

REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY OF THE REPUBLIC OF INDONESIA
NUMBER 24 OF 2017 ON
CRITERIA AND PROCEDURES FOR DRUG REGISTRATION

BY THE BLESSINGS OF GOD ALMIGHTY

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,
REPUBLIC INDONESIA

- Considering :
- a. that in order to protect the public from the distribution of drugs that do not meet the requirements of efficacy, safety, and quality, it is necessary to register drugs before distribution;
 - b. that the provisions of the criteria and procedures for drug registration as stipulated in the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on The Criteria and Procedures for Drug Registration as amended several times by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 17 of 2016 on the Second Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration needs to be adjusted to the latest developments in science and technology;
 - c. that based on the considerations as referred to in point a and point b, it is necessary to issue the Regulation of the Chairperson of the Indonesian Food and Drug Authority on Criteria and Procedures for Drug Registration;

- Observing : 1. Ordinance of Prescription Drugs (*Sterkwerkende Geneesmiddelen Ordonnantie, Staatsblad* 1949:419);
2. Law Number 5 of 1997 on Psychotropic Drugs (State Gazette of the Republic of Indonesia of 1997 Number 10, Supplement to the State Gazette of the Republic of Indonesia Number 3671);
3. Law Number 8 of 1999 on Consumer Protection (State Gazette of the Republic of Indonesia of 1999 Number 42, Supplement to the State Gazette of the Republic of Indonesia Number 3821);
4. 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);
5. 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);
6. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);
7. Regulation of the Minister of Health Number 1010/MENKES/PER/XI/2008 on Drug Registration as amended by Regulation of the Minister of Health Number 1120/MENKES/PER/XII/2008 on Amendment to Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration;
8. Regulation of the Minister of Health Number 1799/MENKES/PER/XII/2010 on Pharmaceutical Industry as amended by Regulation of the Minister of Health Number 16 of 2013 on Amendment to Regulation of the Minister of Health Number 1799/MENKES/PER/XII/2010 on Pharmaceutical Industry (State Bulletin of the Republic of Indonesia of 2013 Number 442);
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.01.23.12.11.10217 of

- 2011 on Compulsory Drugs for Equivalence Test (State Bulletin of the Republic of Indonesia of 2012 Number 120);
10. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.34.11.12.7542 of 2012 on Technical Guidelines for Good Distribution Practices of Drugs (State Bulletin of the Republic of Indonesia of 2012 Number 1268);
 11. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.33.12.12.8195 of 2012 on Implementation of Guidelines for Good Manufacturing Practices of Drugs (State Bulletin of the Republic of Indonesia of 2013 Number 122);
 12. Decision of the Chairperson of the Indonesian Food and Drug Authority Number 02001/SK/KBPOM of 2001 on Organization and Working Procedure of the Indonesian Food and Drug Authority as amended by Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.21.4231 of 2004 on Amendment to Decision of the Chairperson of the Indonesian Food and Drug Authority Number 02001/SK/KBPOM of 2001 on The Organization and Working Procedure of the Indonesian Food and Drug Authority;

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON CRITERIA AND PROCEDURES FOR DRUG REGISTRATION.

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Chairperson Regulation:

1. Drug Registration hereinafter referred to as Registration means the procedure for registration and evaluation of Drugs to obtain approval.

2. Drug means a finished product including Biological Product, which is a substance or combination of substances used to affect or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, treatment, recovery, and improvement of health, and contraception for humans.
3. Biological Product means a product containing biological materials derived from a human, animal, or microorganisms prepared in a conventional way, including extraction, fractionation, reproduction, cultivation, or through biotechnology methods, among others fermentation, genetic engineering, cloning, including but not limited to enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, DNA recombinant products, and immunosuppressants.
4. Contraceptive mean a Drug or device containing a drug that is intended to prevent conception.
5. Narcotic mean a Drug derived from a plant or non-plant, both synthetic and semi-synthetic, which can cause a decrease or change in consciousness, loss of sense, alleviate and relieve of pain and can create an addiction, which is differentiated into categories as stipulated in the Law on Narcotics.
6. Psychotropic mean a drug both natural and synthetic, non-Narcotics, which has psychoactive properties through selective effect on the central nervous system that causes distinctive changes in mental activity and behavior.
7. Marketing Authorization means a form of Registration approval to be distributed in the territory of Indonesia.
8. Marketing Authorization Holder means an Applicant who has obtained a Marketing Authorization for Drugs submitted for Registration.
9. Label means information printed on the packaging.
10. Summary of Product Characteristics/Brochure means complete information approved by the Chairperson regarding the description of Drugs, efficacy, and safety of

Drugs from the data of clinical trial results, and other information that is considered necessary and serves as a source of information for healthcare professional and a reference in the preparation of Product Information for Patients.

11. Product Information means a complete description of Drugs approved by the Chairperson, including efficacy, safety, route of administration and other information deemed necessary that is listed in the Summary of Product Characteristics/Brochures and/or Patient Information Leaflet.
12. Patient Information Leaflet means information for patients approved by the Chairperson regarding the efficacy, safety, and route of administration and other information deemed necessary by using Indonesian that is easy to understand and comprehended by patients.
13. Applicant means Pharmaceutical Industry that has obtained licensing in Pharmaceutical Industry in accordance with the provisions of legislation.
14. Pharmaceutical Industry means a business entity that has a license from the Minister of Health to carry out Drug product or drug substances manufacturing activities.
15. Domestic Pharmaceutical Industry means a Pharmaceutical Industry located in the territory of Indonesia.
16. New Registration means a Registration for Drugs that have not obtained a Marketing Authorization in Indonesia.
17. Variation Registration means the Registration of changes in aspects of administration, efficacy, safety, quality, and/or Product Information and Drug Labels that have been Marketing Authorization in Indonesia.
18. Major Variation Registration means a Variation Registration that has a significant impact on the aspects of efficacy, safety and/or quality of Drugs.
19. Minor Variation Registration means a Variation Registration that does not belong to the category of Major

Variation Registration or Notification Variation Registration.

20. Notification Variation Registration means a Variation Registration that has minimal or no impact at all on aspects of efficacy, safety, and/or quality of Drugs, and does not change the information on the Marketing Authorization.
21. Renewal registration means the registration of extension of the Marketing Authorization validity period.
22. Biosimilar Product means a Biological Product with a similar profile of efficacy, safety, and quality to approved Biological Products.
23. Good Manufacturing Practice, hereinafter abbreviated as GMP means a method of Drugs manufacturing that aims to ensure that the quality of drugs produced is in accordance with the requirements and purposes of use.
24. Active Pharmaceutical Ingredients means a component of drugs that have pharmacological effects.
25. Excipient means a component of drugs that do not have pharmacological effects.
26. Composition means a qualitative and quantitative arrangement of Active Pharmaceutical Ingredients in Drugs.
27. Formula means a qualitative and quantitative arrangement of Active and Excipient Substances in Drugs.
28. New Drug means a Drug with a New Chemical Entity, new dosage form, new strength, or new combination having never been approved in Indonesia.
29. Branded Generic Drug means a Drug with trade names containing Active Pharmaceutical Ingredients with the same Composition, strength, dosage form, route of administration, indications, and posology with originator drugs that have been approved in Indonesia.
30. Generic Drug means a drug with the name according to International Nonproprietary Names Modified determined by the World Health Organization or the name specified in

the national health program.

31. First Generic Drug means the first Generic Drug registered in Indonesia with the same Active Pharmaceutical Ingredients as the Originator Drug approved in Indonesia.
32. Local Drug mean a drug made or packaged primary by the Pharmaceutical Industry in Indonesia.
33. Contract Giver means the Pharmaceutical Industry that delegates the work of manufacturing drugs based on a contract.
34. Contract Acceptor means the Pharmaceutical Industry that accepts Drug manufacturing works based on a contract.
35. Imported Drug means a drug made by the pharmaceutical industry abroad in the form of a Finished Product or a Bulk Product in primary packaging to be distributed in Indonesia.
36. Finished Product means a product having gone through all stages of the manufacturing process.
37. Bulk Product means an ingredient having been processed and only requiring packaging to become Drugs.
38. Contract Drug mean a drug whose manufacture is delegated to other Pharmaceutical Industries.
39. Licensed Drug mean a Drug made by Domestic Pharmaceutical Industry on the basis of a License.
40. License means the delegation of right and authority to use the results of research and development related to efficacy, safety, quality, and technology transfer in the manufacture, and/or use of trade names and marketing of a Drug.
41. Patent Protected Drug mean a Drug that obtains patent protection based on the applicable Patent Law in Indonesia.
42. Investigational New Drug mean a Drug product or drug substances in the form of a new molecule or new Formula, Biological Product/biotechnology being developed and manufactured by a research institution or

Pharmaceutical Industry in Indonesia and/or abroad for use in the nonclinical and/or clinical trial stages in Indonesia with the aim of obtaining a Marketing Authorization in Indonesia.

43. Orphan Drug means an indispensable Drug for the treatment of rare diseases and have proven their safety and effectiveness.
44. Form means a registration form.
45. Day means a work day.
46. Chairperson means the Chairperson of the Indonesian Food and Drug Authority.

CHAPTER II REQUIREMENTS AND CRITERIA¹

Part One Requirements

Article 2

- (1) Drugs to be distributed in the territory of Indonesia must have a Marketing Authorization.
- (2) To obtain a Marketing Authorization as referred to in section (1), registration must be carried out.
- (3) Registration as referred to in section (2) is submitted by the Applicant to the Chairperson.

Article 3

- (1) Exclusion from the provisions as referred to in Article 2 section (1), is intended for Special Access Scheme Drug.
- (2) Special Access Scheme Drug as referred to in section (1) is carried out in accordance with the provisions of legislation.

Part Two

Criteria

Article 4

- (1) Drugs that have Marketing Authorization must meet the following criteria:
 - a. reassuring efficacy and adequate safety are proven through nonclinical and clinical trials or other evidence in accordance with the status of scientific development;
 - b. qualified quality in accordance with the established standards, including the manufacturing process in accordance with GMP and equipped with valid evidence; and
 - c. Product Information and Label contain complete, objective, and non-misleading information that can guarantee the proper, rational, and safe use of the Drugs.
- (2) In addition to meeting the criteria as referred to in section (1), the Drugs must also meet the following criteria:
 - a. specifically for the new Psychotropics, should have advantages compared to Drugs that have been approved to distribute in Indonesia; and
 - b. specifically for Drugs for the national health program, must comply with the requirements set by a government institution administering the national health program.

CHAPTER III

REGISTRATION CATEGORY

Article 5

- (1) Registration consists of:
 - a. New Registration;
 - b. Variation Registration; and
 - c. Renewal Registration.
- (2) New Registration as referred to in section (1) point a consists of:

- a. category 1 : Registration of New Drugs and Biological Products, including Biosimilar Products.
 - b. category 2 : Registration of Generic Drugs and Branded Generic Drugs.
 - c. category 3 : Registration of other preparations containing Drugs with special technology, can be in the form of transdermal patch, implant, and beads.
- (3) Variation Registration as referred to in section (1) point b consists of:
- a. category 4 : Major Variation Registration.
 - b. category 5 : Minor Variation Registration.
 - c. category 6 : Notification Variation Registration.
- (4) Renewal Registration as referred to in section (1) point c falls into category 7.

CHAPTER IV

REGISTRATION REQUIREMENTS

Part One

Drug Names

Article 6

- (1) The registered drug names can use:
- a. generic names; or
 - b. trade names.
- (2) The generic names as referred to in section (1) point a are in accordance with International Nonproprietary Names Modified, determined by the World Health Organization or the names specified in the national health program.
- (3) The trade names as referred to in section (1) point b is the names given by the Applicant as the identity of the Drug.
- (4) The granting of trade names as referred to in section (1) point b is based on an self-assessment and is the responsibility of the Applicant.

- (5) Self-assessment as referred to in section (4) refers to the General Guidelines for Drug Names as contained in Annex I as an integral part of this Agency Regulation.
- (6) In the event that the self-assessment as referred to in section (5) is not in accordance with the General Guidelines for Drug Names as in Annex I, the proposal for the name of the Drug cannot be approved.
- (7) If in the future there is another party who is more entitled to the name of the drug listed in the Marketing Authorization in accordance with the provisions of legislation, the Applicant must change the name of the Drug

Part Two Registration

Article 7

- (1) Registration is carried out by Applicants by submitting registration documents.
- (2) The registered drugs are in the form of:
 - a. Local Drugs; or
 - b. Imported Drugs.

Part Three Registration of Local Drugs

Article 8

- (1) Applicants submitting for Registration of Local Drugs must meet the following requirements of:
 - a. having a license in Pharmaceutical Industry; and
 - b. holding a valid GMP certificate in accordance with the registered type and dosage form.
- (2) Exemption from the provisions as referred to in section (1) point a and point b, is for Registration of Local Drugs carried out by a prospective Pharmaceutical Industry that is under construction.
- (3) Exemption from the provisions as referred to in section (1)

point b, for Registration of Local Drugs carried out by the Pharmaceutical Industry which adds facilities for new dosage forms or the Pharmaceutical Industry which expands manufacturing facilities.

- (4) Requirements for Registration of Local Drugs as referred to in section (2) and section (3) are in the form of recommendations based on the results of inspection on the fulfillment of GMP requirements.
- (5) In the event that the Registration is carried out based on the provisions as referred to in section (2) and section (3), Marketing Authorization will be issued after the Applicant meets the requirements as referred to in section (1).

Part Four

Registration of Local Contract Drug

Article 9

- (1) Registration of Local Contract Drugs can only be submitted by the Contract Giver as the Applicant.
- (2) Registration as referred in section (1) must meet the following requirements of:
 - a. having a license in Pharmaceutical Industry;
 - b. having at least 1 (one) manufacturing facility that has met the GMP requirements; and
 - c. having a contract agreement document.
- (3) The Contract Giver Pharmaceutical Industry and Contract Acceptor Pharmaceutical Industry are responsible for aspects of the efficacy, safety, and quality of the Contract Drug, with the main responsibility being the Contract Giver Pharmaceutical Industry as the Marketing Authorization Holder.
- (4) The Contract Acceptor Pharmaceutical Industry must have a valid GMP certificate in accordance with the manufactured dosage form.
- (5) The Contract Acceptor Pharmaceutical Industry cannot outsource the manufacturing of Contract Drugs to third

parties.

Article 10

- (1) Manufacture of local contract drugs is in the form of:
 - a. whole stages of manufacture; or
 - b. partial stages of manufacture.
- (2) Formula of local Contract Drugs as referred to in section (1) is in the form of:
 - a. Formula from the Contract Giver; or
 - b. Formula from the Contract Acceptor.
- (3) Local Contract Drugs as referred to in section (1) can be manufactured in more than 1 (one) manufacturing site by providing justification.
- (4) Local Contract Drugs as referred to in section (3) must have the same quality, including Formula and product specifications.

Part Five

Imported Drug Registration

Article 11

- (1) Imported drugs are in the form of:
 - a. Imported Drugs in the form of Bulk Products; or
 - b. Imported Drugs in the form of Finished Products.
- (2) Imported Drug Registration is prioritized for:
 - a. Drugs for national health program;
 - b. Investigational new drugs; and/or
 - c. Drugs that are needed but cannot be manufactured locally.

Article 12

Drugs for national health program as referred to in Article 11 section (2) point a are stipulated by the government institution administering the national health program.

Article 13

- (1) Investigational new drugs as referred to in Article 11 section (2) point b consists of:
 - a. Patented drug; or
 - b. Originator drug.
- (2) The originator drug as referred to in section (1) point b is the first Drug to be given a Marketing Authorization in Indonesia based on complete data on efficacy, safety, and quality.

Article 14

- (1) Drugs needed but cannot be manufactured locally as referred to in Article 11 section (2) point c are:
 - a. Drugs that require special technology and manufacturing facilities that are not yet owned by the Pharmaceutical Industry in Indonesia;
 - b. Drugs that require special technology and manufacturing facilities that are already available in Indonesia, but the production capacity is inadequate to meet local demands;
 - c. Drugs that are economically impossible to manufacture domestically because of the need in small quantities; can be in the form of drugs for rare diseases (Orphan Drug) in Indonesia; or
 - d. Drugs centrally manufactured overseas by the multinational pharmaceutical industry that owns the Pharmaceutical Industry in Indonesia by showing a balance of export and import activities.
- (2) Registration of Imported Drugs as referred to in section (1) must be supplemented with the justification that the Drug in question cannot be manufactured in Indonesia.

Article 15

- (1) Registration of Imported Drugs can only be submitted by Applicants that obtain written approval from the pharmaceutical industry abroad.
- (2) Exemption from the provisions of obtaining written

approval from the pharmaceutical industry abroad as referred to in section (1) is for Applicants that are affiliates of the parent company.

- (3) Written approval as referred to in section (1) must include the validity period of partnership.
- (4) The pharmaceutical industry abroad as referred to in section (1) must have a license in Pharmaceutical Industry and meet the GMP requirements as evidenced by:
 - a. license in pharmaceutical industry from a local state authority;
 - b. a valid GMP certificate or other equivalent document issued by a local Drug regulatory authority and/or another country's Drug regulatory authority; and
 - c. report on the results of the latest inspections and related changes not later than 2 (two) years issued by a local Drug regulatory authority and/or another country's Drug regulatory authority.
- (5) If necessary, to ensure the fulfillment of GMP requirements as referred to in section (4), on-site inspection can be conducted at Drug manufacturing facilities in accordance with the provisions of legislation.
- (6) In the event that Imported Drugs as referred to in section (1) whose partial or whole stages of manufacture are carried out by more than 1 (one) Pharmaceutical Industry, whole stages of manufacture must meet the requirements as referred to in section (4).

Article 16

- (1) Registration of Imported Drugs as referred to in Article 14 section (1) must be carried out in stages for technology transfer to be manufactured locally.
- (2) Technology transfer as referred to in section (1) can be in the form of transfer of knowledge/ability in the field of:
 - a. product development;
 - b. production procedures and methods/processes; and/or
 - c. quality control.

- (3) The transfer of technology as referred to in section (1) may be given to affiliates of the overseas pharmaceutical industry in Indonesia or other Pharmaceutical Industries in Indonesia based on an agreement between the owner and recipient of the technology.

Part Six

Narcotic Registration

Article 17

- (1) Narcotic registration can only be submitted by Applicants who have a special license to manufacture Narcotics from the Minister of Health.
- (2) Narcotic Registration as referred to in section (1) is carried out in accordance with the requirements and procedures for registration as stipulated in this Agency Regulation.

Part Seven

Licensed Drug Registration

Article 18

- (1) Licensed Drug Registration is carried out by the Applicants who have obtained the letter of authorization from the licensor.
- (2) Registration as referred to in section (1) must meet the following requirements of:
 - a. having a license in Pharmaceutical Industry;
 - b. having a valid GMP certificate in accordance with the registered type and dosage form; and
 - c. having a license agreement document.
- (3) The license agreement document as referred to in section (2) point c must contain at least:
 - a. information on licensed matters; and
 - b. license validity period.
- (4) The licensor as referred to in section (1) may be:
 - a. Local Pharmaceutical Industry or overseas pharmaceutical industry; or

- b. a domestic or overseas research agency owning Formula and technology.
- (5) The licensor as referred to in section (4) must have proof of status as a Pharmaceutical Industry or research agency.

Part Eight

Registration for Export-Only Drug

Article 19

- (1) Registration for Export-Only Drug is carried out submitted by Applicants.
- (2) Export-Only Drug as referred to in section (1) consist of:
 - a. Local Drugs intended for export only; and
 - b. Imported Drugs for export only
- (3) Applicants of Registration for Local Drugs intended for export only as referred to in section (2) point a must meet the following requirements of:
 - a. having a license in Pharmaceutical Industry; and
 - b. having a valid GMP certificate in accordance with the type and dosage form registered.
- (4) Applicants of Registration for Imported Drugs for export only as referred to in section (2) point b must meet the following requirements of:
 - a. having a license in Pharmaceutical Industry;
 - b. having a valid GMP certificate in accordance with the registered type and dosage form; and
 - c. having obtained written approval from overseas pharmaceutical industry.
- (5) Exported drugs as referred to in section (2) are prohibited to be distributed in the territory of Indonesia.

Part Nine

Patent Protected Drug Registration

Article 20

- (1) Registration for Drugs with Active Pharmaceutical Ingredients that are patented in Indonesia can only be carried out by:
 - a. The Applicant as the Patent holder; or
 - b. Applicants appointed by patent holder.
- (2) The patent as referred to in section (1) must be proven by a patent certificate.

Article 21

- (1) Registration for the First Generic Drugs with Active Pharmaceutical Ingredients that are still patented in Indonesia can be submitted by Applicants which are not patent holders in accordance with the provisions of legislation.
- (2) Registration as referred to in section (1) can be submitted 5 (five) years Prior to the expiry of patent protection.
- (3) Applicants of the First Generic Drug Registration as referred to in section (1), must submit the following documents:
 - a. information on the expiration date of the patent protection period from the authorized institution; and
 - b. data equivalence and/or other data to ensure equality of efficacy, safety, and quality.
- (4) The Marketing Authorization for the submission of the First Generic Drug Registration as referred to in section (1) is issued after the patent protection period expires.

Part Ten

Investigational New Drug Registration

Article 22

- (1) Registration for Drugs with clinical trials conducted in Indonesia must go through the assessment of Investigational New Drugs.
- (2) The assessment of Investigational New Drugs as referred to in section (1) is carried out in accordance with the

provisions of legislation.

Part Eleven
Registration of Generic Drug

Article 23

- (1) Registration of Generic Drug is submitted by Applicants using the generic name as referred to in Article 6 section (2).
- (2) Whole stages of Generic Drug manufacture are carried out locally.
- (3) Exemption from the provisions as referred to in section (2) is for Drugs of which their partial stages of manufacture cannot be carried out domestically.
- (4) In the event that the Applicants already have Branded Generic Drugs with the same Active Pharmaceutical Ingredients, the registered Generic Drugs must be made with the same Formula, source of raw materials, Drug specifications, quality, packaging specifications, manufacturing process, and use the same manufacturing facility.
- (5) The specifications as referred to in section (4) include:
 - a. size;
 - b. form;
 - c. color;
 - d. odor; and
 - e. flavor.
- (6) Generic Drug Labels must include the following information:
 - a. the highest retail price in accordance with the provisions of legislation; and
 - b. green generic logo using the following format:



- (7) The generic logo as referred to in section (6) point b is attached proportionally according to the packaging size.
- (8) In the event that the Applicants submit a Generic Drug

Registration with more than 1 (one) Active Pharmaceutical Ingredients strength, the strength of the Active Pharmaceutical Ingredients must be listed after the dosage form on the packaging with the font size in accordance with the generic name font size.

Part Twelve

Orphan Drug Registration

Article 24

Further provisions regarding Orphan Drug Registration are specifically regulated by the Indonesian FDA Regulation.

CHAPTER V

REGISTRATION PROCEDURES

Part One

General

Article 25

- (1) Registration consists of:
 - a. pre-registration stage; and
 - b. registration stage.
- (2) The application for pre-registration and registration as referred to in section (1) is submitted by Applicants in writing to the Chairperson by attaching the pre-registration and registration documents.
- (3) The application as referred to in section (2) is submitted by filling out the Form in accordance with the example as contained in Annex II as an integral part of this Agency Regulation.
- (4) Instructions for filling the Form as referred to in section (3) are listed in Annex III as an integral part of this Agency Regulation.
- (5) Pre-registration and registration documents must be in Indonesian or English.
- (6) Pre-registration and registration applications can be

submitted electronically in accordance with applicable regulations.

- (7) In the event that electronic Registration cannot be submitted or the electronic system does not work, the Registration submitted manually.

Article 26

- (1) The application for pre-registration and registration as referred to in Article 25 section (1) is subject to a fee as non-tax state revenue in accordance with the provisions of legislation.
- (2) The fee as referred to in section (1) must be paid not later than 10 (ten) Days from the date of the Public Service Payment Order (*Surat Perintah Bayar-Layanan Publik*, SPB-LP) is issued.
- (3) Applicants must confirm the payment of SPB-LP and submit pre-registration or registration documents not later than 3 (three) Days from the date of payment.
- (4) In the event that the Applicants do not confirm the payment of SPB-LP and submit the pre-registration or registration documents as referred to in section (3), the application will be declared canceled.

Paragraph One

Registration Documents

Article 27

- (1) Registration documents as referred to in Article 25 section (2) consists of:
 - a. part I : administrative documents, Product Information and Labels.
 - b. part II : quality documents.
 - c. part III : nonclinical documents.
 - d. part IV : clinical documents.
- (2) The registration documents as referred to in section (1) are prepared in accordance with the ASEAN Common Technical Dossier (ACTD) format and refer to the

procedures for preparing the registration documents as contained in Annex IV as an integral part of this Agency Regulation.

- (3) The registration documents as referred to in section (1) are in accordance with the example as contained in Annex V as an integral part of this Agency Regulation.
- (4) The registration documents as referred to in section (1) are confidential documents used only for evaluation purposes by the competent authority.

Article 28

- (1) The administrative documents as referred to in Article 27 section (1) point a are in accordance with the example as contained in Annex VI as an integral part of this Agency Regulation.
- (2) Quality documents as referred to in Article 27 section (1) point b are contained in Annex VII as an integral part of this Agency Regulation.
- (3) Nonclinical documents as referred to in Article 27 section (1) point c are contained in Annex VIII as an integral part of this Agency Regulation.
- (4) Clinical documents as referred to in Article 27 section (1) point d are contained in Annex IX as an integral part of this Agency Regulation.

Article 29

- (1) Product Information documents as referred to in Article 27 section (1) point a consist of:
 - a. Summary of Product Characteristics/Brochure; and
 - b. Patient Information Leaflet.
- (2) Patient Information Leaflet as referred to in section (1) point b, for the Over the Counter (OTC) Drug must be included in the smallest packaging; it can be catch cover/envelope, blister, or brochure that is firmly attached to the smallest package, which is legible during the use of Drugs.
- (3) The Product Information documents as referred to in

section (1) must at least include the information as contained in Annex X as an integral part of this Agency Regulation.

Article 30

- (1) Label Documents as referred to in Article 27 section (1) point a include tags, strip/blister, ampoule/vial, catch cover/ envelope, and outer wrap.
- (2) The label as referred to in section (1) must include traceable identity to guarantee the validity of the product.
- (3) Further provisions regarding traceable identity to guarantee the validity of the product as referred to in section (2) are regulated in a Agency Regulation.
- (4) The minimum information that must be included on the Label as referred to in section (1) is contained in Annex XI as an integral part of this Agency Regulation.

Article 31

- (1) Patient Information Leaflet as referred to in Article 29 section (1) point b must use Indonesian, Latin, and Arabic numerals.
- (2) The use of a language other than Indonesian as referred to in section (1) may be carried out as long as there is no Indonesian equivalent.
- (3) In addition to using Indonesian as referred to in section (1), Patient Information Leaflet can be added in English according to the agreed information.
- (4) Exemption from the provisions as referred to in section (1) for Export-Only Drugs.

Paragraph Two

Responsibilities of Applicants

Article 32

- (1) Applicants are responsible for:
 - a. the completeness of the submitted documents;
 - b. the correctness and validity of all information contained in the registration documents; and
 - c. changes in data and information on products that are in the process of registration or already have a Marketing Authorization.
- (2) The Applicant's responsibility as referred to in section (1) must be stated in writing in a statement letter as contained in Annex XII as an integral part of this Agency Regulation.
- (3) Any changes to data and/or Product Information as referred to in section (1) point c must obtain the approval of the Chairperson.

Part Two

Pre-registration

Article 33

The application for Drug pre-registration is made for registration screening, including determining the Registration category, the evaluation path, the evaluation fee, and the registration documents.

Article 34

Exemption from the provisions as referred to in Article 33 for:

- a. Registration of Local manufactured Generic Drugs category 2 as referred to in Article 5 section (2) point b;
- b. Registration of Variations Category 4 that does not require clinical trials as referred to in Article 5 section (3) point a, category 5, and category 6 as referred to in Article 5 section (3) point b and point c; and
- c. Renewal registration category 7 as referred to in Article 5 section (4).

Article 35

Application as referred to in Article 33 is submitted by:

- a. filling out the Form as contained in Annex II as an integral part of this Agency Regulation.
- b. submitting proof of payment of pre-registration fees; and
- c. attaching the documents as contained in Annex XIII as an integral part of this Agency Regulation.

Article 36

- (1) Pre-registration results (*Hasil Praregistrasi*, HPR) are published within a maximum period of 40 (forty) days from the receipt of the application as referred to in Article 33.
- (2) HPR as referred to in section (1) is binding and valid for 1 (one) year from the date of issuance.
- (3) In the event that additional data is required, the request for additional data is submitted in writing to Applicant.
- (4) In the event that Applicants are given a letter requesting additional data as referred to in section (3), the calculation of the evaluation timeline as referred to in section (1) is terminated (clock off) until the Applicants submit the requested additional data.
- (5) Not later than 20 (twenty) Days from the date of the letter requesting additional data, the Applicants must submit additional data.
- (6) The calculation of the evaluation timeline will be resumed (clock on) after the Applicants submit the complete additional data.
- (7) In the event that the Applicants are unable to submit additional data within the period of 20 (twenty) Days as referred to in section (5), the Applicants may request an extension of the fulfillment of additional data 1 (one) time accompanied by justification.
- (8) In the event that the Applicants are unable to submit additional data as referred to in section (7), the pre-registration is declared canceled and the fee will not be refunded.

Part Three
Evaluation Pathway

Article 37

- (1) Evaluation pathway consists of:
- a. 7 (seven) Days pathway covering Registration for Export-Only Drug;
 - b. 10 (ten) Days pathway covering Renewal registration;
 - c. 40 (forty) Days pathway covering Minor Variation Registration;
 - d. 100 (one hundred) Days pathway covering:
 - 1) New Registration of New Drugs and Biological Products indicated for the treatment of serious diseases that threaten human life (lifesaving), and/or are easily transmitted to others, and/or there is no or lack of other safe and effective therapeutic options;
 - 2) New Registration of New Drugs and Biological Products based on justification indicated for serious and rare diseases (Orphan Drug) in Indonesia;
 - 3) New Registration of New Drugs, Biological Products, Generic Drugs, and Branded Generic Drugs is intended for national health programs equipped with supporting documents for program requirements or the results of prequalification of the World Health Organization;
 - 4) New Registration of New Drugs and Biological Products that have gone through the Investigational New Drugs developed by a research institution or the Pharmaceutical Industry in Indonesia, made by the Pharmaceutical Industry in Indonesia and at least 1 (one) clinical trial conducted in Indonesia;
 - 5) New Registration of Generic Drugs that have the same Formulas, source of raw materials, Drug

- specifications, quality, packaging specifications, manufacturing process, that have and use the same manufacturing facility as Branded Generic Drugs that have been approved;
- 6) Major Variations Registration with new indications/posology for Drugs intended as referred to in point 1) to point 4);
 - 7) Major Variation Registration regarding quality and Product Information.
- e. 120 (one hundred and twenty) Days pathway covering New Registration of New Drugs and Major Variations Registration with new indications/posology that have been approved in at least 3 (three) countries with an established evaluation system;
 - f. 150 (one hundred and fifty) Days pathway covering New Registration of Generic Drugs and Branded Generic Drugs that are not included in the evaluation path as referred to in point d;
 - g. 300 (three hundred) Days pathway covering New Registration of New Drugs and Biological Products as well as Major Variations Registration with new indications/posology that are not included in the evaluation path as referred to in point d and point e.
- (2) The criteria for determining 120 (one hundred and twenty) Days pathway as referred to in section (1) point e as contained in Annex XIII as an integral part of this Agency Regulation.

Part Four

New Registration

Article 38

- (1) Applications for New Registration are submitted by filling in the form as shown in the example in Annex II and attaching registration documents.
- (2) New Registration document requirements as referred to in

section (1) as contained in Annex XIV as an integral part of this Agency Regulation.

- (3) Exemption from the provisions as referred to in section (2), for the exported Drug Registration in accordance with the requirements as contained in Annex XV as an integral part of this Agency Regulation.

Article 39

- (1) In addition to completing the New Registration documents as referred to in Article 38 section (2), for New Registration category 1 as referred to in Article 5 section (2) point a, Applicants must also submit a risk management plan.
- (2) Further provisions regarding the assessment of risk management plans as referred to in section (1) are regulated in a Indonesian FDA Regulation.

Part Five

Variation Registration

Article 40

- (1) Changes to Drugs that have obtained a Marketing Authorization can be in the form of changes in aspects of administration, efficacy, safety, quality, and/or Product Information and Label.
- (2) The changes as referred to in section (1) must be reported to the Chairperson through the Variation Registration mechanism.
- (3) Application for Variation Registration as referred to in Article 5 section (3) is submitted by filling out the Form as shown in the example as contained in Annex II and attaching the Variation Registration documents in accordance with the proposed changes as referred to in Annex XVI as an integral part of this Agency Regulation.

Article 41

- (1) Exemption from the provisions as referred to in Article 40

section (1) for Notification Variations Registration as referred to in Article 5 section (3) point c, Applicants can make changes and report to the Chairperson not later than 6 (six) months after the changes are made.

- (2) If the reported changes are not in accordance with the type of change as contained in Annex XVI point B point 3, the notification is rejected and the Applicants must submit registration in accordance with the specified Variation Registration category.
- (3) The implementation of changes as referred to in section (1) is carried out through a change control mechanism.
- (4) The changes as referred to in section (1) may be verified directly and the Applicants must be able to show documentation regarding the proposed changes.
- (5) If the verification results are not in accordance with the type of notification change reported, the notification is rejected and the Applicants may be subject to sanctions in accordance with the provisions of legislation.

Part Six

Renewal Registration

Article 42

- (1) Renewal Registration is submitted not sooner than 12 months and not later than 2 (two) months before the expiration of the Marketing Authorization.
- (2) Exemption from the provisions as referred to in section (1), the application for Renewal Registration without changes can be submitted not later than 1 (one) month before the end of the Marketing Authorization period.
- (3) Application for Renewal Registration as referred to in section (1) and section (2) is submitted by filling out the Form as shown in the example in Annex II and attaching the Renewal Registration documents as contained in Annex XVII as an integral part of this Agency Regulation.
- (4) The extension of the Marketing Authorization as approval of the application for Renewal Registration as referred to

in section (1) and section (2) is valid since the end of the old Marketing Authorization period, as long as there is no:

- a. changes in Active Pharmaceutical Ingredients;
 - b. changes in Drug manufacturers;
 - c. changes in Applicant;
 - d. changes in dosage form;
 - e. changes in formula;
 - f. changes in type and size of packaging; and/or
 - g. violation of the provisions of legislation.
- (5) In case of the application for Renewal Registration containing any of the matters as referred to in section (4) point a to point f, the Registration is processed in accordance with the Variation Registration category.
- (6) Drugs that fail to be re-registered until the time period as referred to in section (1) and section (2), can be re-submitted as New Registration by following the procedures as regulated in Article 25 to Article 39.

Part Seven

Samples of Drugs and Reference Standards

Article 43

The Chairperson may require the Applicants to submit samples of Drugs, pharmaceutical substances, and reference standards as needed.

CHAPTER VI

EVALUATION AND ISSUANCE OF DECISIONS

Part One

Evaluation

Article 44

- (1) Submission of Registration applications that has been declared fulfilling the completeness of the documents as referred to in Article 27 section (1), is evaluated.
- (2) The evaluation as referred to in section (1) is an

assessment of the aspects of efficacy, safety, quality, Product Information, and/or Label in accordance with the criteria and categories of Registration as referred to in Article 4 and Article 5.

- (3) The evaluation as referred to in section (1) is carried out in accordance with the evaluation pathway as referred to in Article 37.
- (4) The calculation of the evaluation timeline as referred to in section (2) in accordance with the evaluation pathway as referred to in Article 37 is counted from the receipt of the registration documents as referred to in Article 27 section (1).

Article 45

- (1) The evaluation as referred to in Article 44 is carried out on efficacy and safety data based on scientific evidence and guidelines for the assessment of safety efficacy by the Efficacy-Safety Evaluation Team.
- (2) The National Drug Evaluation Team (*Tim Penilai Obat Nasional*, TPON) conducts discussions on the results of the evaluation as referred to in section (1) and provides recommendations for decisions to the Chairperson.
- (3) In the event that a detailed technical clarification and/or explanation is needed on the registration documents as referred to in Article 27 section (1), TPON can request clarification from the Applicants through a hearing.
- (4) For the implementation of the hearing as referred to in section (3), the Chairperson delivers a written notification to the Applicants.
- (5) The Chairperson submits the decision on the results of the evaluation as referred to in section (2) in writing to the Applicants not later than 30 (thirty) Days from the implementation of the TPON periodic meeting.

Article 46

- (1) Evaluation of quality data is carried out by the Quality Evaluation Team according to the criteria as referred to in

Article 4 section (1) point b based on the validity of document information and the latest GMP inspection data.

- (2) The information in the quality document as referred to in section (1) must use valid and actual data, the Formula is in accordance with the Formula to be marketed, and the manufacturing process has been validated.
- (3) If necessary, to ensure the validity of the document information as referred to in section (1), a local inspection is carried out at the Drug manufacturing facility (in situ).

Article 47

- (1) Evaluation of Product Information and Label is carried out by the Product Information and Label Evaluation Team to ensure that the information contained in the Product Information and Label is in accordance with the criteria as referred to in Article 4 section (1) point c.
- (2) Evaluation of Product Information and Label as referred to in section (1) refers to:
 - a. the results of the evaluation of efficacy, safety, and quality as referred to in Article 45 and Article 46;
 - b. Information on New Drug Products that have been approved by the Chairperson; or
 - c. Drug information standards set by the Chairperson.

Article 48

- (1) In the event that additional data is required, the Chairperson delivers a written request for additional data to Applicants.
- (2) The Applicants must submit additional data as referred to in section (1) not later than 100 (one hundred) Days from the date of request for additional data.
- (3) In the event that Applicants are unable to submit additional data within the period of 100 (one hundred) Days as referred to in section (2), the Applicants may submit a justification for extension to fulfill the additional data 1 (one) time accompanied by justification.

- (4) In the event that additional data is required as referred to in section (1), the calculation of the evaluation timeline is terminated (clock off).
- (5) The calculation of the evaluation timeline will be resumed (clock on) after the Applicants submit the complete additional data.
- (6) In the event that Applicants fail to comply with the provisions as referred to in section (2) and section (3), the Registration is declared canceled and the fee will not be refunded.
- (7) Registration declared canceled as referred to in section (6), can be re-submitted by following the procedure as regulated in Article 25 to Article 43.

Part Two

Issuance of Decisions

Article 49

- (1) The decision of the Chairperson on Registration is given by considering:
 - a. evaluation results of registration documents and/or recommendations of TPON/Efficacy-Safety Evaluation Team/Quality Evaluation Team/Product Information and Label Evaluation Team; and/or
 - b. results of on-site inspection at the Drug manufacturing facility (in situ).
- (2) The decision as referred to in section (1) is in the form of:
 - a. granting of approval; or
 - b. rejection:
- (3) Granting of approval as referred to in section (2) point a is only issued to Applicants who meet the administrative requirements and provisions as referred to in in Article 4.
- (4) Rejection as referred to in section (2) point b is given if the registration document does not fulfill the provisions as referred to in Article 4.

Paragraph One

Approval

Article 50

- (1) Prior to the issuance of the approval as referred to in Article 49 section (2) point a, an approvable letter may be issued.
- (2) In the event that an approvable letter is issued as referred to in section (1), Applicants may:
 - a. Conduct manufacturing Drugs of commercial scale Drugs; or
 - b. Conduct importation of imported Drugs.
- (3) In the event that the Applicant conduct importation of Imported Drugs as referred to in section (2) point b, the requirement must have a Marketing Authorization to use the approvable letter for the issuance of import certificate or import approval letter.
- (4) The approvable letter as referred to in section (1) is not intended as a substitute for Marketing Authorization and can only be used for 1 (one) time importation.
- (5) The approvable letter as referred to in section (1) is valid for no longer than 2 (two) years since the date the approvable letter is issued.

Article 51

- (1) The approval as referred to in Article 49 section (2) point a is notified in writing to the Applicants in the form of:
 - a. Marketing Authorization;
 - b. Export-only approval; or
 - c. Variation Registration approval.
- (2) The Marketing Authorization as referred to in section (1) point a is issued if the results of commercial scale Drug manufacture meet the requirements or have submitted proof of importation.

Article 52

- (1) Variation Registration Approval as referred to in Article 51 section (1) point c is in the form of:

- a. New Marketing Authorization; or
 - b. Variation Registration approval letter which is an addendum of Marketing Authorization.
- (2) Variation Registration Approval as referred to in section (1) is carried out not later than 6 (six) months since the date the approval is issued.
 - (3) The old agreement can still be produced not later than 6 (six) months after the issuance of a new agreement as long as the new agreement has not been implemented.
 - (4) The Drugs in accordance with the old approval manufactured before the implementation of the Variation Registration approval as referred to in section (3) can be distributed as long as they still meet the quality requirements.
 - (5) The Applicants are obligated to report the quantity, batch number, and expiration date of the last batch distributed prior to the implementation of the Variation Registration as referred to in section (3) to the Chairperson.
 - (6) Exemption from the provisions as referred to in section (2) to section (4) is for changes of:
 - a. Applicant; or
 - b. tightening of safety aspects as a follow-up to the results of surveillance, implemented in accordance with the provisions stipulated.

Paragraph Two

Rejection

Article 53

- (1) The Chairperson delivers the rejection as referred to in Article 49 section (2) point b in writing to the Applicants.
- (2) In the event that the Registration application is rejected, the Registration paid fee will not be refunded.
- (3) The rejected registration as referred to in section (1) can be re-submitted by following the procedures as regulated in Article 25 to Article 43.

Part Three

Appeal

Article 54

- (1) In the event of any objection to the rejection decision as referred to in Article 49 section (2) point b, the Applicants may submit a written request for appeal to the Chairperson.
- (2) The appeal as referred to in section (1) may be submitted within a period of not later than 6 (six) months as of the date of rejection letter and can only be applied for 1 (one) time.

Article 55

In the event of any objection to the results of the evaluation of efficacy and safety as referred to in Article 49 section (1) point a, the Applicants may submit a written request for appeal to the Chairperson not later than 20 (twenty) Days from the date of notification letter of the results of the evaluation of efficacy and safety and can only be applied for 1 (one) time.

Article 56

- (1) A request for appeal as referred to in Article 54 and Article 55 may be conducted through the mechanism of hearing and/or submitting documents in the form of new data and/or existing data with justification.
- (2) Discussion on the request for appeal as referred to in Article 54 and Article 55 is conducted not later than 100 (one hundred) Days from the date the document is received.

Part Four

Re-submission of Registration

Article 57

- (1) In the event that the Registration is rejected, the Applicants may re-submit the Registration by following the procedures as regulated in Article 25 to Article 43.
- (2) In the event that the Registration is rejected due to failed

to meet the criteria of efficacy and safety, in addition to having to follow the provisions as referred to in section (1), the resubmission of registration can only be submitted with new data and not sooner than 1 (one) year after the date of rejection letter.

CHAPTER VII

MARKETING AUTHORIZATION VALIDITY PERIOD

Article 58

- (1) Marketing Authorization and export only approvals are valid for a maximum of 5 (five) years as long as they meet the provisions of legislation.
- (2) In the event that the Marketing Authorization is not re-registered as referred to in Article 42 section (1) and section (2), the Drugs cannot be manufactured and/or distributed, and the marketed drugs must be recalled.
- (3) Exemption from the provisions as referred to in section (1), is for Drug Registration based on the agreement/appointment with a validity period of less than 5 (five) years, the validity period of the Marketing Authorization in accordance with the validity period of cooperation in the agreement document.
- (4) The Expired Marketing Authorization may be renewed as long as they meet the criteria as regulated in Article 42.

Article 59

In the event that the agreement/appointment as referred to in Article 58 section (3) is terminated before the expiration of the Marketing Authorization period, the relevant Drug Marketing Authorization is revoked.

CHAPTER VIII

IMPLEMENTATION OF MARKETING AUTHORIZATION

Article 60

- (1) Pharmaceutical Industry that has obtained Marketing Authorization is required to make and send manufacturing reports or reports on the import of Imported Drugs to the Chairperson.
- (2) Manufacturing reports or reports on the import of Imported Drugs as referred to in section (1) is carried out in accordance with the provisions of legislation.
- (3) The manufacturing reports or reports on the import of Imported Drugs as referred to in section (1) do not eliminate the obligation for the Pharmaceutical Industry to submit other reports in accordance with the provisions of legislation.

Article 61

- (1) Drug Marketing Authorization holder is obligated to monitor the efficacy, safety, and quality of the Drugs during the Drugs are distributed and is obligated to report the results to the Chairperson.
- (2) Monitoring the efficacy, safety, and quality of the Drugs during the Drugs distributed as referred to in section (1) is carried out in accordance with the provisions of legislation.

CHAPTER IX
RE-EVALUATION

Article 62

- (1) Drugs that have been granted a Marketing Authorization may be subject to re-evaluation.
- (2) The re-evaluation as referred to in section (1) is conducted if based on the monitoring results as referred to in Article 61 section (2), there is the latest data and information on the efficacy, safety, and quality of the Drugs.
- (3) The re-evaluation implementation as referred to in section (1) as contained in Annex XVIII as an integral part of this Agency Regulation.

- (4) The decision on the re-evaluation as referred to in section (2) is in the form of:
 - a. Label changes;
 - b. Composition/Formula improvements;
 - c. the provision of usage restrictions;
 - d. changes in the Drug category;
 - e. recall of Drugs from distribution; and/or
 - f. Marketing Authorization suspension/revocation.
- (5) The decision as referred to in section (4) is submitted in writing to the Marketing Authorization holder for follow-up.

CHAPTER X SANCTIONS

Article 63

- (1) Violations of the provisions in this Agency Regulation may be subject to administrative sanctions in the form of:
 - a. written warning;
 - b. cancellation of the Registration process;
 - c. suspension of Drug Marketing Authorization;
 - d. revocation of Drug Marketing Authorization; and/or
 - e. prohibition to register for 2 (two) years.
- (2) Administrative sanctions as referred to in section (1) point b and/or point e may be imposed based on or in the case of:
 - a. not complying with the provisions as referred to in Article 4;
 - b. not complying with the provisions as referred to in Article 32 section (1) point b; and/or
 - c. invalid data as referred to in Article 46.
- (3) Administrative sanctions as referred to in section (1) point c and/or point d may be imposed based on or in the case of:
 - a. not performing obligations as referred to in Article 60 section (1) and section (2);
 - b. Pharmaceutical Industry License of Marketing

Authorization holder is revoked; and/or

- c. Marketing Authorization holder commits violations in the field of production, distribution, promotion, and/or Drug Label.

CHAPTER XI MISCELLANEOUS PROVISIONS

Article 64

- (1) To ensure the stability of the drugs in the form of solid oral dosage forms, the registration of Drugs in a bottle contains a maximum of 100 (one hundred) pills.
- (2) Registration of Drugs in bottle packaging as referred to in section (1) can only be done for Drugs with stable Active Pharmaceutical Ingredients.

Article 65

If Applicants carry out a Registration that has more than 1 (one) Active Pharmaceutical Ingredients strength, then it must have different specifications such as size, shape, and/or color.

CHAPTER XII TRANSITIONAL PROVISION

Article 66

Registrations that have been submitted prior to the enforcement of this Agency Regulation are still being processed based on the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration as amended several times, and last by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 17 of 2016 on the Second Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration.

CHAPTER XIII CLOSING PROVISIONS

Article 67

At the time this Agency Regulation comes into force:

1. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration (State Bulletin of the Republic of Indonesia of 2011 Number 634);
2. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 3 of 2013 on Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration (State Bulletin of the Republic of Indonesia of 2013 Number 540);
3. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 17 of 2016 on the Second Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedures for Drug Registration (State Bulletin of the Republic of Indonesia of 2016 Number 1140);

are repealed and declared ineffective.

Article 68

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

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

Issued in Jakarta
on 24 November 2017

CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY OF THE REPUBLIC OF INDONESIA

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 24 November 2017

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

signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2017 NUMBER 1692

Jakarta, 30 March 2022

Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia

DIRECTOR GENERAL OF LEGISLATION,

