter referred to as Particular Medicine, shall be medicine that works within the central nervous system other than narcotics and psycotropics, which when used exceeding the therapic doses may cause adict and specific change in mental activity and behavior, consisting of medicines in the form of Tramadol, Triheksifenidil, Klorpromazin, Amitriptilin and/or Haloperidol.

2. Pharmaceutical industry shall be business entity holding License from the Minister of Health or Head of Capital Investment Coordinating Board to produce medicines or medicinal stuff.

3. Pharmaceutical Wholesaler, hereinafter referred to as PBF, shall be company in the form of legal business entity holding License to procure, store, distribute medicines and/or medicinal stuff in large volume that conforms the provisions in the statutory regulation.

4. PBF Branch shall be PBF Branch that has been recognized to procure, store, distribute medicines and/or mecidinal stuff in large volume that conforms the provisions in the statutory regulation.

5. Drugstore shall be pharmaceutical service facilities shall be place where pharmaceutical practice is exercised by Pharmacist.

6. Pharmaceutical service shall be direct service and responsible to patients pertaining to pharmaceutical preparation with the purpose to accomplish particular result to improve quality of patient's life.

7. Hospital Pharmaceutical Installation shall be functional operating unit conducting all activities on pharmaceutical service at Hospital.

8. Clinicl Pharmaceutical Installation shall be part of the Clinic that function to operate, coordinate, govern, and supervise all pharmaceutical service activity and exercise management over pharmaceutical technology.

9. Statement Letter of Import, hereinafter referred to as SKI, shall be Statement Letter to import medicinal stuff, traditional medicinal stuff, supplement stuff, supplement stuff issued by the Minister of Health, and Food stuff into the territory of Indonesia.

10. Head of Supervisory Body shall be Head of Medicine and Food Supervisory Body.

CHAPTER II

S C O P E

Article 2

(1) Particular Medicines regulated under this Regulation consistis of medicines containing:

a. Tramadol;

b. Triheksifenidil;

c. Chlorpromazin;

d. Amitriptilin; and/or

e. Haloperidol.

(2) Such particular Medicines as referred to in paragraph (1) may be used only in providing service to the Minister of Health and/or science.

CHAPTER III

MANAGEMENT

Article 3

Management of particular Medicines covers:

a. procurement;

b. storage;
c. manufacturing;
d. distribution;
e. delivery;
f. treatment / handling of medicines not used up / unsold;
g. recall of medicines (recall);
h. destruction; and
i. recording and reporting.

Article 4

The particular Medicines as referred to in Article 3 shall be managed according to the guideline as set forth in the ATTACHMENT constituting inseparable part of this Regulation.

Article 5

Particular Medicines existing under the control of Pharmaceutical industry, PBF, Drug Store, Hospital Pharmaceutical Installation, and Clinic Pharmaceutical Istallation must be managed according to the guideline as referred to in Article 4.

CHAPTER IV

ADMINISTRATIVE PENALTY

Article 6

(1) Other than subject to criminal penalty based on the provision in the statutory regulation, viollation of the provision as governed in this Regulation of the Head of Supervisory Body, it is also subject to administrative penalty.

(2) The administrative penalty referred to in paragraph (1) may be in the form of:
a. reminder;
b. serious reminder;
c. temporary termination of activity;
d. revocation of license for distribution;
e. recommendation to revoke recognition; and/or
f. recommendation to revoke the license.

(3) The administrative penalty referred to in paragraph (2) letter c on Pharmaceutical industry may be imposed on all activities or part of activities.

(4) The administrative penalty referred to in paragraph (2) letter e on PBF Branch must be addressed to the Department of the Ministry of Health of Province or regional work unit instrument issuing the License.

(5) The administrative penalty referred to in paragraph (2) letter f for Pharmaceutical industry and PBF must the addressed to the Minister of Health or Head of Capital Investment Coordinating Board.

Article 7

(1) Drug Store, Hospital Pharmaceutical Installation, and Clinicl Pharmaceutical Installation not exercising management of particular Medicines as governed in this Regulation of the Head of Supervisory Body may be subject to administrative penalty in the form of recommendation:
   a. reminder;
   b. serious reminder;
   c. temporary termination of activity; and/or
   d. revocation of license.

(2) The administrative penalty referred to in paragraph (1) letter a through letter d must be addressed to the Department of the Ministry of Health of Province, Department of the Ministry of Health of Regency / Municipality or work unit of regional instrument issuing the License.

CHAPTER V

TRANSITIONAL PROVISION

Article 8

(1) By the time this Regulation of the Head of Supervisory Body takes effect, any Pharmaceutical industry , PBF, Drug Store, Hospital Pharmaceutical Installation, or Clini Pharmaceutical Installation exercising management of Medicines and/or Particular Medicinal stuff shall be obliged to conform the provisions as governed in this Regulation of the Head of Supervisory Body within one (1) year as of the date this Regulation of the Head of Supervisory Body comes to force.

(2) Except for the provision referred to in paragraph (1), import of medicinal stuff into the territory of the Republic of Indonesia must conform the provisions as governed in Regulation of the Head of this Supervisory

Body within three (3) months effective as of this Regulation of Head of Supervisory Body comes to force.

CHAPTER VI

CLOSING PROVISION

Article 9

This Regulation of the Head of Supervisory Body comes to force on the date it is stipulated.

For public cognizance, this Regulation of the Head of this Body shall be announced by placing it in the State Gazette of the Republic of Indonesia

Stipulated in Jakarta

Dated May 9, 2016

HEAD OF MEDICINES AND FOOD SUPERVISORY BODY

OF THE REPUBLIC OF INDONESIA,

sgd.

ROY A. SPARRINGA

Enacted in Jakarta

Dated May 18, 2016

DIRECTOR GENERAL OF STATUTORY REGULATION

MINISTRY OF LAW AND HUMAN RIGHTS

OF THE REPUBLIC OF INDONESIA,

sgd.

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA

YEAR 2016 NUMBER 764

Note from Editor:

- Due to technical reason no ATTACHMENT is provided herein.

( MA )